

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

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**AMENDMENT NO. 2  
TO  
FORM 10**

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**GENERAL FORM FOR REGISTRATION OF SECURITIES**  
Pursuant to Section 12(b) or (g) of the Securities Exchange Act of 1934

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**CORONADO BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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**Delaware**  
(State or other jurisdiction  
of incorporation)

**000-54463**  
(Commission File Number)

**20-5157386**  
(IRS Employer Identification No.)

**15 New England Executive Park**  
**Burlington, Massachusetts**  
(Address of principal executive offices)

**01803**  
(Zip Code)

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

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

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

**Common Stock, \$.001 par value**  
(Title of Class)

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

Accelerated filer   
Smaller reporting company

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## EXPLANATORY NOTE

Coronado Biosciences, Inc. is filing this General Form for Registration of Securities on Form 10 (the "Registration Statement") to register its common stock, par value \$0.001 per share, pursuant to Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). Unless otherwise mentioned or unless the context requires otherwise, when used in this prospectus, the terms "Coronado," "Company," "we," "us," and "our" refer to Coronado Biosciences, Inc.

## FORWARD LOOKING STATEMENTS

Statements in this Form 10 or in the documents incorporated by reference herein 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 "Risk Factors" including, in particular, risks relating to:

- the results of research and development activities;
- uncertainties relating to preclinical and clinical testing, financing and strategic agreements and relationships;
- the early stage of products under development;
- our need for substantial additional funds;
- government regulation;
- patent and intellectual property matters;
- dependence on third party manufacturers; and
- competition.

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

## WHERE YOU CAN FIND MORE INFORMATION ABOUT US

When this registration statement becomes effective, we will begin to file reports, proxy statements, information statements and other information with the United States Securities and Exchange Commission (the "SEC"). You may read and copy this information, for a copying fee, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information on its Public Reference Room. Our SEC filings will also be available to the public from commercial document retrieval services, and at the Web site maintained by the SEC at <http://www.sec.gov>.

Our Internet website address is <http://www.coronadobiosciences.com>. Information contained on the website does not constitute part of this registration statement. When this registration statement is effective, we will make available, through a link to the SEC's Web site, electronic copies of the materials it files with the SEC (including annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, the Section 16 reports filed by executive officers, directors and 10% stockholders and amendments to those reports).

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**Item 1. Business.****Overview**

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

- CNDO-201, a biologic comprising *Trichuris suis* ova (“TSO”), the microscopic eggs of the pig 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.

**CNDO-201**

In January 2011, in connection with our acquisition of the assets of Asphelia Pharmaceuticals, Inc. (“Asphelia”), we acquired the exclusive rights to CNDO-201 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 of CNDO-201.

CNDO-201 is comprised of TSO, 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. Based on a recent meeting with the U.S. Food and Drug Administration (“FDA”), we plan to file an Investigational New Drug Application (“IND”) with the FDA by the end of the third quarter of 2011 and commence a single dose, dose escalation study in patients with Crohn’s. This study is expected to be completed by the end of 2011. Assuming acceptable tolerance in this study, we expect to initiate a multi-center phase 2 clinical trial in Crohn’s in the United States shortly thereafter. We also plan to have discussions with the FDA regarding the requirements to initiate a Phase 2 trial in patients with MS.

**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. We are aware of a Phase 1 clinical trial of CNDO-109 in seven patients with high-risk acute myeloid leukemia (“AML”) which demonstrated that the therapy was well tolerated with manageable adverse events given the advanced state of the disease. Although the primary endpoint of the Phase 1 clinical trials was safety, based on the data obtained from the preclinical studies and this Phase 1 study, we believe that CNDO-109 has the potential to benefit patients with a wide variety of hematologic and solid cancers.

We have agreed with the FDA on a plan to submit an IND for a multi-center Phase 1/2 clinical trial in patients with relapsed AML currently planned for early 2012. We intend 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 Biologics License Application (“BLA”) in the United States and similar marketing applications in other countries.

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## 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. Autoimmune disorders include inflammatory bowel disease (“IBD”) such as Crohn’s and UC, MS, rheumatoid arthritis, lupus, asthma and type-1 diabetes. According to a 2010 Decision Resources report, in the U.S. 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.

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- $\alpha$  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 1989 article in *Gut*, 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 ulcerative colitis 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).

Each of these diseases is believed to be associated with an excessive inflammatory response by the T helper (Th) cells.

### *Oncology Therapeutics Markets*

The American Cancer Society estimates that over 1.5 million people in the U.S. are expected to be diagnosed with cancer in 2010, excluding basal and squamous cell skin cancers and in situ carcinomas (other than urinary bladder carcinomas). This is an increase of approximately 25% from the estimated number of new cancer diagnoses of approximately 1.2 million 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 1999 and 2005 still averages only 68% according to the American Cancer Society. According to that same source, cancer is the second leading cause of mortality in the U.S. behind heart disease. Overall, the American Cancer Society estimates that approximately one in four deaths in the U.S. is due to cancer.

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

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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**

### ***CNDO-201***

CNDO-201 is a biologic product candidate comprising TSO for the treatment of autoimmune diseases. We initially plan to investigate TSO for the treatment of Crohn's, UC and MS. CNDO-201 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 and a member of our scientific advisory board. 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 disease and ulcerative colitis. 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.

### **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 idea 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, asthma 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)- $\beta$ , 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.

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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 disease 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 2004, 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.

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.

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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-Gd $\beta$ ) 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-Gd $\beta$  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 second half of 2012.

Currently, OvaMed’s European sublicensee for gastroenterology indications is conducting a Phase 2b clinical trial of TSO in Crohn’s in a multi-center European clinical trial expected to enroll approximately 212 patients.

### **Our Clinical Trial Program**

As the result of a recent pre-IND meeting held among representatives of our company, OvaMed and the FDA, we will commence our clinical program with this product with a single dose, dose escalation study in patients with Crohn’s disease. The study is expected to be completed by the end of 2011. Assuming acceptable tolerance from this study, we expect to begin a multicenter phase 2 study in the first quarter of 2012 in patients with Crohn’s disease. The FDA indicated that no additional pre-clinical studies are required to open the IND in the United States, which is expected to be submitted by the end of the third quarter of this year. We also plan to have discussions with FDA regarding the requirements to initiate a Phase 2 trial in MS patients.

### **Manufacturing**

We have contracted with OvaMed to produce and supply us with all of our requirements of CNDO-201. OvaMed 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 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.

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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 Professor Mark Lowdell at the Royal Free Hospital in London and others when they noted that patients who could mount an immune response to their acute myeloid leukemia (“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. Professor 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.

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 Professor 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 indicate NK cells can remain active for weeks. Due to the complex manufacturing requirements, we anticipate developing CNDO-109 activated NK cell therapy using a third party centralized GMP-compliant processing center.

### **Completed Clinical Trial**

We are aware of a Phase 1 clinical trial of CNDO-109 activated haploidentical NK cells conducted at the Royal Free Hospital in London in patients with high risk (i.e. chemo-sensitive relapsed/refractory) AML who were not eligible for a stem cell transplant. Although the clinical trial was not randomized and included only seven patients, most of these high-risk patients had remission durations and overall survival that were much greater than expected based on their poor risk factors. The principal adverse event observed in this Phase 1 clinical trial was prolonged aplasia with reduction of the red cell, white cell, and platelet counts, which were managed successfully with hospitalization, transfusions, prophylactic antibiotics, and administration of cytokines for hematopoietic stimulation.



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## **Our Clinical Program**

We plan to submit an IND for the CNDO-109 activated NK cell product in the U.S. in early 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 using CNDO-109 to activate NK cells to treat MRD in AML patients with relapsed/refractory disease. We are also planning selected pilot Phase 1 clinical trials in other tumor types, including multiple myeloma, renal cell carcinoma 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 ("MCB") and a working cell bank ("WCB") of CTV-1 cells in collaboration with 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**

### ***Sublicense Agreement with OvaMed GmbH***

In January 2011, in connection with our acquisition of the assets of Asphelia relating to CNDO-201, 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 CNDO-201 in North America, South America and Japan. OvaMed's patent rights arise, in turn, from an exclusive license granted in 2005 by the University of Iowa Research Foundation ("UIRF") to OvaMed covering inventions and related intellectual property rights that arose as a result of research relating to CNDO-201 performed by Dr. Weinstock and his colleagues while employed by the University of Iowa.

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 CNDO-201, and additional milestone payments upon the achievement of regulatory milestones relating to subsequent indications. In the event that CNDO-201 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 20% to 10% of such consideration depending on the stage of clinical development at the time of the sublicense), as well as an annual license maintenance fee and reimbursement of patent costs. We are responsible for all clinical development and regulatory activities and costs relating to licensed products in the territory covered by the OvaMed License. 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 CNDO-201 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.

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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 and for patent reimbursement costs. We agreed that, subject to certain conditions, the IND would initially be submitted by OvaMed and subsequently transferred to us, and that we would commence an FDA-approved clinical trial within 12 months after the IND is accepted by the FDA.

***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 for the treatment of cancer-related and other 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 may be required to make future milestone payments totaling up to approximately \$22 million upon the achievement of various milestones related to regulatory events for the first three indications for which CNDO-109 is developed. 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 30% to 20% 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 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 Progenitor Cell Therapy, LLC ("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.

The PCT agreement will expire on the completion of all services provided in the statement(s) of work executed by the parties. We may terminate the PCT agreement with 45 days' notice to PCT if PCT is in default of its material obligations under the PCT agreement or any statement of work and such default is not cured within such 45 day period and may terminate the PCT agreement without cause upon 60 days' written notice to PCT. PCT

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may terminate the PCT agreement with 30 days' notice to us if we are in default of our material obligations under the PCT agreement or any statement of work and such default is not cured within such 30 day period.

The PCT agreement and any statement of work thereunder may not be assigned in whole or in part by either party without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed, except we may assign the PCT agreement and statements of work without PCT's consent in the event of a merger, acquisition, or transfer of all of our assets related to the PCT agreement to a third party that is not an affiliate of ours, provided further that such assignee, in the reasonable opinion of PCT has financial resources and financial strength comparable to ours.

## **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.

### ***CNDO-201***

Under the OvaMed License, we have exclusive rights to U.S. Patent Nos. 6,764,838, 7,250,173 and 7,833,537, owned by the University of Iowa ("UI") and licensed by UI to OvaMed. These patents claim methods of producing a pharmaceutical preparation 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 *T. suis* helminthic parasite preparation, respectively. These patents are scheduled to expire in December 2018, except for the '537 patent, which is set to expire about nine months later. By operation of the patent term restoration provisions of the patent laws, we may choose to restore the term of one of these patents or any others that may be granted prior to marketing approval of CNDO-201 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 altering regulatory T cell activity. Any patents that mature from this second patent family would not expire until at least November 2023.

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 biosimilar versions of 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.

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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 U.S. and foreign counterpart applications including pending U.S. 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.

Additionally, a second International Patent Application (No. PCT/GB2010/051135) has recently been filed with the European Patent Office directed to various aspects of our anticipated CNDO-109 clinical product and its methods of manufacture. This application has an international filing date of July 9, 2010 and, accordingly, any patents eventually issuing therefrom will expire in 2030 absent any further patent term extension. A subsequent provisional patent application was filed with the United States Patent and Trademark Office directed to treatment of viral infections using CNDO-109. This application was filed in March 2011 and will be converted into an international PCT application in March 2012, such that any patents issuing therefrom will expire in 2032 absent any further patent term extension. Each of these applications were filed at our direction on behalf of UCLB and are included in the license agreement with UCLB.

### **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 CNDO-201, 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. CNDO-201, 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) and Teva Pharmaceuticals Industries, Ltd.'s Copaxone (Glatiramer Acetate) 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

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Corporation's Clolar (clofarabine), currently approved as a treatment for ALL, Eisai Corporation's Dacogen (decitabine), currently approved as a treatment for 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 CNDO-201 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, API 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 CNDO-201 at pre-determined prices. 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;

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- 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

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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 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 initially 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.

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### ***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.

### ***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.

### ***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

### ***International Regulation***

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

### ***Employees***

As of August 22, 2011, we had 11 full-time employees.



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## 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 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 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 and milestone 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 CNDO-201, the company from which we sublicense CNDO-201, OvaMed, licenses CNDO-201 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 CNDO-201 are, therefore, also subject to OvaMed's performance of its obligations to UIRF, certain of which are outside of our control. For example, upon our acquisition of this license from Asphelia, we paid certain overdue patent cost reimbursement obligations to UIRF.

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 our licensor of CNDO-201, OvaMed, and UIRF could adversely affect our ability to develop and commercialize CNDO-201. 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

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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:

- 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.

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.

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***We may experience delays in the commencement of our clinical trials or in the receipt of data from third parties, which could result in increased costs and delay our ability to pursue regulatory approval.***

Delays in the commencement of clinical trials and delays in the receipt of data from preclinical or clinical trials conducted or managed by third parties, such as CROs, could significantly impact our product development costs and the time required to commercialize our products. Before we can initiate clinical trials in the United States for our product candidates, we need to submit the results of preclinical testing to the FDA as part of an IND, along with other information including information about product chemistry, manufacturing and controls and our proposed clinical trial protocol.

We currently plan to rely on preclinical, clinical and quality data from third parties, including, as applicable, OvaMed, UCLB, BioReliance and PCT, as well as any third party contractors on which the foregoing entities may rely, for the IND submissions for both CNDO-201 and CNDO-109. If we are unable to use such data for any reason, including as a result of a contract dispute with any such third party, the insolvency of or cessation of business by any such third party or other reasons outside of our control, it will delay our plans for IND filings, and clinical trial plans. If those third parties do not make this data available to us, we will likely, on our own, have to develop all the necessary preclinical and clinical data which will lead to additional delays and increase the costs of our development of the product candidates. In addition, the FDA may require us to conduct additional preclinical testing for any product candidate before it allows us to initiate the clinical testing under any IND, which may lead to additional delays and increase the costs of our preclinical development. Even assuming an active IND for a product candidate, 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 contract research organizations (“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. Further, a clinical trial may be suspended or terminated by us, an IRB, an ethics committee or a Data Monitoring Committee overseeing the clinical trial, any of our clinical trial sites 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

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

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

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.

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***We rely completely on OvaMed 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 CNDO-201. 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 its European sublicensee for gastroenterology indications. If OvaMed becomes unable or unwilling to deliver sufficient quantities of CNDO-201 to us on a timely basis and in accordance with applicable specifications and other regulatory requirements, there would be a significant interruption of our CNDO-201 supply, which would materially adversely affect clinical development and 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.

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. 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.

***If we are unable to establish sales and marketing capabilities or fail to enter into agreements with third parties to market 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 development 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 development 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;

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- 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;
  - 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.

***If product liability lawsuits are brought against us, we may incur substantial liabilities and may be required to limit commercialization 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 intend to obtain clinical liability insurance prior to the commencement of any clinical trials, our coverage may not be sufficient to cover claims that may be made against us. 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.

***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

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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 depends upon our ability to protect our intellectual property and our proprietary technologies, 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 and OvaMed are responsible for prosecuting and maintaining patent protection relating to CNDO-201 and UCLB is responsible for prosecuting and maintaining patent protection for CNDO-109, in each case at our expense. If UIRF, 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 it 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 U.S. government and other international governmental bodies to limit the scope of patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by United States courts, allowing foreign competitors a better opportunity to create, develop, and market competing products.

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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. If any of these events occurs, or we otherwise lose protection for our trade secrets or proprietary know-how, the value of this information may be greatly reduced.

***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, which we may have to pay 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



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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 \$3.8 million, \$3.7 million and \$10.0 million for the years ended December 31, 2008, 2009 and 2010, respectively. At June 30, 2011, we had an accumulated deficit of approximately \$46.5 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 efforts 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, reduce or eliminate our development programs or commercialization efforts.***

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2008, 2009 and 2010, we incurred research and development expenses of approximately \$2.9 million, \$2.3 million and \$8.3 million, respectively. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates, manufacturing clinical supplies and potentially expanding our development programs. We believe that our cash on hand will sustain our operations through 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, past 2012. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to 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 when required or on acceptable terms, we may have to significantly delay, significantly curtail or eliminate one or more of our product 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.

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***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"), commencing the year following our first annual report required to be filed with the SEC, our management will be required to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

As a private company with limited resources, historically we have not had 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 have 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 continue to identify deficiencies and weaknesses in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

### **Risks Associated with our Capital Stock**

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

At June 30, 2011, Lindsay A. Rosenwald, M.D., a member of our board of directors, beneficially owned approximately 18.3% 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 7.8% 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.

***No public market exists for our securities and we cannot assure you that our common stock will be listed on any securities exchange or quoted on any over-the-counter quotation system or that an active trading market will ever develop for any of our securities.***

There is no public market for our capital stock. Following the effectiveness of this Form 10, we intend to register for resale under the Securities Act of 1933, as amended (the "Securities Act"), the common stock issuable upon conversion of our preferred stock and will seek to list our common stock on the NYSE Amex or the NASDAQ Stock Market. We cannot assure you that we will be able to meet the initial listing standards of any of such markets or any other stock exchange, or predict the timing of such listing or that, if listed, we will be able to maintain such a listing. If our common stock is listed on an over-the-counter system, an investor may find it more difficult to dispose of shares or obtain accurate quotations as to the market value of our common stock.

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***Because we are becoming a reporting company under the Exchange Act by means of filing this Form 10, we may not be able to attract the attention of research analysts at major brokerage firms.***

Because we do not intend to become a reporting company by conducting an underwritten initial public offering (“IPO”) of our common stock, we do not expect security analysts of major brokerage firms to provide coverage of our company in the near future. In addition, major investment banks may be less likely to agree to underwrite secondary offerings on our behalf than they might if we were to become a public reporting company by means of an IPO. The failure to receive research coverage or support in the market for our shares will have an adverse effect on our ability to develop a liquid market for our common stock.

***Our common stock may become subject to the SEC’s penny stock rules, so broker-dealers may experience difficulty in completing customer transactions and trading activity in our securities may be adversely affected.***

The SEC has adopted regulations which generally define “penny stock” to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock may be less than \$5.00 per share for some period of time and therefore would be a “penny stock” according to SEC rules, unless we are listed on a national securities exchange. Under these rules, broker-dealers who recommend such securities to persons other than institutional accredited investors must:

- make a special written suitability determination for the purchaser;
- receive the purchaser’s prior written agreement to the transaction;
- provide the purchaser with risk disclosure documents which identify certain risks associated with investing in “penny stocks” and which describe the market for these “penny stocks” as well as a purchaser’s legal remedies; and
- obtain a signed and dated acknowledgment from the purchaser demonstrating that the purchaser has actually received the required risk disclosure document before a transaction in a “penny stock” can be completed.

If required to comply with these rules, broker-dealers may find it difficult to effectuate customer transactions and trading activity in our securities may be adversely affected.

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

Even if an active trading market develops for our common stock, 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.

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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

***Following the effectiveness of this Form 10, we intend to file a registration statement on Form S-1 to register for resale the shares underlying our preferred stock. The availability of a substantial number of shares for resale may adversely impact any trading market that may develop for our common stock.***

We intend to file a registration statement on Form S-1 under the Securities Act shortly following the effectiveness of this Form 10 to permit the resale of the shares of common stock underlying our outstanding preferred stock. Following the effective date of such registration statement, a large number of shares of common stock will become available for sale in the public market. In addition, there are approximately 7.0 million shares of common stock outstanding, as well as a substantial number of shares of our common stock underlying outstanding options and warrants. The availability of a substantial number of shares for resale under the registration statement or pursuant to Rule 144 promulgated under the Securities Act 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.

***Delaware law and our charter may inhibit a takeover that stockholders consider favorable and could also limit the market price of our common stock.***

We are governed by the provisions of Section 203 of Delaware General Corporate Law. These provisions may prohibit large stockholders, in particular those owning 15% or more of our outstanding voting stock, from merging or combining with us. In addition, our certificate of incorporation authorizes the issuance of preferred stock having such rights and preferences as our board of directors may determine without any further action by our stockholders. These provisions of Delaware law and our certificate of incorporation may prevent or frustrate any attempt by our stockholders to change our management or the direction in which we are heading and could reduce the price that investors might be willing to pay for shares of our common stock in the future.

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## Item 2. Financial Information.

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

#### Forward-Looking Statements

Statements in the following discussion and throughout this report that are not historical in nature are "forward-looking statements". You can identify forward-looking statements by the use of words such as "expect," "anticipate," "estimate," "may," "will," "should," "intend," "believe," and similar expressions. Although we believe the expectations reflected in these forward-looking statements are reasonable, such statements are inherently subject to risk and we can give no assurances that our expectations will prove to be correct. Actual results could differ from those described in this report because of numerous factors, many of which are beyond our control. These factors include, without limitation, those described under Item 1A "Risk Factors." We undertake no obligation to update these forward-looking statements to reflect events or circumstances after the date of this report or to reflect actual outcomes. Please see "Forward Looking Statements" at the beginning of this Form 10.

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.

#### Overview

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

- CNDO-201, a biologic comprising TSO for the treatment of autoimmune diseases such as Crohn's and MS that we sublicense from OvaMed ; 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 CNDO-201 sublicense 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 and paid cash of \$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. Under the terms of the sublicense agreement, 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 CNDO-201 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 CNDO-201 from OvaMed at pre-determined prices.

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 \$100,000 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. 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.

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## **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. 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 include fees to:

- contract research organizations 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; and
- vendors in connection with the preclinical development activities.

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 contract research organizations 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.

Expenses related to annual license fees are accrued on a pro rata basis throughout the year. Milestone payments are recognized and accrued upon achievement of each milestone event.

### ***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 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.

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Determining the appropriate fair value of stock-based awards requires the use of subjective assumptions. In the absence of a public trading market for our common stock, we conducted periodic assessments of the valuation of our common stock. These valuations were performed concurrently with the achievement of significant milestones or with major 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.** Because our stock is not publicly traded, we must estimate the fair value of common stock, as discussed in “Common Stock Valuations” below.
- **Expected Term.** Due to the limited exercise history of the Company’s own 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.
- **Volatility.** As we do not have a 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 U.S. 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, 2008, 2009, and 2010, stock-based compensation expense was \$25,000, \$39,000 and \$2.3 million, respectively. For the six month periods ended June 30, 2010 and 2011, stock-based compensation expense was \$2.0 million and \$0.4 million, respectively. As of December 31, 2010, we had approximately \$1.8 million of total unrecognized compensation expense, net of related forfeiture estimates which we expect to recognize over a weighted-average period of approximately 2.4 years.

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

### ***Common Stock Valuations***

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.

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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 or are expected to be granted at the 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;
- 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 the 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 Preferred Stock 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 the Company's shares are not publicly traded, a discount for lack of marketability was applied. This lack of marketability discount was estimated to be 10% for the 2010 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 the Company's common stock was used as an input in determining the fair value of the warrants, restricted stock and stock options at various period of time.



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## Results of Operations

### *General*

To date, we have not generated any revenues from operations and at June 30, 2011 had an accumulated deficit of \$46.5 million primarily as a result of expenditures for research and development, general and administrative expenses and purchase of in-process research and development. 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 model. For the years ended December 31, 2008, 2009 and 2010 and the six months ended June 30, 2011, R&D expenses were \$2.9 million, \$2.3 million, \$8.3 million and \$3.4 million, respectively, and such expenses were \$19.3 million for the period from inception (June 28, 2006) to June 30, 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 contract research organizations, 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 approvals.

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 June 30, 2011, direct, external development costs incurred for our CNDO-109 product development program were \$3.4 million, including \$0, \$0.4 million and \$2.1 million, respectively, for the years ended December 31, 2008, 2009 and 2010 and \$0.8 million and \$0.8 million, respectively, for the six months ended June 30, 2010 and 2011. From inception through June 30, 2011, direct, external development costs incurred for our CNDO-201 product development program were \$0.4 million, including \$0, \$0 and \$0.2 million, respectively, for the years ended December 31, 2008, 2009 and 2010 and \$0 and \$0.2 million, respectively, for the six months ended June 30, 2010 and 2011, but excluding \$20.7 million of in-process-research and development costs related to our acquisition of the product in the six month period ended June 30, 2011. Our results of operations for the years ended December 31, 2008, 2009 and 2010 and the six months ended June 30, 2010 and 2011 include direct, external development costs incurred in connection with two product development programs that have been discontinued. From inception through June 30, 2011, such expenses totaled \$5.2 million.

### *General and Administrative ("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, 2008, 2009 and 2010 and the six months ended June 30, 2011, G&A expenses were \$0.3 million, \$0.3 million, \$0.9 million and \$2.2 million, respectively, and such expenses were \$4.0 million from inception through June 30, 2011. We anticipate G&A expenses will increase in future periods, reflecting:

- support of our expanded research and development activities;

- an expanding infrastructure and increased professional fees associated with being a reporting company under the Exchange Act; and
- increased business development activity.

**Comparison of Years Ended December 31, 2010 and 2009**

(\$ in thousands)	For the Year Ended December 31,		Variance	
	2010	2009	\$	%
<b>Operating expenses:</b>				
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%
<b>Interest income</b>	61	—	61	NM
Interest expense, net	(1,535)	(1,053)	(482)	46%
Other income	733	—	733	NM
Net loss	<u>\$(9,982)</u>	<u>\$(3,666)</u>	<u>\$(6,316)</u>	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 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, net, 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.

### Comparison of Years Ended December 31, 2009 and 2008

(\$ in thousands)	For the Year Ended December 31,		Variance	
	2009	2008	\$	%
<b>Operating expenses:</b>				
Research and development	\$ 2,270	\$ 2,895	\$(625)	(22)%
General and administrative	343	348	(5)	(1)%
Loss from operations	(2,613)	(3,243)	630	(19)%
Interest income	—	18	(18)	NM
Interest expense, net	(1,053)	(573)	(480)	84%
Net loss	<u>\$(3,666)</u>	<u>\$(3,798)</u>	<u>\$ 132</u>	<u>(3)%</u>

NM -Not meaningful

R&D expenses were \$2.3 million for the year ended December 31, 2009, compared to \$2.9 million for the year ended December 31, 2008. The \$0.6 million decrease was primarily attributable to reduced service provider fees related to our discontinued product development programs.

G&A expenses remained relatively stable during the years ended December 31 2008 and 2009 and consisted primarily of internal salaries and external legal and accounting costs.

Interest income for the years ended December 31, 2009 and 2008 was not significant.

Interest expense, net for the year ended December 31, 2009 was \$1.1 million compared to \$0.6 million for the year ended December 31, 2008. This increase of \$0.5 million is primarily attributable to the issuance of a second bridge note of \$3.5 million in the third quarter of 2009.

### Comparison of Six Months Ended June 30, 2011 and 2010

(\$ in thousands)	For the Six Months Ended June 30,		Variance	
	2011	2010	\$	%
<b>Operating expenses:</b>				
Research and development	\$ 3,381	\$ 4,521	\$ (1,133)	-25%
General and administrative	2,187	249	1,938	778%
In-process research and development	20,706	—	20,706	NM
Loss from operations	(26,281)	(4,770)	(21,511)	451%
Interest income	41	8	33	413%
Interest expense, net	(36)	(1,473)	1,437	NM
Net loss	<u>\$(26,276)</u>	<u>\$(6,235)</u>	<u>\$(20,041)</u>	<u>321%</u>

NM -Not meaningful

R&D expenses during the six months ended June 30, 2011 decreased \$1.1 million, or 25%, from the six months ended June 30, 2010. This was primarily due to a \$1.6 million decrease in stock-based compensation expense related to the vesting of restricted common stock issued to non-employees in 2007 and a \$0.7 million decrease in development costs related to discontinued product candidates. These decreases were partially offset by increased personnel costs of \$0.6 million attributable to increased staffing, \$0.4 million of consulting costs related to

development of our current product candidates and \$0.2 million of external development costs related to CNDO-201. We expect our R&D expenses to increase in future quarters as we commence our clinical programs for CNDO-201 and CNDO-109. We also expect to incur a milestone-related charge of \$1.5 million in the three month period ending September 30, 2011 relating to the filing of an IND for CNDO-201.

G&A expenses during the six months ended June 30, 2011 increased \$1.9 million, or 778%, from the six months ended June 30, 2010, reflecting the substantial increase in the level of our business activity during 2011. The increase in G&A expenses consisted of a \$1.2 million increase in professional fees, consisting primarily of legal and accounting fees associated with the acquisition of CNDO-201, an audit of our financial statements and the completion of an equity financing, as well as a \$0.5 million increase in personnel costs and a \$0.1 million increase in stock-based compensation expense.

On January 7, 2011, we acquired from Asphelia a sublicense and related agreements for CNDO-201, an early stage development compound, and assumed certain liabilities of Asphelia. In exchange for the assets, we issued 2,525,677 Series B shares valued at \$6.38 per share, assumed the PCP promissory note of \$750,000 and a cash payment of approximately \$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 and assumption of related liabilities was \$20.7 million, which was recorded as in-process research and development expense in the consolidated statement of operations for the six months ended June 30, 2011.

In the six months ended June 30, 2011, we incurred \$34,000 of interest expense related to the PCP note of \$750,000 which was assumed in connection with the Asphelia acquisition. In the six months ended June 30, 2010, the \$1.5 million of interest expense 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 for the six months ended June 30, 2011 compared to the same period last year was primarily due to higher cash balances.

### Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities. At June 30, 2011, we had cash and cash equivalents of \$29.6 million. 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. As of August 22, 2011, we had cash and cash equivalents of \$27.8 million. The following table summarizes our funding sources as of June 30, 2011:

(\$ in thousands)			
<u>Issue</u>	<u>Year</u>	<u>No. Shares</u>	<u>Proceeds</u>
Related party promissory notes (1)	2006	NA	\$ 21
Common Stock	2007	4,762,226	5
Related party promissory notes (1)	2007	NA	1,493
Related party promissory notes (1)	2008	NA	315
Bridge note financing and warrants (1)	2008	NA	4,070
Related party promissory notes	2009	NA	90
Related party promissory note and warrants	2009	NA	570
Bridge note financing and warrants(1)	2009	NA	3,500
Related party promissory notes (1)	2010	NA	302
Series A Redeemable Convertible Preferred Stock, net	2010	2,584,166	21,681
Series C Redeemable Convertible Preferred Stock, net (2)	2011	4,612,624	<u>22,906</u>
			<u>\$54,953</u>

(1) Aggregate outstanding principal and interest converted to 1,773,719 shares of Series A Convertible Preferred Stock in 2010.

(2) Net proceeds are estimated.

As of December 31, 2010, all notes and other debt was either repaid or converted into our Series A shares. At June 30, 2011, we had outstanding \$750,000 of promissory notes due to PCP which we assumed from Asphelia. These notes are due in December 2013.

The warrant liability of \$1.3 million at June 30, 2011 reflects the value of the warrants for Series C shares issued to the placement agent for their services in connection with the Series C Convertible Preferred Stock financing ("Series C Financing"). This liability will be marked-to-market at each reporting date and will be reclassified to equity upon effectiveness of a Form S-1 that registers the common stock underlying the Series C shares.

Management believes that cash and cash equivalents, including cash raised in the Series C Financing, are sufficient to sustain operations through 2012 based on our existing business plan and given the ability to control the timing of significant expense commitments.

We expect to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its product candidates. We will require additional financing to develop, obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. 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. Our failure to raise capital as and when needed could have a negative impact on our financial condition and our ability to pursue our business strategies. If adequate funds are not available to us, we may be required to delay, reduce or eliminate research and development programs.

### ***Cash Flows for the Three Years Ended December 31, 2010, 2009 and 2008***

<i>(\$ in thousands)</i>	For the Year Ended December 31,		
	2010	2009	2008
<b>Statement of Cash Flows Data:</b>			
Total cash provided by (used in):			
Operating activities	\$(5,677)	\$(2,351)	\$(3,523)
Investing activities	(13)	(2)	—
Financing activities	<u>19,042</u>	<u>3,856</u>	<u>3,445</u>
Increase (decrease) in cash and cash equivalents	<u>\$13,352</u>	<u>\$ 1,503</u>	<u>\$ (78)</u>

#### **Operating Activities**

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 government grant received in 2010.

Cash used in operating activities decreased \$1.2 million from the year ended December 31, 2008, to the year ended December 31, 2009 primarily due to cash provided from a \$0.6 million net change in the components of operating assets and liabilities, a \$0.2 million increase in noncash interest expense, a \$0.2 million amortization of deferred financing costs and a \$0.1 million decrease in net loss.

#### **Investing Activities**

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

#### **Financing Activities**

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.

Cash provided by financing activities increased \$0.4 million from the year ended December 31, 2008 to the year ended December 31, 2009, primarily due to increased borrowings.

### **Cash Flows for the Six Months Ended June 30, 2011 and 2010**

(\$ in thousands)	For the Six Months Ended June 30,	
	2011	2010
<b>Statement of Cash Flows Data:</b>		
Total cash provided by (used in):		
Operating activities	\$ (4,358)	\$(2,468)
Investing activities	(3,843)	(5)
Financing activities	22,986	9,837
Increase in cash and cash equivalents	<u>\$14,785</u>	<u>\$ 7,364</u>

### **Operating Activities**

Net cash used in operating activities increased \$1.9 million from the six months ended June 30, 2010 to the six months ended June 30, 2011. The increase in net loss of \$19.8 million was offset by \$20.7 million of noncash expense for in-process research and development expense related to the Asphelia asset purchase less a \$1.6 million decrease in stock-based compensation and a \$0.8 million decrease in the change in fair value of the senior convertible note warrant liability.

### **Investing Activities**

Net cash used in investing activities was \$3.8 million for the six months ended June 30, 2011 and consisted of cash payments related to the Asphelia asset purchase.

### **Financing Activities**

Net cash provided by financing activities in the six months ended June 30, 2011 of \$23.0 million consisted primarily of \$22.9 million of net proceeds from the Series C Financing. Net cash provided by financing activities in the six months ended June 30, 2010 of \$9.8 million consisted primarily of \$9.5 million of net proceeds from the issuance of our Series A shares.

### **Contractual Obligations and Commitments**

The following table summarizes our contractual obligations as of June 30, 2011, excluding amounts related to contingent milestone payments, as described below.

(\$ in thousands)	Payments due by period				
	Total	Less than 1 year	1 to 3 years	4 to 5 years	After 5 years
Notes Payable and interest	\$ 956	\$ 75	\$ 881	\$ —	\$ —
Annual sublicense fees (1)	3,750	250	750	500	2,250
Purchase and other obligations	1,646	419	1,227	—	—
<b>Total</b>	<u>\$6,352</u>	<u>\$ 744</u>	<u>\$2,858</u>	<u>\$500</u>	<u>\$2,250</u>

(1) Annual sublicense fees are projected through 2025. We have a right to terminate the related sublicense with a 30 day notice period.

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**Contingent Milestone Payments**

Based on our development plans and license agreements in effect as of June 30, 2011, we have committed to make potential future milestone payments to our licensors upon achievement of certain development or regulatory milestones for each indication for which the licensed product is developed. Under the license agreement for CNDO-201, the milestone payments aggregate approximately \$5.45 million for the first indication and \$2 million for each subsequent indication. Under the UCLB license, the milestone payments aggregate approximately \$22 million for the first three indications. Because the achievement of these milestones had not occurred as of June 30, 2011, such contingencies have not been recorded in our financial statements. We anticipate that we may incur expense for approximately \$1.5 million of milestone payments in 2011, which would be paid in 2012, provided various development and regulatory milestones are achieved. Amounts related to contingent milestone payments are not included in the contractual obligations table above due to the uncertainty of the successful achievement of certain development activities, regulatory approval and commercial milestones.

**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, 2009 and 2010. Our existing debt is at a fixed rate and we currently do not have exposure to foreign currency fluctuations.

**Internal Control Over Financial Reporting**

Pursuant to Section 404 of SOX, commencing the year following our first annual report required to be filed with the SEC, our management will be required to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Exchange Act, we may need to upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

As a private company with limited resources, historically we have not had 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 have 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 continue to 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.

### Net Operating Loss Tax Carry-Forwards

As of December 31, 2010, we had net operating loss carryforwards of approximately \$6.3 million to offset future federal income taxes through 2024. 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 annual limitations, lack of future taxable income, or future ownership changes that could result in the expiration of the carryforwards before they are utilized. At December 31 2010, we recorded a 100% valuation allowance against our deferred tax assets of approximately \$6.6 million, as our management believes it is uncertain that they will 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.

### Item 3. Properties.

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

### Item 4. Security Ownership of Certain Beneficial Owners and Management.

The following table sets forth, as of August 15, 2011, certain information concerning the beneficial ownership of our common stock by (i) each stockholder known by us to own beneficially five percent or more of our outstanding common stock; (ii) each director; (iii) each named executive officer; and (iv) all of our executive officers and directors as a group, and their percentage ownership and voting power.

<u>Name and Address of Beneficial Owner (1)</u>	<u>Shares Beneficially Owned</u>	<u>Percentage Total Voting Power(2)</u>
Glenn L. Cooper, M.D.	126,745(3)(4)	*
Bobby W. Sandage, Jr., Ph.D.	10,000(3)(5)	*
Dale Ritter	5,000(3)(6)	*
David J. Barrett	0(8)	*
Jimmie Harvey, Jr., M.D.	8,333(7)	*
J. Jay Lobell	331,508(7)(9)	1.8%
Michael W. Rogers	0(8)	*
Lindsay A. Rosenwald, M.D.	3,392,353(7)(10)	18.3%
Eric K. Rowinsky, M.D.	64,487(3)(11)	*
Hillel Gross (12)	1,000,000	5.4%
Manchester Securities Corp.	1,731,279(13)	9.3%
Brookline Investments Inc.	1,052,825(14)	5.7%
All officers and directors as a group (9 persons)(15)	3,991,261	20.9%

\* Less than 1%.

- (1) Unless otherwise indicated, the address of such individual is c/o Coronado Biosciences, Inc., 15 New England Executive Park, Burlington, Massachusetts 01803.
- (2) Based upon an aggregate of 7,028,059 shares of common stock and 11,496,186 shares of preferred stock issued and outstanding as of June 30, 2011. We have three series of preferred stock outstanding, Series A shares, Series B shares and Series C shares. Each series of preferred stock votes 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). Each share of preferred stock is convertible into one share of common stock.



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- (3) Represents shares underlying preferred stock, as well as options that are exercisable in the next 60 days.
  - (4) Does not include options to purchase an aggregate of 193,490 shares of common stock that are not exercisable in the next 60 days.
  - (5) Does not include options to purchase an aggregate of 300,000 shares of common stock that are not exercisable in the next 60 days.
  - (6) Includes shares held jointly by Mr. Ritter and his spouse. Does not include options to purchase an aggregate of 120,000 shares of common stock that are not exercisable in the next 60 days.
  - (7) Does not include options to purchase 16,667 shares of common stock that are not exercisable in the next 60 days.
  - (8) Does not include options to purchase 25,000 shares of common stock that are not exercisable in the next 60 days.
  - (9) Includes 27,175 shares of common stock issuable upon the exercise of a warrant that Mr. Lobell may be deemed to beneficially own as a limited partner of PCP.
  - (10) Includes (a) 1,197,270 shares underlying preferred stock, of which 395,369 shares are held directly by Dr. Rosenwald, 130,343 shares are held by Capretti Grandi, LLC and 671,558 shares are held by PBS, and (b) 2,186,750 shares of common stock, of which 2,047,632 shares are held directly by Dr. Rosenwald, 40,640 shares are held by Capretti Grandi, LLC, 71,303 shares are held by PBS and 27,175 shares are issuable upon the exercise of warrants issued to PCP. Dr. Rosenwald has voting and dispositive control over the shares held by Capretti Grandi, LLC, PBS and PCP. Does not include (i) 453,822 shares of common stock (including shares underlying preferred stock) held by LAR Family Trusts or (ii) 1,000,000 shares of common stock held by trusts established for the benefit of Dr. Rosenwald's family, over which Dr. Rosenwald does not have any voting or dispositive control.
  - (11) Does not include options to purchase 128,993 shares of common stock that are not exercisable in the next 60 days.
  - (12) Mr. Gross is the trustee of four trusts established for the benefit of Lindsay Rosenwald and his family, which own an aggregate of 1,000,000 shares of our capital stock as follows: (a) Lindsay A. Rosenwald 2000 Irrevocable Indenture of Trust dated May 24, 2000 (Delaware) owns 720,000 shares of common stock; (b) Lindsay A. Rosenwald Alaska Irrevocable Indenture of Trust dated August 28, 2001 owns 80,000 shares of common stock; (c) Lindsay A. Rosenwald Nevada Irrevocable Indenture of Trust dated January 6, 2003 owns 100,000 shares of common stock; and (d) Lindsay A. Rosenwald Rhode Island Irrevocable Indenture of Trust dated August 28, 2001 owns 100,000 shares of common stock. Mr. Gross may be deemed to beneficially own the shares held by these trusts because he has sole voting and dispositive control over all shares held by these trusts. Mr. Gross's address is c/o AmTrust Financial Services, 59 Maiden Lane, 6th Floor, New York, NY 10038.
  - (13) Includes 1,525,398 shares underlying preferred stock, including 178,890 shares held by Elliot Associates, L.P. and 268,336 shares held by Elliot International, each affiliates of Manchester Securities Corp. ("Manchester"). Manchester's address is 712 Fifth Avenue, New York, NY 10019. Mr. Paul E. Singer has voting and dispositive power over these shares.
  - (14) Includes 318,087 shares of common stock and 734,738 shares underlying preferred stock. The shares are held by Brookline Coronado Investment Fund LLC, CSA Biotechnology Fund I, LLC and CSA Biotechnology Fund II (collectively, "Brookline"). The address of these entities is c/o Brookline Investments, Inc., 2501 Twentieth Place South, Suite 275, Birmingham, AL 35223. Mr. Rainer Twiford has voting and dispositive power over these shares.
  - (15) Includes the shares referred to in footnotes (3), (4), (5), (6), (7), (8), (9), (10) and (11) above.

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**Item 5. Directors and Executive Officers.**

The following table sets forth certain information about our executive officers, key employees and directors as of the date of this Registration Statement.

<u>Name</u>	<u>Age</u>	<u>Position</u>
Glenn L. Cooper, M.D.	58	Executive Chairman, Director
Bobby W. Sandage, Jr., Ph.D.	57	President and Chief Executive Officer, Director
Dale Ritter	60	Senior Vice President, Finance, Chief Accounting Officer and Acting Chief Financial Officer
Eric K. Rowinsky, M.D.	54	Director, Vice Chairman
David J. Barrett	34	Director
Jimmie Harvey, Jr., M.D.	59	Director
J. Jay Lobell	48	Director
Michael W. Rogers	51	Director
Lindsay A. Rosenwald, M.D.	54	Director

None of the events listed in Item 401(f) of Regulation S-K has occurred during the past ten years and that is material to the evaluation of the ability or integrity of any of our directors, director nominees or executive officers.

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

**Executive Officers**

**Glenn L. Cooper, M.D.** has served as a member of our board of directors since October 2009, as our executive chairman since July 2010 and served as our acting chief executive officer from December 2010 to April 2011. Dr. Cooper has extensive leadership experience in the pharmaceutical and biotechnology industries with expertise in transforming development stage companies into commercial organizations. From 1993 to 2009, Dr. Cooper was the chairman and chief executive officer of Indevus Pharmaceuticals, Inc., a specialty pharmaceuticals company. Indevus was acquired by Endo Pharmaceuticals, Inc. in March 2009. Prior to joining Indevus in 1993, Dr. Cooper held numerous executive level positions, including president and chief executive officer of Progenitor, Inc., executive vice president and chief operating officer of Sphinx Pharmaceuticals Corporation, and various clinical and regulatory positions with Eli Lilly and Company. Dr. Cooper also serves on the board of directors of Gentium S.p.A. and Repligen Corporation. Dr. Cooper holds a B.A. from Harvard College and received his M.D. from Tufts University School of Medicine. Based on Dr. Cooper's position as the executive chairman, his other senior management experience and service on boards of directors in the biotechnology and pharmaceutical industries, our board of directors believes that Dr. Cooper has the appropriate set of skills to serve as a member of the board.

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

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the University of Arkansas and a Ph.D. in clinical pharmacy from Purdue University. Based on Dr. Sandage's position as the president and chief executive officer, his substantial experience in the pharmaceutical industry and service on boards of directors in the biotechnology and pharmaceutical industries, our board of directors believes that Dr. Sandage has the appropriate set of skills to serve as a member of the board.

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

#### **Non-Employee Directors**

**Eric K. Rowinsky, M.D.** has served as a member of our board of directors, as our vice chairman and a consultant since October 2010 and is responsible for overseeing our clinical development plan for acute myeloid leukemia and solid tumor malignancies. Dr. Rowinsky is an internationally renowned expert in oncology with a distinguished background in academics and industry. Following an oncology fellowship at Johns Hopkins, he became an assistant professor of oncology at Johns Hopkins and then an associate professor at Johns Hopkins. Dr. Rowinsky then became a professor of medicine and director for drug development, cancer therapy and research at University of Texas, San Antonio. In 2004, Dr. Rowinsky became chief medical officer and senior vice president (later promoted to executive vice president) of ImClone Systems, Inc., a cancer therapeutics company, and spear-headed the further clinical development of Erbitux (cetuximab injection) and eight additional monoclonal antibodies, prior to ImClone's acquisition by Eli Lilly & Company in 2008. He remained at ImClone as a consultant until December 2010. Dr. Rowinsky is and has been a consultant to multiple biotech companies in cancer drug development and serves on the boards of directors of Biogen-Idec Inc., Neoprobe Inc, PreScience Labs Inc., and DLVR, Inc., each of which are life sciences companies. During the past five years, Dr. Rowinsky has also served on the boards of directors of Tapestry Pharmaceuticals, Inc. and Adventrx Pharmaceuticals, Inc., which are life sciences companies. Dr. Rowinsky has been an advisor to academic, industrial and FDA advisory boards and has more than 300 peer-reviewed publications. Dr. Rowinsky received his B.A. from New York University and his M.D. from Vanderbilt University School of Medicine. Based on Dr. Rowinsky's service on boards of directors in the biotechnology and pharmaceutical industries and his extensive experience and background in oncology, our board of directors believes that Dr. Rowinsky has the appropriate set of skills to serve as a member of the board.

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

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

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

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

**Lindsay A. Rosenwald, M.D.** has served as a member of our board of directors since October 2009. Since November 2008, Dr. Rosenwald has served as Co-Portfolio Manager & Partner of Opus Point Partners, LLC ("Opus"), an asset management and broker dealer in the life sciences industry. Prior to that, from August 1991 to October 2008, he served as the Chairman of Paramount BioCapital, Inc. ("PBC"). Over the last 23 years, Dr. Rosenwald has acted as a biotechnology entrepreneur and been instrumental in the founding and recapitalization of numerous public and private biotechnology and life sciences companies. Dr. Rosenwald received his B.S. in finance from Pennsylvania State University and his M.D. from Temple University School of Medicine. Based on Dr. Rosenwald's biotechnology and pharmaceutical industry experience and in-depth understanding of our business, our board of directors believes that Dr. Rosenwald has the appropriate set of skills to serve as a member of the board.

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## **Item 6. Executive Compensation.**

### **Compensation Discussion and Analysis**

#### ***Introduction***

This Compensation Discussion and Analysis explains our compensation philosophy, policies and practices with respect to our named executive officers. To date, executive compensation decisions have been made by the entire board of directors. Following the effectiveness of this Form 10, we expect to establish a compensation committee of the board that will be responsible for creating and reviewing the compensation of our executive officers as well as overseeing our compensation and benefit plans and policies and administering our equity incentive plans.

#### ***Compensation Philosophy***

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

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

Our board of directors believes that our executive compensation programs should include short- and long-term components, including cash and equity-based compensation, and should reward consistent performance that meets or exceeds expectations. The board evaluates both performance and compensation to make sure that the compensation provided to executives remains competitive relative to compensation paid by companies of similar size and stage of development operating in the life sciences industry, taking into account our relative performance and our own strategic objectives.

#### ***Setting Executive Compensation***

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

#### ***Elements of Executive Compensation***

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

- base salary;
- annual discretionary bonuses; and
- long-term compensation in the form of stock options.

#### **Base Salary**

Base salaries for our executives are initially established through arm's-length negotiation at the time the executive is hired, taking into account such executive's qualifications, experience, prior salary, the scope of his

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

We hired Glenn L. Cooper, M.D., to serve as our executive chairman in July 2010. Initially, Dr. Cooper was compensated as a consultant for a monthly fee of \$25,000. This amount was determined as part of the negotiation of Dr. Cooper's compensation, conducted on our behalf by Dr. Rosenwald and our former chief executive officer and approved by the board of directors. In April 2011, Dr. Cooper's consulting arrangement was transitioned into an employment arrangement and his annual base salary of \$300,000 was approved by the board of directors at that time.

We hired our former executive vice president, chief operating officer, chief financial officer, Gary G. Gemignani, in May 2010. Mr. Gemignani's base salary for 2010 was set at \$350,000, which was determined as part of the negotiation of Mr. Gemignani's employment agreement, conducted on our behalf by Dr. Tesi and approved by the board of directors. In February 2011, our board of directors approved a 2% increase to the base salary of Mr. Gemignani, based on increased responsibilities in the absence of a full time chief executive officer and audit oversight responsibilities. In May 2011, Mr. Gemignani's title was changed to vice president of special projects, pending the termination of his employment at the end of June 2011.

In June 2010, our board of directors approved an increase to the base salary of our then-chief executive officer, Raymond J. Tesi, M.D., as part of the negotiation of an amended and restated employment agreement with Dr. Tesi. The annual base salary for Dr. Tesi was increased from \$350,000 to \$420,000 based on a reallocation of the percentage of his total compensation from discretionary bonus to annual salary. Dr. Tesi's employment was terminated in September 2010.

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

We hired Dale Ritter to serve as our senior vice president, finance, chief accounting officer and acting chief financial officer in May 2011. Mr. Ritter's base salary for 2011 was set at \$250,000. This salary was determined as part of the negotiation of Mr. Ritter's employment agreement, which was conducted by Drs. Cooper and Sandage on our behalf and approved by the board of directors. In approving the salary, the board considered Mr. Ritter's requested salary and the salaries of other members of the management team. Mr. Ritter's salary was most similar to that of Mr. Gemignani, reflective of the fact that Mr. Ritter succeeded to much of Mr. Gemignani's responsibilities, while taking in account the fact this his role as acting chief financial officer is temporary until such time as we retain a full time chief financial officer.

#### **Discretionary Bonuses**

In addition to the payment of base salaries, we believe that discretionary bonuses can play an important role in providing appropriate incentives to our executives to achieve its strategic objectives. As part of the annual performance reviews, the board of directors has in the past, and the compensation committee will, in the future, review and analyze each executive officer's overall performance against such executive's base salary. Currently,

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we have not set any specific goals. Dr. Sandage and Mr. Ritter are eligible for a maximum discretionary bonus of 50% and 40%, respectively, pursuant to the terms of their employment agreements. In addition, Dr. Sandage is eligible for additional discretionary bonuses of \$62,500, \$125,000, \$250,000, and \$500,000 based on milestones tied to reaching a market capitalization of \$125 million, \$250 million, \$500 million and \$1 billion, respectively. Our executive chairman, Dr. Cooper, is not generally eligible for a discretionary bonus.

Following the end of 2010, our board of directors reviewed the annual performance of Mr. Gemignani, the only executive officer eligible for a discretionary bonus, as well as our overall performance and approved the payment of a discretionary bonus to Mr. Gemignani in the amount of \$175,000. Such discretionary bonus was paid in cash and was provided in order to continue to motivate the executive to achieve our financial and business objectives and was paid in part based on achievements made by the executive and by us during 2010.

### **Long-term Incentive Program**

We believe that by providing our executives the opportunity to increase their ownership of our stock, the best interests of stockholders and executives will be more aligned and we will encourage long-term performance. The stock awards enable our executive officers to participate in the appreciation of the value of our stock, while personally participating in the risks of business setbacks. We have not adopted stock ownership guidelines and our stock incentive plan has provided our executive officers the only means to acquire equity or equity-linked interests in our company. We do not have any program, plan or obligation that requires us to grant equity compensation on specified dates. Authority to make equity grants to executive officers rests with our board of directors, which considers the recommendations of the executive chairman and the chief executive officer for officers other than themselves, and will in the future take into account recommendation of the compensation committee.

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

In 2010, certain named executive officers were awarded stock options under the 2007 plan in the amounts indicated in the section below entitled "Grants of Plan-Based Awards." The awards were reviewed for consistency internally among the management team and were determined by members of the board of directors to be consistent with other companies in which the members have experience.

In October 2010, as part of the long-term equity incentive program described above, our board of directors awarded Dr. Cooper, Dr. Tesi and Mr. Gemignani stock options under the 2007 plan in the aggregate amounts of 290,235, 144,120 and 200,000 shares, respectively.

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

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

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In February 2011, Mr. Gemignani was awarded an additional option to purchase 25,000 shares of our common stock under the 2007 Plan. The number of shares was approved by the board. In approving the number of shares, the board considered Mr. Gemignani's increased level of responsibilities described above.

In the absence of a public trading market for our common stock, the board of directors has determined the fair market value of our common stock in good faith based upon consideration of a number of relevant factors including the status of development efforts, financial status and market conditions and based upon valuations obtained from an independent valuation firm.

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

### **Executive Employment Agreements**

We entered into employment agreements with Dr. Cooper and Dr. Sandage in April 2011 and with Mr. Ritter in May 2011. The employment agreements provide for at-will employment, base salary, incentive bonuses, standard employee benefit plan participation and recommendations for initial stock option grants. The employment agreements were each subject to execution of standard proprietary information and invention agreements and proof of identity and work eligibility in the United States. Prior to his employment agreement, Dr. Cooper was party to a consulting agreement with us, which was entered into in August 2010.

Dr. Sandage and Mr. Ritter are each entitled to severance and change in control benefits pursuant to their employment, the terms of which are described below under "Potential Payments Upon Termination or Change in Control." We believe that these severance and change in control benefits help us from a retention standpoint and they are particularly necessary in an industry, such as ours, where there has been market consolidation. We believe that they help these executive officers maintain continued focus and dedication to their assigned duties to maximize stockholder value if there is a change of control. We believe that these severance and change in control benefits are an essential element of our overall executive compensation package. Dr. Cooper is not entitled to severance or change in control benefits.

### **Perquisites**

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

### **Other Compensation**

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

### **Deductibility of Compensation under Section 162(m)**

Section 162(m) of the Internal Revenue Code of 1986 limits our deduction for federal income tax purposes to not more than \$1 million of compensation paid to certain executive officers in a calendar year. Compensation above



\$1 million may be deducted if it is “performance-based compensation.” We have not yet established a policy for determining which forms of incentive compensation awarded to our executive officers will be designed to qualify as “performance-based compensation.” To maintain flexibility in compensating executive officers in a manner designed to promote our objectives, the board of directors has not adopted a policy that requires all compensation to be deductible. However, it is expected that the compensation committee will evaluate the effects of the compensation limits of Section 162(m) on any compensation it proposes to grant in the future and that future compensation will be provided in a manner consistent with our best interests and those of our stockholders.

### ***Risk Analysis of our Compensation Plans***

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

### ***Summary Compensation Table***

The following table provides information regarding the compensation paid during the year ended December 31, 2010 to our principal executive officer, principal financial officer and certain of our other executive officers, who are collectively referred to as “named executive officers” elsewhere in this Form 10. Because Dr. Sandage and Mr. Ritter were not executive officers during 2010, they are not included in the following table.

<u>Name and Principal Position</u>	<u>Year</u>	<u>Salary</u>	<u>Bonus</u>	<u>Option Awards (1)</u>	<u>All Other Compensation</u>	<u>Total</u>
Glenn L. Cooper, M.D. (2) Executive Chairman	2010	—	—	\$453,695	\$ 137,500	\$591,195
Raymond J. Tesi, M.D. (3) Former President and Chief Executive Officer	2010	\$259,583	\$300,000	\$255,222	\$ 45,565	\$860,370
Gary Gemignani (4) Former Executive Vice President, Chief Operating Officer, Chief Financial Officer	2010	\$211,458	\$175,000	\$312,640	—	\$699,098

- (1) Represents the aggregate grant date fair value computed in accordance with FASB ASC Topic 718. One-third of the shares subject to each of the options granted to our named executive officers vest on each anniversary of the grant date, October 5, 2010, such that all of the shares subject to the options will be vested three years after such date.
- (2) Dr. Cooper became our executive chairman in July 2010. Dr. Cooper’s 2010 “Option Awards” and “All Other Compensation” amounts are compensation that Dr. Cooper earned pursuant to a consulting agreement with us.
- (3) Dr. Tesi served as our president and chief executive officer from June 2007 to September 2010. He served as our principal financial and accounting officer from June 2007 to May 2010, during which time we operated without a chief financial officer. Dr. Tesi’s 2010 “All Other Compensation” amount is reimbursement of moving expenses.
- (4) Mr. Gemignani served as our executive vice president, chief operating officer and chief financial officer from May 2010 to May 2011. Mr. Gemignani ceased serving as our principal financial and accounting officer in May 2011 when Mr. Ritter joined us.

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### **Potential Payments Upon Termination or Change in Control**

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

We entered into an employment agreement with Dr. Tesi, our former president and chief executive officer, in June 2010, which superseded a prior employment agreement between Dr. Tesi and us. In January 2011, in connection with the termination of Dr. Tesi's employment in September 2010, we entered into a separation agreement with Dr. Tesi entitling him to severance benefits. The terms of Dr. Tesi's separation agreement supersede the terms of his employment agreement. The separation agreement provides that, in exchange for Dr. Tesi's full release of claims against us, he was entitled to: (i) salary continuation for six months following the effectiveness of the release of claims and (ii) acceleration of vesting for one-third of the options held by him at the time of separation.

We entered into an employment agreement with Mr. Gemignani, our former executive vice president, chief operating officer, chief financial officer, in June 2010. In connection with the termination of Mr. Gemignani's employment in June 2011, we entered into a separation agreement with Mr. Gemignani entitling him to severance benefits. The terms of Mr. Gemignani's separation agreement supersede the terms of his employment agreement. The separation agreement provides that, in exchange for Mr. Gemignani's full release of claims against us, he was entitled to: (i) salary continuation for six months following termination and the effectiveness of the release of claims, (ii) a one-time payment of \$89,250, which represented a prorated bonus amount for 2011, (iii) acceleration of vesting for one-third of the options held by him at the time of separation, and (iv) extension of the post-termination exercise period of the accelerated options from three months to six months.

In April 2011, we entered into an employment agreement with Dr. Sandage, our president and chief executive officer, which provides if we terminate Dr. Sandage without cause or he resigns for good reason, he will be entitled to: (i) severance payments at a rate equal to his base salary then in effect for a period of one year following his termination date and (ii) accelerated vesting of one-third of his stock option shares. In addition, if Dr. Sandage is terminated without cause within six months following a change in control, 100% of the shares subject to options and other equity awards granted to him will fully vest as of the date of his execution of a release in connection with such termination. Cause is defined as (a) his willful failure, disregard or refusal to perform his material duties or obligations under the employment agreement which, to the extent it is curable by Dr. Sandage, is not cured within thirty (30) days after we give written notice to him; (b) any willful, intentional or grossly negligent act having the effect of materially injuring (whether financially or otherwise) the business or reputation of us or any of our affiliates; (c) willful misconduct by him with respect to any of the material duties or obligations under the employment agreement, including, without limitation, willful insubordination with respect to lawful directions received from the board of directors which, to the extent it is curable by Dr. Sandage, is not cured within thirty (30) days after we give written notice to him; (d) indictment of any felony involving moral turpitude (including entry of a *nolo contendere* plea); (e) the determination, after a reasonable and good-faith investigation by us, that he engaged in some form of harassment or discrimination prohibited by law (including, without limitation, age, sex or race harassment or discrimination), unless the actions were specifically directed by the board of directors; (f) material misappropriation or embezzlement of the property of us or our affiliates (whether or not a misdemeanor or felony); or (g) a material breach of any of the provisions of the employment agreement, of any company policy, and/or of his proprietary information and inventions agreement. Good reason is defined as (x) a material reduction of Dr. Sandage's base salary unless such reduction occurs in connection with a company-wide decrease in executive compensation, (y) a material breach of the employment agreement by us; or (z) a material adverse change in his duties, authority, or responsibilities relative to his duties, authority, or responsibilities in effect immediately prior to such reduction.

In April 2011, we entered into an employment offer letter with Mr. Ritter, our senior vice president, finance, chief accounting officer and acting chief financial officer, which provides if we terminate Mr. Ritter without

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

We have routinely granted and will continue to grant our named executive officers stock options under the 2007 plan. For a description of the change in control provisions in such equity incentive plan applicable to these stock options, see “—Equity Incentive Plans—2007 Stock Incentive Plan” below.

The following table sets forth potential payments payable to our named executive officers upon a termination of employment without cause or resignation for good reason or termination of employment without cause or resignation for good reason following a change in control. The table below reflects amounts payable to our executive officers assuming their employment was terminated on December 31, 2010 and, if applicable, a change in control also occurred on such date. Because Dr. Sandage and Mr. Ritter were not executive officers during 2010 they are not included in the following table.

Name	Upon Termination without Cause or Resignation for Good Reason— No Change in Control			Upon Termination without Cause or Resignation for Good Reason— Change in Control		
	Cash Severance	Value of Accelerated Vesting (1)	Total	Cash Severance	Value of Accelerated Vesting (1)	Total
Glenn Cooper, M.D.	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Raymond J. Tesi, M.D. (2)	\$210,000	\$ 28,824	\$238,824	\$420,000	\$ 86,472	\$506,472
Gary G. Gemignani (3)	\$175,000	\$ 40,000	\$215,000	\$350,000	\$120,000	\$470,000

- (1) The value of accelerated vesting is equal to \$1.96 per share (the assumed fair market value of a share of our common stock on December 31, 2010 for the purposes hereof), multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price.
- (2) Dr. Tesi’s employment agreement provided that: (a) if he was terminated without Cause or resigned for Good Reason, not in connection with a change of control, he would have received 6 months of salary continuation and accelerated vesting of 1/3 of the number of options outstanding and (b) if he was terminated without Cause or resigned for Good Reason within in the 12 months following a Change of Control he would have received 12 months of salary continuation and accelerated vesting of 100% of the number of options outstanding. Dr. Tesi’s employment with us terminated effective as of September 2010, and, as of the date of this filing, Dr. Tesi is not eligible for payments upon a change in control.
- (3) Mr. Gemignani’s employment agreement provided that: (a) if he was terminated without Cause or resigned for Good Reason, not in connection with a change of control, he would have received 6 months of salary continuation and accelerated vesting of 1/3 of the number of options outstanding and (b) if he was terminated without Cause or resigned for Good Reason within in the 12 months following a Change of Control he would have received 12 months of salary continuation and accelerated vesting of 100% of the number of options outstanding. Mr. Gemignani’s employment with us terminated effective as of June 2011, and, as of the date of this filing, Mr. Gemignani is not eligible for payments upon a change in control.

#### **Grants of Plan-Based Awards**

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

The following table sets forth certain information regarding grants of plan-based awards to our named executive officers for 2010. Because Dr. Sandage and Mr. Ritter were not executive officers during 2010 they are not included in the following table.

<u>Name</u>	<u>Grant Date</u>	<u>All other option awards: number of securities underlying options (#)</u>	<u>Exercise or base price of option awards (\$/share) (1)</u>	<u>Grant date fair value of option awards (\$)(2)</u>
Glenn L. Cooper, M.D.	10/05/2010	290,235	\$1.37	\$453,695
Raymond J. Tesi, M.D. (3)	10/05/2010	144,120	\$1.37	\$255,222
Gary Gemignani (4)	10/05/2010	200,000	\$1.37	\$312,640

- (1) Represents the per share fair market value of our common stock, as determined in good faith by our board of directors on the grant date.
- (2) Amounts listed represent the aggregate fair value amount computed as of the grant date of each option and award during 2010 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 14, *Stock-Based Compensation*, of the Notes to the Financial Statements. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our named executive officers will only realize compensation to the extent the trading price of our common stock is great than the exercise price of such stock options.
- (3) Dr. Tesi served as our president and chief executive officer from June 2007 to September 2010. Pursuant to Dr. Tesi's separation agreement dated January 1, 2011, the vesting of 48,040 of such options were accelerated and all were exercised in March of 2011.
- (4) Mr. Gemignani served as our executive vice president, chief operating officer and chief financial officer from May 2010 to May 2011. Pursuant to Mr. Gemignani's separation agreement dated June 3, 2011, the vesting of 75,000 of such options were accelerated, all of which are still outstanding as of June 30, 2011.

#### ***Outstanding Equity Awards At Fiscal Year-End***

The following table sets forth certain information regarding all outstanding equity awards held by our named executive officers as of December 31, 2010. As of December 31, 2010, none of the options held by our named executive officers were exercisable. Because Dr. Sandage and Mr. Ritter were not executive officers during 2010 they are not included in the following table.

<u>Name</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Option Exercise Price (\$)</u>	<u>Option Expiration Date</u>
Glenn L. Cooper, M.D.	290,235	\$1.37	10/04/2020 (1)
Raymond J. Tesi, M.D. (2)	144,120	\$1.37	10/04/2020 (1)
Gary Gemignani (3)	200,000	\$1.37	10/04/2020 (1)

- (1) 1/3<sup>rd</sup> of the total of number of shares subject to each option vest on each annual anniversary of the applicable grant.
- (2) Dr. Tesi served as our president and chief executive officer from June 2007 to September 2010.
- (3) Mr. Gemignani served as our executive vice president, chief operating officer and chief financial officer from May 2010 to May 2011.

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### ***Option Exercises and Stock Vested***

Our named executive officers did not exercise any stock option awards during the year ended December 31, 2010.

### ***Pension Benefits***

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

### ***Non-Qualified Deferred Compensation***

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

### ***Equity Incentive Plans***

#### **2007 Stock Incentive Plan**

Our board of directors adopted and our stockholders approved our 2007 plan in June 2007 and January 2008, respectively. As of June 30, 2011, 58,040 shares of common stock have been issued under the 2007 plan pursuant to the exercise of options, 2,517,170 shares of common stock were issued as restricted stock awards under the 2007 plan and options to purchase an aggregate of 1,459,070 shares of common stock remain outstanding.

The purpose of the 2007 plan is to provide us with the flexibility to use shares, cash, options or other awards based on our common stock as part of an overall compensation package to provide performance-based compensation to attract and retain qualified personnel. We believe that awards under the 2007 plan may serve to broaden the equity participation of key employees and further link the long-term interests of management and stockholders. Awards under the 2007 plan include shares, cash, options, stock appreciation rights, or a similar right with a fixed or variable price related to the fair market value of the shares and with an exercise or conversion privilege related to the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. Such awards include, without limitation, options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative.

There are 6,000,000 shares of common stock reserved for issuance under the 2007 plan, of which 1,965,720 shares are available for issuance as of June 30, 2011.

### ***Administration***

The 2007 plan is administered by our board of directors or a committee designated by the board of directors. With respect to grants of awards to our officers or directors, the 2007 plan will be administered by our board of directors or a designated committee in a manner that permits such grants to be exempt from Section 16(b) of the Exchange Act. Grants of awards to covered employees as defined under Section 162(m) of the Internal Revenue Code of 1986, as amended (the "Code"), will be made only by a committee comprised solely of two or more directors eligible to serve on a committee making awards. The board of directors has the full authority to select recipients of the grants, determine the extent of the grants, establish additional terms, conditions, rules or procedures to accommodate rules or laws of applicable non-U.S. jurisdictions, adjust awards and to take any other action deemed appropriate; however, no action should be taken that is inconsistent with the terms of the 2007 plan.

### ***Available Shares***

Subject to adjustment upon certain corporate transactions or events, a maximum of 6,000,000 shares of our common stock may be issued under the 2007 plan. In addition, subject to adjustment upon certain corporate

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

#### *Eligibility and Types of Awards*

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

#### ***Stock Options***

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

The plan administrator determines the term of the stock options granted under the 2007 plan, up to a maximum of 10 years, except in the case of certain incentive stock options, as described below. Unless the terms of an optionholder's stock option agreement provide otherwise, if an optionholder's relationship with us, or any of our affiliates, ceases for any reason other than disability or death, the optionholder may exercise any options vested as of the date of termination but only during the post-termination exercise period designated in the optionholder's stock option agreement. The plan administrator may determine such other portion of the optionholder's unvested award that may be exercised during the post-termination exercise period. The optionholder's stock option agreement may provide that upon the termination of the optionholder's relationship with us, for cause, the optionholder's right to exercise its options shall terminate concurrently with the termination of the relationship. If an optionholder's service relationship with us, or any of its affiliates, ceases due to disability or death, or an optionholder dies within a certain period following cessation of service, the optionholder or beneficiary may exercise any vested options for a period of 12 months. The option term may be extended in the event that exercise of the option following termination of service is prohibited by applicable securities laws or such longer period as specified in the stock option agreement but in no event beyond the expiration of its term.

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

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

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

#### ***Stock Awards and Restricted Stock***

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

#### ***Other Awards***

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

#### ***Corporate Transactions***

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

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

#### ***Amendment and Termination***

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

### Non-Executive Director Compensation

The following table and related footnotes show the compensation paid during the fiscal year ended December 31, 2010 to our non-executive directors. Because Messrs. Barrett and Rogers were not directors during 2010 they are not included in the following table.

Name	Fees Earned or paid in Cash	Option Awards (1)	All Other Compensation	Total
Jimmie Harvey, M.D. (2)	\$ 10,000	\$ 39,080	—	\$ 49,080
J. Jay Lobell (3)	\$ 10,000	\$ 39,080	—	\$ 49,080
Lindsay A. Rosenwald, M.D. (4)	\$ 10,000	\$ 39,080	—	\$ 49,080
Eric K. Rowinsky, M.D. (5)	—	\$337,459	\$ 62,500(6)	\$399,959

- (1) Amounts listed represent the aggregate fair value amount computed as of the grant date of each option and award during 2010 in accordance with FASB ASC Topic 718. Assumptions used in the calculation of these amounts are included in Note 14, *Stock-Based Compensation*, of the Notes to Financial Statements. As required by SEC rules, the amounts shown exclude the impact of estimated forfeitures related to service-based vesting conditions. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options.
- (2) The aggregate number of shares subject to Dr. Harvey's outstanding option award as of December 31, 2010 was 25,000 shares. 1/3 of the total of number of shares subject to this option vest on each annual anniversary of the applicable grant date for so long as Dr. Harvey continues to serve on our board.
- (3) The aggregate number of shares subject to Mr. Lobell's outstanding option award as of December 31, 2010 was 25,000 shares. 1/3 of the total of number of shares subject to this option vest on each annual anniversary of the applicable grant date for so long as Mr. Lobell continues to serve on our board.
- (4) The aggregate number of shares subject to Dr. Rosenwald's outstanding option award as of December 31, 2010 was 25,000 shares. 1/3 of the total of number of shares subject to this option vest on each annual anniversary of the applicable grant date for so long as Dr. Rosenwald continues to serve on our board.
- (5) The aggregate number of shares subject to Dr. Rowinsky's outstanding option award as of December 31, 2010 was 193,490 shares. 1/3 of the total of number of shares subject to this option vest on each annual anniversary of the applicable grant date for so long as Dr. Rowinsky continues to serve on our board.
- (6) Represents payments pursuant to a consulting agreement between us and Dr. Rowinsky.

In September 2010, we entered into a consulting agreement with Dr. Rowinsky, one of our directors, pursuant to which we granted an option to purchase 193,490 shares of common stock at an exercise price equal to \$1.37, the fair market value at the time of grant, to Dr. Rowinsky in connection with his service as our vice chairman. In addition, Dr. Rowinsky is paid \$250,000 per year for his services as our vice chairman.

In October 2010, our board of directors adopted a compensation program for our non-employee directors ("the Non-Employee Director Compensation Policy"). Pursuant to the Non-Employee Director Compensation Policy, each member of our board of directors who is not our employee and who is not otherwise receiving compensation from us pursuant to another arrangement, will receive an annual cash retainer of \$30,000, payable quarterly, and received an initial option grant to purchase up to 25,000 shares of our common stock. Such stock options vest in three annual installments.

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

- breach of their duty of loyalty to the corporation or its stockholders;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;



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- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
  - transaction from which the directors derived an improper personal benefit.

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

We have entered, and intend to continue to enter, into separate indemnification agreements with our directors and executive officers, in addition to the indemnification provided for in our amended and restated bylaws. These agreements, among other things, require us to indemnify our directors and executive officers for certain expenses, including attorneys' fees, judgments, fines and settlement amounts incurred by a director or executive officer in any action or proceeding arising out of their services as one of our directors or executive officers, or any of our subsidiaries or any other company or enterprise to which the person provides services at our request. We believe that these bylaw provisions and indemnification agreements are necessary to attract and retain qualified persons as directors and officers.

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

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

#### ***Compensation Committee Interlocks and Insider Participation***

None of our officers currently serves, or has served during the last completed fiscal year, on the compensation committee or board of directors of any other entity that has one or more officers serving as a member of our board of directors.

#### **Item 7. Certain Relationships and Related Transactions, and Director Independence.**

##### **Related Party Transactions**

The following is a description of transactions since January 1, 2008 to which we have been a party, in which the amount involved exceeded or will exceed \$120,000, and in which any of our directors, executive officers or beneficial owners of more than 5% of our capital stock, or an affiliate or immediate family member thereof, had or will have a direct or indirect material interest, other than compensation, termination and change-in-control arrangements, which are described under "Executive Compensation."

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## ***Convertible Note and Equity Financings***

### **2008 Bridge Financing**

Between February 2008 and April 2008, we issued convertible promissory notes in an aggregate amount of \$4.1 million (“2008 Notes”). The 2008 Notes bore interest at the rate of 8% to 10% per annum and, as extended, matured on September 30, 2010. Manchester Securities Corp. (“Manchester”), a holder of more than 5% of our capital stock, purchased \$2.0 million principal amount of 2008 Notes. In April 2010, the 2008 Notes held by Manchester, together with accrued interest, were converted into 411,763 shares of our Series A Convertible Preferred Stock (“Series A shares”). Brookline, a holder of more than 5% of our capital stock, purchased \$1.5 million principal amount of 2008 Notes. In April 2010, the 2008 Notes held by Brookline, together with accrued interest, were converted into 307,212 Series A shares.

### **2009 Bridge Financing**

Between July 2009 and September 2009, we issued convertible promissory notes in an aggregate amount of \$3.5 million (“2009 Notes”). The 2009 Notes bore interest at the rate of 8% to 10% per annum and, as extended, matured on September 30, 2010.

### **2010 Series A Financing**

In April 2010 and August 2010, we issued an aggregate of 2,584,166 Series A shares for an aggregate purchase price of \$21.7 million (not including the conversion of the 2008 Notes and the 2009 Notes) to investors (the “Series A Financing”). Lindsay A. Rosenwald, M.D., one of our directors and principal stockholders, and Brookline, a principal stockholder, purchased 98,164 and 328,963 Series A shares, respectively, for a purchase price of \$8.39 per share.

### **2011 Series C Financing**

Between May 2011 and June 30, 2011, we issued an aggregate of 4,612,624 Series C shares for an aggregate purchase price of \$25.8 million (the “Series C Financing”). The following table sets forth the number of Series C shares purchased by our officers, directors and principal stockholders in the Series C Financing:

<u>Name</u>	<u>Number of Series C shares Purchased</u>
Glenn L. Cooper, M.D.	30,000
Bobby W. Sandage, Jr., Ph.D.	10,000
Dale and Debra Ritter	5,000
Lindsay A. Rosenwald	214,669
Manchester Securities Corp. (2)	447,226

- (1) Additional detail regarding these stockholders and their equity holdings is provided in “Security Ownership of Certain Beneficial Owners and Management.”
- (2) Represents 178,890 Series C shares purchased by Elliot Associates and 268,336 purchased by Elliot International.

### ***Asphelia Asset Purchase***

In January 2011, we acquired certain assets of Asphelia relating to CNDO-201 pursuant to an asset purchase agreement. The consideration paid for the assets included the assumption of certain Asphelia liabilities and the issuance of 2,525,677 Series B shares. At the time of such acquisition, Mr. Lobell, one of our directors, was the chief executive officer and a director of Asphelia and Dr. Rosenwald, one of our directors and a principal stockholder, was a significant stockholder of Asphelia. One liability assumed from Asphelia was a 10% senior

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promissory note (the “PCP Note”) dated January 2009 issued by Asphelia to PCP, an entity whose managing member is Dr. Rosenwald, in the principal amount of \$750,000. Interest on the PCP Note is at the rate of 10% per annum payable quarterly, in arrears, and the principal matures on the earliest of (i) December 31, 2013 and (ii) the consummation of a merger, share exchange or other similar transaction.

#### ***Other Loans***

In December 2007, January 2008, February 2008, May 2009 and July 2009, we issued future advance promissory notes of \$415,000 to Capretti Grandi, LLC, \$415,000 to the LAR Family Trusts, and \$1,391,000 to PBS, all entities affiliated with Dr. Rosenwald. In 2009, we repaid \$600,000 of the principal and related interest of the PBS notes. All remaining principal and accrued interest on these promissory notes converted into Series A shares in connection with the first closing of the Series A Financing in April 2010.

In January 2009, May 2009 and June 2009, we issued 10% senior promissory notes to PCP, an entity affiliated with Dr. Rosenwald and Mr. Lobell, two of our directors, in the aggregate principal amount of \$570,000. These promissory notes were repaid in full on September 30, 2010.

#### ***Placement Agency Agreements***

Dr. Rosenwald is the chairman, chief executive officer and sole stockholder of PBC, which served as the placement agent for the offerings of our convertible debt and equity securities in 2008, 2009 and 2010. Pursuant to the engagement agreement for such prior offerings, PBC has a right of first refusal to act as the lead-finder, placement agent or other similar agent in relation to any securities offerings on our behalf during the 18-month period following the date of the final closing of the last offering for which it was our placement agent, which occurred on August 30, 2010. In connection with the provision of placement agency services by PBC for our Series A shares, we paid an aggregate of \$2.2 million in cash fees and issued PBC warrants to purchase an aggregate of 258,418 shares of our common stock at an exercise price of \$8.39 per share. In connection with the placement of our convertible debt, we paid Paramount \$529,000 in cash and issued to PBC 90,226 warrants to purchase common stock at \$9.229 per share. All of such warrants were subsequently transferred by PBC to other individuals and entities. PBC waived its right of first refusal to act as placement agent for our 2011 Series C Financing.

In October 2010, Dr. Rosenwald indirectly acquired a controlling interest in National Securities Corporation (“National”), which served as the placement agent for the Series C Financing in May and June 2011, through an investment in National Holdings Corporation, the 100% owner and parent of National. Dr. Rosenwald’s investment is through Opus, which beneficially owns approximately 23.6% of National Holdings Corporation. Dr. Rosenwald beneficially owns a 50% interest in Opus. In connection with this private placement, National received commissions of \$2.6 million and five year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of \$5.39 per share, which were subsequently transferred by National to other individuals and entities.

#### ***Services Agreements***

From June 2006 to June 2008, PBS, of which Dr. Rosenwald is the sole member, provided us with certain drug development, professional, administrative and back office support services pursuant to a services agreement. In return for the services provided, we paid PBS \$25,000 per month and reimbursed PBS for its actual out-of-pocket expenses of up to \$5,000 per month. From July 2008 through June 2011, PBS contributed back office support at a determined value of \$10,000 per quarter. In addition to Dr. Rosenwald, one of our non-employee directors, Mr. Lobell, is an employee, president and chief operating officer of PBS.

In 2010, we entered into consulting agreements with two of our directors, Drs. Cooper and Rowinsky, each as more fully described in “Executive and Director Compensation—Non-Employee Director Compensation.” The 2010 letter agreement with Dr. Cooper was superseded by the employment agreement we entered into with him in April 2010.

In July 2011, the board approved an employment agreement with Eli Renov, a nephew of Dr. Lindsay Rosenwald. Pursuant to the agreement, as compensation for providing certain international investor relations services, Mr. Renov receives a monthly salary of \$12,500 and is eligible for a maximum discretionary bonus of 25% of his base salary. Mr. Renov was granted an option to purchase 30,000 shares of our common stock at an exercise price of \$2.95 per share.

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

### ***Stock Options Granted to Executive Officers and Directors***

We have granted stock options to our executive officers and directors, as more fully described in the section entitled “Executive and Director Compensation.”

### ***Indemnification Agreements***

We have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, as described in “Executive and Director Compensation—Limitation of Liability and Indemnification.”

## **Director Independence**

### ***Board Leadership Structure***

Our board of directors has a chairman, Dr. Cooper, who has authority, among other things, to call and preside over board meetings to set meeting agendas and to determine materials to be distributed to the board of directors. Accordingly, the chairman has substantial ability to shape the work of the board of directors. We believe that separation of the positions of chairman and chief executive officer reinforces the independence of the board in its oversight of our business and affairs. In addition, we believe that having a separate board chairman creates an environment that is more conducive to objective evaluation and oversight of management’s performance, increasing management accountability and improving the ability of the board of directors to monitor whether management’s actions are in the best interests of us and our stockholders. As a result, we believe that having a separate board chairman can enhance the effectiveness of the board of directors as a whole.

### ***Role of the Board in Risk Oversight***

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

## **Board Committees**

In July 2011, our board of directors established an audit committee comprised of Messrs. Rogers, Barrett and Lobell, each of whom is a non-employee member of the board of directors. Mr. Rogers serves as the chair of the audit committee. The audit committee operates under a charter approved by our board.

The functions of this committee include, among other things:

- evaluating the performance, independence and qualifications of our independent auditors and determining whether to retain our existing independent auditors or engage new independent auditors;

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

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

Following the effectiveness of this Form 10, we expect to establish a compensation committee of the board that will be responsible for creating and recommending the compensation of our executive officers to our board of directors, overseeing our compensation and benefit plans and policies and administering our equity incentive plans.

#### **Item 8. Legal Proceedings.**

We are not party to any pending legal proceedings.

#### **Item 9. Market Price of and Dividends on the Registrant's Common Equity and Related Stockholder Matters.**

##### **Market information**

There is no established public trading market in our common stock. Our securities are not listed for trading on any national securities exchange nor are bid or asked quotations reported in any over-the-counter quotation service.

##### **Equity Compensation Plans**

We expect that in the future we will file a registration statement on Form S-8 under the Securities Act registering the common stock subject to outstanding options or reserved for issuance under our 2007 plan. That registration statement will become effective immediately upon filing, and shares covered by that registration statement will thereupon be eligible for sale in the public markets, subject to grant of the underlying awards, vesting provisions and Rule 144 limitations applicable to our affiliates.

##### **Holders**

As of June 30, 2011, there were 7,028,059 shares of common stock outstanding, which were held by approximately 329 record stockholders. In addition, there were 4,357,885 Series A shares outstanding, which

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were held by approximately 269 record holders, there were 2,525,677 Series B shares outstanding, which were held by approximately 29 record holders and there were 4,612,624 Series C shares outstanding, which were held by approximately 343 record holders. As of June 30, 2011, each Series A share, Series B share and Series C share was convertible into one share of common stock.

As of the date of this Registration Statement, we have no present commitments to issue shares of our capital stock to any 5% holder, director or nominee, other than pursuant to the exercise of outstanding options and warrants as more fully set forth elsewhere in this Form 10.

#### ***Dividends***

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

#### ***Stock Not Registered Under the Securities Act; Rule 144 Eligibility***

Our common stock and convertible preferred stock, including our common stock and convertible preferred stock underlying outstanding options and warrants, have not been registered under the Securities Act. Accordingly, the shares of common stock and preferred stock issued and outstanding and the shares of common stock and preferred stock issuable upon the exercise of any options and warrants may not be resold absent registration under the Securities Act and applicable state securities laws or an available exemption thereunder.

#### ***Rule 144***

Shares of our common stock that are restricted securities will be eligible for resale in compliance with Rule 144 (“Rule 144”) or Rule 701 (“Rule 701”) of the Securities Act, subject to the requirements described below. “Restricted Securities,” as defined under Rule 144, were issued and sold by us in reliance on exemptions from the registration requirements of the Securities Act. These shares may be sold in the public market only if registered or if they qualify for an exemption from registration, such as Rule 144 or Rule 701. Below is a summary of the requirements for sales of our common stock pursuant to Rule 144, as in effect on the date of this Form 10, after the effectiveness of this Form 10.

#### ***Affiliates***

Affiliates will be able to sell their shares under Rule 144 beginning 90 days after the effectiveness of this Form 10, subject to all other requirements of Rule 144. In general, under Rule 144, an affiliate would be entitled to sell within any three-month period a number of shares that does not exceed one percent of the number of shares of our common stock then outstanding. Sales under Rule 144 are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us.

Persons who may be deemed to be our affiliates generally include individuals or entities that control, or are controlled by, or are under common control with, us and may include our directors and officers, as well as our significant stockholders.

#### ***Non-Affiliates***

For a person who has not been deemed to have been one of our affiliates at any time during the 90 days preceding a sale, sales of our shares of common stock held longer than six months, but less than one year, will be subject only to the current public information requirement and can be sold under Rule 144 beginning 90 days after the effectiveness of this Form 10. A person who is not deemed to have been one of our affiliates at any time during the 90 days preceding a sale, and who has beneficially owned the shares proposed to be sold for at least one year, is entitled to sell the shares without complying with the manner of sale, public information, volume limitation or notice provisions of Rule 144 upon the effectiveness of this Form 10.

### **Rule 701**

Rule 701 under the Securities Act, as in effect on the date of this Form 10, permits resales of shares in reliance upon Rule 144 but without compliance with certain restrictions of Rule 144, including the holding period requirement. Most of our employees, executive officers, directors or consultants who purchased shares under a written compensatory plan or contract may be entitled to rely on the resale provisions of Rule 701, but all holders of Rule 701 shares are required to wait until 90 days after the effective date of this Form 10 before selling their shares under Rule 701.

### **Securities Authorized for Issuance Upon the Exercise of Warrants**

As of June 30, 2011, there were outstanding warrants to purchase the following shares of our capital stock:

<u>Description</u>	<u>Number of shares subject to such warrants</u>	<u>Weighted-average exercise price of such warrants</u>
Common Stock	527,535	\$7.18
Series C Convertible Preferred Stock	461,263	\$5.59

For more information about the material terms of these warrants, please see “Item 11. Description of Registrant’s Securities to be Registered.”

### **Securities Authorized for Issuance Under Equity Compensation Plans**

The following table sets forth information regarding our equity compensation plans as of December 31, 2010. There are no equity compensation plans that have not been approved by our security holders.

<u>Plan Category</u>	<u>Number of securities to be issued upon exercise of outstanding options, warrants and rights</u>	<u>Weighted-average exercise price of outstanding options, warrants and rights</u>	<u>Number of securities remaining available for future issuance under equity compensation plans</u>
Equity compensation plans approved by security holders	1,132,110	\$1.37	2,350,720

### **Item 10. Recent Sales of Unregistered Securities.**

The following list sets forth information regarding all securities sold or issued for services by us since January 2008:

- (1) Between February 2008 and April 2008, we issued convertible promissory notes in an aggregate amount of \$4,070,000 to investors. These notes, plus accrued interest, converted into 835,724 Series A shares in April 2010.
- (2) In February 2008, in connection with the placement of the 2008 Notes, we issued warrants to purchase an aggregate of 48,510 shares of our common stock with an exercise price of \$9.229 per share. These warrants were initially issued to PBC. PBC subsequently transferred these warrants to other entities and individuals.
- (3) In January 2009, May 2009 and June 2009, in connection with borrowings under 10% senior promissory notes, we issued warrants to purchase an aggregate of 27,175 shares of our common stock with an exercise price of \$9.229 per share to PCP.
- (4) Between July 2009 and September 2009, we issued convertible promissory notes in an aggregate principal amount of \$3,500,000 to investors. These notes, plus accrued interest, converted into 628,755 Series A shares in April 2010.
- (5) In July 2009, in connection with the placement of convertible promissory notes in the 2009 bridge financing, we issued warrants to purchase an aggregate of 41,716 shares of our common stock with an exercise price of \$9.229 per share. These warrants were initially issued to PBC, which acted as the exclusive placement agent for the 2009 bridge financing. PBC subsequently transferred these warrants to other entities and individuals.

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- (6) In April 2010, May 2010, June 2010, July 2010 and August 2010, we issued an aggregate of 2,584,166 Series A shares to investors for an aggregate purchase price of \$21.7 million (not including the conversion of the bridge notes referenced in items (1) and (4) above).
  - (7) In April 2010, May 2010, June 2010, July 2010 and August 2010, in connection with the placement of the Series A shares, we issued warrants to purchase an aggregate of 258,418 shares of our common stock with an exercise price of \$8.39 per share. These warrants were initially issued to PBC, which acted as the exclusive placement agent for the Series A Financing. PBC subsequently transferred these warrants to other entities and individuals.
  - (8) In November 2010, in connection with the engagement of Coltin Securities, Inc. for placement agency services, we issued to Coltin a warrant to purchase 41,716 shares of common stock with an exercise price of \$9.23 per share.
  - (9) In January 2011, we acquired certain assets of Asphelia relating to CNDO-201 pursuant to an asset purchase agreement. The consideration paid for the assets included the issuance of 2,525,677 Series B shares to Asphelia. These shares have been or will be distributed to Asphelia's designees.
  - (10) In February 2011, we issued warrants to purchase an aggregate of 50,000 shares of our common stock with an exercise price of \$1.37 per share to two individuals as compensation for services rendered and related to CNDO-201.
  - (11) In March 2011, we issued a warrant to purchase up to an aggregate of 60,000 shares of common stock with an exercise price of \$1.37 per share to our former corporate secretary, as partial compensation under a consulting agreement.
  - (12) In May 2011 and June 2011, we issued an aggregate of 4,612,624 Series C shares for an aggregate purchase price of \$25.8 million.
  - (13) In May 2011 and June 2011, in connection with the Series C Financing in (12) above, we issued warrants to purchase 461,263 Series C shares with an exercise price of \$5.59 per share. These warrants were issued to National Securities Corporation, which acted as the exclusive placement agent for the Series C Financing.
  - (14) From January 1, 2008 to June 30, 2011, we granted stock options under our 2007 plan to purchase an aggregate of 1,517,110 shares of our common stock (net of cancellations) to our employees, directors and consultants, having exercise prices ranging from \$1.37 to \$2.69 per share. Of these, options to purchase 58,040 shares of common stock have been exercised through June 30, 2011 for aggregate consideration of \$79,515, each at an exercise price of \$1.37 per share.
  - (15) In July 2009, we issued 5,000 shares of common stock to a consultant as compensation for services rendered.
  - (16) In April 2010, we issued 23,836 shares of common stock to a consultant as compensation for services rendered.
  - (17) From 2006 until March 2010, we issued promissory notes in the aggregate principal amount of \$1,621,000 to three related parties. In April 2010, these notes, plus accrued interest, were converted into 309,240 Series A shares.

The offers, sales and issuances of the securities described in paragraphs (1), (2), (3), (4), (5), (6), (7), (8), (9), (10), (11), (12), (13), (15), (16) and (17) were deemed to be exempt from registration under the Securities Act in reliance on Rule 506 of Regulation D in that the issuance of securities to the accredited investors did not involve a public offering. The recipients of securities in each of these transactions acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions was an accredited investor under Rule 501 of Regulation D.



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The offers, sales and issuances of the securities described in paragraph (14) were deemed to be exempt from registration under the Securities Act in reliance on Rule 701 in that the transactions were under compensatory benefit plans and contracts relating to compensation as provided under Rule 701. The recipients of such securities were our employees, directors or bona fide consultants and received the securities under our 2007 plan. Appropriate legends were affixed to the securities issued in these transactions. Each of the recipients of securities in these transactions had adequate access, through employment, business or other relationships, to information about us.

#### **Item 11. Description of Registrant's Securities to be Registered.**

##### ***Common Stock***

As of June 30, 2011, we had 50,000,000 authorized shares of common stock, par value \$0.001 per share.

As of June 30, 2011, there were 7,028,059 shares of common stock outstanding. As of June 30, 2011, there were 1,986,605 shares of common stock subject to outstanding options and warrants and 11,957,449 shares of common stock issuable upon conversion of outstanding preferred stock and warrants to purchase Series C shares. Each holder of common stock is entitled to one vote for each share of common stock held on all matters submitted to a vote of the stockholders, including the election of directors. Our amended and restated certificate of incorporation and amended and restated bylaws do not provide for cumulative voting rights. Subject to preferences that may be applicable to any then outstanding preferred stock, the holders of our outstanding shares of common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of legally available funds. In the event of our liquidation, dissolution or winding up, holders of common stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of our debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of preferred stock. Holders of our common stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to the common stock. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of our preferred stock that are outstanding or that we may designate and issue in the future. All of our outstanding shares of common stock are fully paid and nonassessable.

##### ***Registration Rights***

Holders of our Series A shares, Series B shares and Series C shares have the right to require us to register with the SEC the shares of common stock issuable upon conversion of such preferred stock so that those shares of common stock may be publicly resold, or to include those shares in any registration statement we file. In addition, certain holders of our outstanding warrants to purchase common stock and the holders of warrants to purchase preferred stock have the right to require us to register the shares of common stock underlying such warrants for resale to the public. The shares of common stock issuable upon conversion of the outstanding shares of preferred stock, and the shares of common stock issuable upon the exercise of the outstanding warrants which include such registration rights are hereinafter referred to as the "Underlying Securities."

*Demand registration rights.* At any time beginning 180 days after the earlier of (i) the effective date of an initial offering of our equity securities pursuant to an effective registration statement and (ii) the first date on which the common stock trades on a national securities exchange or an Over-the-Counter Bulletin Board, the holders of at least a majority of the Underlying Securities having registration rights have the right to demand that we file one registration statement. These registration rights are subject to specified conditions and limitations, including the right of the underwriters to limit the number of shares of Underlying Securities included in any such registration under certain circumstances.

*Form S-3 registration rights.* If we are eligible to file a registration statement on Form S-3, each holder of shares of Underlying Securities having registration rights has the right to demand that we file no more than one

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registration statement for the holders on Form S-3 in any 12-month period so long as the aggregate offering price, before any underwriters' discounts or commissions, of securities to be sold under the registration statement on Form S-3 is at least \$5,000,000, subject to specified exceptions, conditions and limitations.

*"Piggyback" registration rights.* If we register any securities for public sale, stockholders with registration rights will have the right to include their shares in the registration statement. The underwriters of any underwritten offering will have the right to limit the number of shares having registration rights to be included in the registration statement.

*Expenses of registration.* We will pay all expenses, other than underwriting discounts and commissions, relating to all demand registrations, Form S-3 registrations and piggyback registrations.

*Expiration of registration rights.* The registration rights described above will terminate, as to a given holder of registrable securities, when such holder of registrable securities can sell all of such holder's registrable securities pursuant to Rule 144 promulgated under the Securities Act in a single transaction without registration or any other restrictions.

*Registration rights applicable to Series C shares and certain other stockholders.* In addition to the registration rights set out above, we have agreed that, within 60 days of the first day that shares of our capital stock are registered pursuant to Section 12 of the Exchange Act (the "Public Date"), we shall file a resale registration statement covering the resale of all shares of common stock issuable upon conversion of the Series C shares (or less than all, if we are limited in the number of shares that we can include on such resale registration statement by regulation or the requirements of any exchange), and use our commercially reasonable efforts to have the registration statement declared effective within 120 days after the Public Date. The agreement provides for us to pay liquidated damages equal to 1% of the purchase price per month, up to a maximum of 10%, in the event we fail to file the registration statement within the 60 day time period.

We intend to file a registration statement on Form S-1 under the Securities Act shortly following the effectiveness of this Form 10 to permit the resale of the shares of common stock underlying our outstanding preferred stock. Registration of these shares under the Securities Act would result in the shares becoming freely tradable without restrictions under the Securities Act immediately upon the effectiveness of such registration. Any sales of securities by holders of these shares could adversely affect the trading prices, if any, of our common stock.

#### ***Information Rights***

Each holder of our Series A shares who previously held 2008 Notes and 2009 Notes with an aggregate principal amount of at least \$2,000,000 (of which there is currently only one, the "Entitled Holder") is entitled to information rights with respect to us for so long as such holder beneficially owns at least five percent of our issued and outstanding voting securities, determined on an as-if-converted-to-common-stock basis. Such Entitled Holder is generally entitled to access to our properties, books and records, quarterly and annual financial statements and other miscellaneous documents. Such information rights are subject to confidentiality obligations and will terminate on the date upon which we become subject to the periodic reporting requirements of the Exchange Act.

#### ***Participation Rights***

Pursuant to an agreement between us and Manchester, Manchester has a participation right to purchase its pro rata percentage of any equity securities (subject to customary exceptions) issued by us until the date that is 18 months after Manchester's stock is registered for resale under the Securities Act. The "pro rata percentage" is

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equal to the ratio of (a) the number of shares of our capital stock which Manchester is deemed to beneficially own immediately prior to the issuance of such equity securities, to (b) the total number of shares of our common stock outstanding (including all shares of common stock issued or issuable upon conversion of the preferred stock or upon the exercise of any outstanding warrants or options) immediately prior to the issuance of the equity securities. In lieu of giving notice to Manchester prior to the issuance of equity securities, we may elect to give notice to such stockholder within ten (10) days after the issuance of equity securities. In that case, Manchester shall have ninety (90) days from the date of receipt of such notice to elect to purchase up to the number of shares that would, if purchased by it, maintain such its *pro rata* share of our equity securities after giving effect to all such purchases.

#### ***Anti-Takeover Provisions***

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that might have an anti-takeover effect. These provisions, which are summarized below, may have the effect of delaying, deterring or preventing a change in control of our company. They could also impede a transaction in which our stockholders might receive a premium over the then-current market price of our common stock and our stockholders' ability to approve transactions that they consider to be in their best interests.

Our amended and restated certificate of incorporation permits our board of directors to issue preferred stock. We could authorize the issuance of a series of preferred stock which would grant to holders preferred rights to our assets upon liquidation, the right to receive dividend coupons before dividends would be declared to holders of shares of our existing preferred stock and our existing preferred stock and common stock. Our current stockholders have no redemption rights. In addition, as we have a large number of authorized but unissued shares, our board of directors could issue large blocks of voting stock to fend off unwanted tender offers or hostile takeovers without further stockholder approval.

We are subject to Section 203 of the Delaware General Corporation Law. In general, Section 203, subject to specific exceptions, prohibits a publicly-held Delaware corporation from engaging in any "business combination" with any "interested stockholder" for a period of three years following the date that the stockholder became an interested stockholder, unless:

- prior to that date, the board of directors approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;
- upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85 percent of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the number of shares outstanding those shares owned by directors, officers and specific employee stock plans; or
- on or after that date, the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of the holders of at least 66 2/3 percent of the outstanding voting stock that is not owned by the interested stockholder.

Section 203 defines "business combination" to include:

- any merger or consolidation involving the corporation and the interested stockholder;
- any sale, lease, exchange, mortgage, transfer, pledge or other disposition of 10 percent or more of the assets of the corporation involving the interested stockholder;
- subject to limited exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

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- any transaction involving the corporation that has the effect of increasing the proportionate share of the corporation's stock of any class or series beneficially owned by the interested stockholder; and
  - the receipt by the "interested stockholder" of the benefit of any loans, advances, guarantees, pledges or other financial benefits provided by or through the corporation.

In general, an "interested stockholder" is an entity or individual who, together with affiliates and associates, owns, or within three years prior to the determination of the "interested stockholder" status owned, 15 percent or more of a corporation's outstanding voting stock.

The provisions of Section 203 could encourage companies interested in acquiring us to negotiate in advance with our board of directors since the stockholder approval requirement would be avoided if our board of directors approves either the business combination or the transaction that results in the stockholder becoming an interested stockholder. These provisions also could have the effect of preventing changes in our management or could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interests.

## **Item 12. Indemnification of Directors and Officers.**

### *Amended and Restated Bylaws*

Pursuant to our amended and restated bylaws, our directors and officers will be indemnified to the fullest extent allowed under the laws of the State of Delaware for their actions in their capacity as our directors and officers.

We must indemnify any person made a party to any threatened, pending, or completed action, suit, or proceeding, whether civil, criminal, administrative, or investigative ("Proceeding") by reason of the fact that he is or was a director, against judgments, penalties, fines, settlements and reasonable expenses (including attorney's fees) ("Expenses") actually and reasonably incurred by him in connection with such Proceeding if: (a) he conducted himself in good faith, and: (i) in the case of conduct in his own official capacity with us, he reasonably believed his conduct to be in our best interests, or (ii) in all other cases, he reasonably believes his conduct to be at least not opposed to our best interests; and (b) in the case of any criminal Proceeding, he had no reasonable cause to believe his conduct was unlawful.

We must indemnify any person made a party to any Proceeding by or in the right of us, by reason of the fact that he is or was a director, against reasonable expenses actually incurred by him in connection with such proceeding if he conducted himself in good faith, and: (a) in the case of conduct in his official capacity with us, he reasonably believed his conduct to be in our best interests; or (b) in all other cases, he reasonably believed his conduct to be at least not opposed to our best interests; provided that no such indemnification may be made in respect of any proceeding in which such person shall have been adjudged to be liable to us.

No indemnification will be made by unless authorized in the specific case after a determination that indemnification of the director is permissible in the circumstances because he has met the applicable standard of conduct.

Reasonable expenses incurred by a director who is party to a proceeding may be paid or reimbursed by us in advance of the final disposition of such Proceeding in certain cases.

We have the power to purchase and maintain insurance on behalf of any person who is or was our director, officer, employee, or agent or is or was serving at our request as an officer, employee or agent of another corporation, partnership, joint venture, trust, other enterprise, or employee benefit plan against any liability asserted against him and incurred by him in any such capacity or arising out of his status as such, whether or not we would have the power to indemnify him against such liability under the provisions of the amended and restated bylaws.

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### ***Delaware Law***

We are incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law provides that a Delaware corporation may indemnify any persons who are, or are threatened to be made, parties to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of such corporation), by reason of the fact that such person was an officer, director, employee or agent of such corporation, or is or was serving at the request of such person as an officer, director, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by such person in connection with such action, suit or proceeding, provided that such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests and, with respect to any criminal action or proceeding, had no reasonable cause to believe that his or her conduct was illegal. A Delaware corporation may indemnify any persons who are, or are threatened to be made, a party to any threatened, pending or completed action or suit by or in the right of the corporation by reason of the fact that such person was a director, officer, employee or agent of such corporation, or is or was serving at the request of such corporation as a director, officer, employee or agent of another corporation or enterprise. The indemnity may include expenses (including attorneys' fees) actually and reasonably incurred by such person in connection with the defense or settlement of such action or suit provided such person acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the corporation's best interests except that no indemnification is permitted without judicial approval if the officer or director is adjudged to be liable to the corporation. Where an officer or director is successful on the merits or otherwise in the defense of any action referred to above, the corporation must indemnify him or her against the expenses which such officer or director has actually and reasonably incurred. Our amended and restated certificate of incorporation and amended and restated bylaws provide for the indemnification of our directors and officers to the fullest extent permitted under the Delaware General Corporation Law.

Section 102(b)(7) of the Delaware General Corporation Law permits a corporation to provide in its certificate of incorporation that a director of the corporation shall not be personally liable to the corporation or its stockholders for monetary damages for breach of fiduciary duties as a director, except for liability for any:

- transaction from which the director derives an improper personal benefit;
- act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payment of dividends or redemption of shares; or
- breach of a director's duty of loyalty to the corporation or its stockholders.

Our amended and restated certificate of incorporation and amended and restated bylaws include such a provision. Expenses incurred by any officer or director in defending any such action, suit or proceeding in advance of its final disposition shall be paid by us upon delivery to us of an undertaking, by or on behalf of such director or officer, to repay all amounts so advanced if it shall ultimately be determined that such director or officer is not entitled to be indemnified by us.

Section 174 of the Delaware General Corporation Law provides, among other things, that a director who willfully or negligently approves of an unlawful payment of dividends or an unlawful stock purchase or redemption may be held liable for such actions. A director who was either absent when the unlawful actions were approved, or dissented at the time, may avoid liability by causing his or her dissent to such actions to be entered in the books containing minutes of the meetings of the board of directors at the time such action occurred or immediately after such absent director receives notice of the unlawful acts.

### ***Indemnification Agreements***

As permitted by the Delaware General Corporation Law, we have entered, and intend to continue to enter, into separate indemnification agreements with each of our directors and executive officers, that require us to

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indemnify such persons against any and all expenses (including attorneys' fees), witness fees, damages, judgments, fines, settlements and other amounts incurred (including expenses of a derivative action) in connection with any action, suit or proceeding, whether actual or threatened, to which any such person may be made a party by reason of the fact that such person is or was a director, an officer or an employee of us or any of our affiliated enterprises, provided that such person acted in good faith and in a manner such person reasonably believed to be in or not opposed to our best interests and, with respect to any criminal proceeding, had no reasonable cause to believe his or her conduct was unlawful. The indemnification agreements also set forth certain procedures that will apply in the event of a claim for indemnification thereunder.

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

We have an insurance policy covering its officers and directors with respect to certain liabilities, including liabilities arising under the Securities Act or otherwise.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to our directors, officers or controlling persons, we have been advised that in the opinion of the SEC this indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable.

**Item 13. Financial Statements and Supplementary Data.**

The information required by this item may be found beginning on page F-1 of this Form 10.

**Item 14. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.**

None.

**Item 15. Financial Statements and Exhibits.**

(a) Financial Statements filed as part of this registration statement:

**Consolidated Financial Statements:**

Consolidated Balance Sheets as of December 31, 2010 and 2009.

Consolidated Statements of Operations for the year ended December 31, 2010, 2009 and 2008.

Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit at December 31, 2010, 2009, 2008, 2007 and 2006.

Consolidated Statements of Cash Flows for the year ended December 31, 2010, 2009 and 2008.

Notes to Consolidated Financial Statements as of December 31, 2010 and 2009.

**Condensed Consolidated Financial Statements:**

Condensed Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010.

Condensed Consolidated Statements of Operations for the six months ended June 30, 2011 and 2010.

Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit Period from June 28, 2006 through June 30, 2011.

Condensed Consolidated Statements of Cash Flows for the six months ended June 30, 2011 and 2010.

Notes to Condensed Consolidated Financial Statements.

(b) Exhibits.

See the Exhibit Index attached hereto which is incorporated by reference.

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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 convertible preferred stock and stockholders' 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, 2010 and December 31, 2009, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2010 and, cumulatively, for the period from June 28, 2006 (date of inception) to December 31, 2010 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP  
Florham Park, New Jersey  
July 15, 2011



**Coronado Biosciences, Inc. and Subsidiary**  
**(a development stage enterprise)**  
**Consolidated Balance Sheets**  
*(\$ in thousands)*

	As of December 31,	
	2010	2009
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 14,862	\$ 1,510
Prepaid and other current assets	55	5
Total current assets	14,917	1,515
Computer equipment, net of accumulated depreciation	22	15
Deferred financing costs	—	157
Total Assets	<u>\$ 14,939</u>	<u>\$ 1,687</u>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 476	\$ 628
Accounts payable – related party	46	—
Accrued expenses	1,037	525
Senior convertible notes	—	7,570
Interest payable – senior convertible notes	—	795
Notes payable – related parties	—	1,319
Interest payable – related parties	—	252
PCP Interest payable – related party	—	38
Borrowings under line of credit	—	80
Total current liabilities	1,559	11,207
PCP Notes payable – related party	—	570
Total Liabilities	<u>1,559</u>	<u>11,777</u>
Commitments and Contingencies (Note 6)		
Convertible Preferred Stock Series A, \$.001 par value, 10,000,000 shares authorized 4,357,885 shares issued and outstanding at December 31, 2010, net of issuance costs (liquidation value of \$54,844 at December 31, 2010). At December 31, 2009, no issued or outstanding shares.	29,277	—
Stockholders' Deficit:		
Common Stock, \$.001 par value, 50,000,000 shares authorized, 4,791,102 shares issued and outstanding at December 31, 2010. At December 31, 2009, 30,000,000 share authorized and 4,767,266 shares issued and outstanding.	5	5
Additional paid-in capital	4,312	137
Deficit accumulated during the development stage	(20,214)	(10,232)
Total Stockholders' Deficit	<u>(15,897)</u>	<u>(10,090)</u>
Total Liabilities, Convertible Preferred Stock and Stockholders' Deficit	<u>\$ 14,939</u>	<u>\$ 1,687</u>

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 per share amounts)*

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to December 31, 2010
	2010	2009	2008	
Operating expenses:				
Research and development	\$ 8,341	\$ 2,270	\$ 2,895	\$ 15,959
General and administrative	900	343	348	1,859
Loss from operations	(9,241)	(2,613)	(3,243)	(17,818)
Interest income	61	—	18	79
Interest expense, net	(1,535)	(1,053)	(573)	(3,208)
Other income	733	—	—	733
Net loss	<u>\$ (9,982)</u>	<u>\$ (3,666)</u>	<u>\$ (3,798)</u>	<u>\$ (20,214)</u>
Basic and diluted net loss per common share	<u>\$ (2.24)</u>	<u>\$ (1.01)</u>	<u>\$ (1.39)</u>	
Weighted average common shares outstanding – basic and diluted	<u>4,453,786</u>	<u>3,612,769</u>	<u>2,731,212</u>	

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

**Coronado Biosciences, Inc. and Subsidiary**  
**(a development stage enterprise)**  
**Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit**  
*(\$ in thousands)*

	Preferred stock		Common stock		Additional paid-in capital	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 Series A Convertible Preferred Stock, including the fair value of Common Stock warrants	—	(2,912)	—	—	621	—	621
Reclassification of warrant liability at fair value	—	—	—	—	234	—	234
Change in fair value of embedded conversion feature related to the Related Party Notes and Senior Convertible Notes	—	—	—	—	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)

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, 2010
	2010	2009	2008	2010
<b>Cash flows from operating activities:</b>				
Net loss	\$ (9,982)	\$ (3,666)	\$ (3,798)	(20,214)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	2,329	39	25	2,405
Noncash interest	236	493	302	1,031
Noncash interest – related parties	34	101	105	286
Contribution of services by stockholder	40	40	20	100
Issuance of Common Stock to non-employee for services	82	—	—	83
Change in fair value of common stock warrant liability	234	—	—	234
Change in fair value of embedded conversion feature	831	—	—	831
Issuance of Common Stock warrants to non-employee for services	38	—	—	38
Amortization of deferred financing costs	157	415	166	737
Depreciation expense	6	5	5	19
Changes in operating assets and liabilities:				
Other current assets	(51)	203	(119)	(55)
Interest payable – related parties	(38)	38	—	—
Accounts payable and accrued expenses-related parties	46	—	—	46
Accounts payable and accrued expenses	361	(19)	(229)	1,513
Net cash used in operating activities	<u>(5,677)</u>	<u>(2,351)</u>	<u>(3,523)</u>	<u>(12,946)</u>
<b>Cash flows from investing activities:</b>				
Purchase of computer equipment	(13)	(2)	—	(41)
Net cash used in investing activities	<u>(13)</u>	<u>(2)</u>	<u>—</u>	<u>(41)</u>
<b>Cash flows from financing activities:</b>				
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	316	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 borrowings under line of credit	—	40	40	80
Payment of line of credit	(80)	—	—	(80)
Proceeds from Senior Convertible Notes	—	3,500	4,070	7,570
Payment of debt issue costs	—	(344)	(381)	(737)
Payment of notes payable – related parties	—	—	(600)	(600)
Proceeds from issuance of Common Stock	—	—	—	5
Net cash provided by financing activities	<u>19,042</u>	<u>3,856</u>	<u>3,445</u>	<u>27,849</u>
<b>Increase / (decrease) in cash and cash equivalents</b>	<b>13,352</b>	<b>1,503</b>	<b>(78)</b>	<b>14,862</b>
Cash and cash equivalents – beginning of period	1,510	7	85	—
Cash and cash equivalents – end of period	<u>\$14,862</u>	<u>\$ 1,510</u>	<u>\$ 7</u>	<u>\$ 14,862</u>
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid for interest	\$ 81	\$ 7	\$ —	\$ 88
<b>Supplemental disclosure of non-cash financing and investing activities:</b>				
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

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)**  
**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 development-stage biopharmaceutical company focused on novel immunotherapy 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. We continue to report as a development stage enterprise since planned principal operations have not yet commenced. Since inception, no revenue has been recognized and the Company has incurred net losses and negative cash flows from operations.

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit during the development stage of \$20.2 million as of December 31, 2010. 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. During 2010, the Company issued 4,357,885 shares of Series A Convertible Preferred Stock resulting in gross proceeds to the Company of \$21.7 million (see Note 11). All debt securities have either been repaid or converted into shares of Series A Convertible Preferred Stock as of December 31, 2010. Between May 2011 and July 2011, the Company issued 4,612,624 shares of Series C Convertible Preferred Stock resulting in net proceeds to the Company of approximately \$22.8 million (see Note 17). Management believes that cash and cash equivalents on hand, including cash raised in the Series C Preferred Stock financing (see Note 17) are sufficient to sustain operations through 2012 based on its existing business plan and given the ability to control the timing of significant expense commitments.

The Company expects to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its product candidates. The Company will require additional financing to develop, obtain regulatory approvals, 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 could 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 may be required to delay, reduce or eliminate research and development programs, reduce or eliminate commercialization efforts and pursue merger or acquisition strategies.

Operations of the Company are subject to certain risks and uncertainties, including, among others, 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 experience, 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 our 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.

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**Coronado Biosciences, Inc. and Subsidiary**  
**(a development stage enterprise)**  
**Notes to the Consolidated Financial Statements**

**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 Common and Preferred Stock, Common Stock warrants, stock options, accrued expenses, provisions for income taxes and contingencies. Due to the uncertainty inherent in such estimates, actual results may differ from our estimates.

**Segment Reporting**

The Company operates as one segment, in which management uses one measure of profitability, and all of the Company's assets are located in the United States of America. The Company is managed and operated as one business. The 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.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of cash and certain highly liquid investments with original maturities of less than three months. The Company maintains balances at financial institutions which may exceed Federal Deposit Insurance Corporation insured limits.

**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 Company's Senior Convertible Notes, PCP Notes 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 Convertible Preferred Stock offering were recorded as a reduction to its 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

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**Coronado Biosciences, Inc. and Subsidiary**  
**(a development stage enterprise)**  
**Notes to the Consolidated Financial Statements**

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 party contract research organizations for preclinical studies, investigative sites for clinical trials, consultants, 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 considering estimated forfeiture rates. For stock-based compensation awards to nonemployees, the Company remeasures the fair value of the nonemployee 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 nonemployee 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. In the absence of a public trading market of the Company's Common Stock, the Company commenced periodic contemporaneous assessments of the valuation of the Company's Common Stock. These valuations were performed concurrently with the achievement of significant milestones or with major financing. The Company considered numerous objective and subjective factors, including but not limited to the following factors:

- Arms length private transactions involving the Company's Convertible Preferred Stock;
- Financial and operating performance;

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**Coronado Biosciences, Inc. and Subsidiary**  
**(a development stage enterprise)**  
**Notes to the Consolidated Financial Statements**

- 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 a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future 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.

#### **Recently Issued Accounting Standards**

In June 2011, the Financial Accounting Standards Board ("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.

In June 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.

### **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 Convertible Preferred Stock are entitled to a dividend equal (on an as-if-converted to Common Stock basis) to the amount paid or set aside for each share of Common Stock. Additionally, holders of restricted Common Stock are entitled to all cash



**Coronado Biosciences, Inc. and Subsidiary**  
**(a development stage enterprise)**  
**Notes to the Consolidated Financial Statements**

dividends, when 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 of the periods presented.

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares 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 shares and common share 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.

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

*(\$ in thousands except per share amounts)*

	For the Year Ended December 31,		
	2010	2009	2008
<b>Historical net loss per share:</b>			
<i>Numerator</i>			
Net loss attributed to common stockholders	\$ (9,982)	\$ (3,666)	\$ (3,798)
<i>Denominator</i>			
Weighted-average common shares outstanding –			
Denominator for basic and diluted net loss per share	4,453,786	3,612,769	2,731,212
Basic and diluted net loss per share attributed to common stockholders	\$ (2.24)	\$ (1.01)	\$ (1.39)

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:

	As of December 31,		
	2010	2009	2008
Series A Convertible Preferred Stock	2,601,812	—	—
Unvested restricted Common Stock	327,385	1,151,997	2,031,054
Warrants to purchase Common Stock	143,637	—	—
Senior Convertible Note warrants	90,226	63,963	40,085
PCP note warrants	27,175	21,871	—
Option to purchase Common Stock	292,747	—	—
	<u>3,482,982</u>	<u>1,237,831</u>	<u>2,071,139</u>

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**4. Computer Equipment**

Computer equipment consisted of the following:

<i>(\$ in thousands)</i>	As of December 31,	
	2010	2009
Computer equipment	\$ 41	\$ 28
Less: Accumulated depreciation	(19)	(13)
Computer equipment, net	<u>\$ 22</u>	<u>\$ 15</u>

Depreciation expense for the years ended December 31, 2010, 2009, and 2008 and the period from inception to December 31, 2010 was \$6,000, \$5,000, \$5,000 and \$19,000, respectively, and was recorded as general and administrative expense in the consolidated statement of operations.

**5. Accrued Expenses**

Accrued expenses consisted of the following:

<i>(\$ in thousands)</i>	As of December 31,	
	2010	2009
Salaries, bonuses and related benefits	\$ 553	\$ 289
Professional fees	309	130
Research and development expenses	143	95
Other	32	11
Total accrued expenses	<u>\$ 1,037</u>	<u>\$ 525</u>

For the year ended December 31, 2010, the Company incurred costs related to the termination of certain employees, including wages and other related employment benefits of \$225,000, which was recorded as a component of research and development expenses in the consolidated statement of operations. At December 31, 2010, an accrued liability of \$210,000 remained for future payments of severance costs and is included in salaries, bonuses and related benefits above.

**6. Commitments and Contingencies**

**Operating Lease Obligations**

In October 2010, the Company entered into a three month agreement for office facilities under an operating lease. The agreement contains a recurring renewal clause for a period of three months unless either party provides 60 days' notice.

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

**Indemnification**

In accordance with its Certificate of Incorporation and bylaws, 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.

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**Legal Proceedings**

In the ordinary course of business, the Company and its subsidiaries may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers and/or third parties (including tort claims for personal injury and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages. At December 31, 2010 and 2009, no claims have been brought by and against the Company and its subsidiary.

**7. Employee Benefit Plans**

On January 1, 2008, the Company adopted a defined contribution (401k) 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. As of December 31, 2010 the Company has elected not to pay discretionary matching contributions.

**8. Fair Value Measurement**

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

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

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

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

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

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

The Company valued its warrant liabilities using a binomial option pricing model (see Note 13).

The Company's only financial instrument that was measured at fair value as of December 31, 2009 was its related party notes of \$1.3 million and was determined to be a level 3 liability within the fair value hierarchy. There were no assets or liabilities that were required to be measured at fair value as of December 31, 2010.

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

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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.

**9. Related Party Transactions**

**Services Agreement**

In November 2006, the Company entered into a consulting contract with Paramount BioSciences, LLC, ("PBS") an affiliate of a significant stockholder and director of the Company, under which PBS provided certain drug development, professional, administrative and accounting services. Total fees for the period from inception to December 31, 2010 were \$550,000.

**Placement Agent**

Paramount BioCapital, Inc. ("PBC"), an affiliate of a significant stockholder and director of the Company, acted as placement agent for the private placement of the Company's Senior Convertible Notes, PCP Notes, and Series A Convertible Preferred Stock (see Notes 11 and 12). For the services rendered, PBC received cash payment for commissions and reimbursement of expenses as well as warrants to purchase common shares (see Notes 11 and 14).

**Other Related Parties**

One of the Company's principal stockholders and a director of the Company who is also director and chairman, chief executive officer and a significant stockholder of PBS and PBC, beneficially owns approximately 25.7% of the Company's issued and outstanding capital stock. In addition, certain trusts established for the benefit of this principal stockholder and director's family members beneficially own an aggregate of approximately 11.9% of the Company's outstanding capital stock.

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

See Note 10 for related party debt instruments and Note 13 for related party warrant issuances.

**10. Debt**

Total outstanding debt consisted of the following:

<i>(\$ in thousands)</i>	As of December 31,	
	2010	2009
Related party notes	\$—	\$ 1,319
PCP notes	—	570
Senior Convertible Notes	—	7,570
Line of credit facility	—	80
Total outstanding debt	—	9,539
Less: current portion	—	(8,969)
Total long-term debt	\$—	\$ 570

During 2010, the PCP Notes and the Line of credit facility were repaid and all other debt was converted to Series A Convertible Preferred Stock.

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**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 largest shareholder and 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 one of the Company's largest shareholders and a director (the "First Trust Note" and "Second Trust Note").

The Related Party Notes mature and were payable on the respective stated maturity date 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 provide that all unpaid principal and accrued interest shall be automatically converted upon the occurrence of one of the following events:

(1) Qualified Financing

All unpaid principal and unpaid accrued interest on the Related Party Notes shall be automatically converted into the Company's equity securities issued in the Company's next equity financing (or series of related equity 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 in such qualified financing.

(2) Reverse Merger

If the reverse merger consideration is greater than or equal to \$10 million, all unpaid principal and unpaid accrued interest on the Related Party Notes shall be automatically converted into the Common Stock at a conversion price per share equal to 75% times (i) reverse merger consideration minus principal amount under Senior Convertible Notes and Related Party Notes divided by (ii) number of outstanding shares (fully diluted common shares excluding warrants).

(3) Sale of the Company

Lesser of:

- 75% of the value of sales proceeds received in such transaction less the unpaid principal amount under Senior Convertible Notes and Related Party Notes divided by the number of outstanding shares (fully diluted excluding options and warrants with exercise price in excess of Related Party Notes conversion price)
- \$50M divided by the number of outstanding shares (fully diluted excluding options and warrants with exercise price in excess of Related Party Notes conversion price).

On February 5, 2010, the Company amended the Related Party Notes to extend the maturity date to September 30, 2010 and change the conversion price factor for the above events from 75% to 70%.

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The 2008 and 2009 Related Party Notes amendments were treated as extinguishments and the loss on extinguishment, which was not material, was recorded in additional paid-in capital. The 2010 Related Party Notes amendment was 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.

On April 26, 2010, the Company completed a qualified equity financing and principal and accrued interest totaling \$1.6 million automatically converted into 273,046 shares of Series A Convertible Preferred Stock 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 shares of Series A Convertible Preferred Stock at a per share price of \$8.39.

**Paramount Credit Partners, LLC (“PCP”) Promissory Notes (the “PCP Notes”)**

On January 22, 2009, May 28, 2009, and June 24, 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 one of the Company’s largest shareholders and director. All unpaid principal and accrued interest outstanding under the PCP Notes were payable on December 31, 2013 or earlier if certain events occur. 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 or a reverse merger or sale of the Company.

On September 29, 2010, the outstanding principal and accrued interest totaling \$0.6 million was repaid in cash.

In conjunction with entering into the PCP Notes, the Company issued warrants to purchase 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. The debt discount was not material and was amortized to interest expense in the consolidated statement of operations over the term of the PCP Notes.

PBC received cash commissions equal to 2% of the gross proceeds of the PCP Notes and expense reimbursements as compensation for its services as the placement agent. These costs were capitalized as deferred financing fees and are amortized to interest expense in the consolidated statement of operations over the term of the PCP Notes.

**Senior Convertible Notes**

In February 2008, March 2008 and April 2008, the Company issued 8% convertible promissory notes for cash proceeds of \$4.1 million (the “2008 Senior Convertible Notes”) that are 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 a Company 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.

In July 2009, August 2009, and September 2009 the Company issued 8% convertible promissory notes for cash proceeds of \$3.5 million (the “2009 Senior Convertible Notes”) that are 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.

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Additionally, 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 one of the following events:

(1) Qualified Financing

The Senior Convertible Notes shall be automatically converted into the Company's equity securities issued in the Company's next equity financing (or series of related equity 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 in such qualified financing.

(2) Reverse Merger

If the reverse merger consideration is greater than or equal to \$10 million, the Senior Convertible Notes shall be automatically converted into the Common Stock at a conversion price per share equal to 75% times (i) reverse merger consideration minus principal amount under Senior Convertible Notes and Related Party Notes divided by (ii) number of outstanding shares (fully diluted common shares excluding warrants).

(3) Sale of the Company

Lesser of:

- 75% of the value of sales proceeds received in such transaction less the unpaid principal amount under Senior Convertible Notes and Related Party Notes divided by the number of outstanding shares (fully diluted excluding options and warrants with exercise price in excess of Senior Convertible of Notes conversion price)
- \$50M divided by the number of outstanding shares (fully diluted excluding options and warrants with exercise price in excess of Senior Convertible Note conversion price).

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.

On February 5, 2010, the Company amended the Senior Convertible Notes to extend the maturity date to September 30, 2010 and modify the conversion price factor for the above events from 75% to 70%. 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 Note holders 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.

On April 26, 2010, the Company completed a qualifying financing and principal and accrued interest totaling \$8.6 million automatically converted into 1,464,479 shares of Series A Convertible Preferred Stock at a per share price of \$5.87. In addition, the liability of \$0.6 million related to the repayment premium was reversed to interest expense upon the conversion of the Senior Convertible Notes to Series A Preferred Stock.

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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 2008, amortization of deferred financing costs was \$0.2 million, \$0.4 million and \$0.2 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 is secured by collateral pledged by PBS. As of December 31, 2009, the Company had borrowings outstanding of \$80,000. The line of credit was repaid in full and closed during 2010.

Interest expense includes the following:

<i>(\$ in thousands)</i>	For the Years Ended December 31,			Period from June
	2010	2009	2008	28, 2006 (Date of Inception) to
Interest expense	\$ 237	\$ 493	\$ 302	\$ 1,032
Interest expense – related parties	76	145	105	374
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	166	737
Total interest expense	\$ 1,535	\$ 1,053	\$ 573	\$ 3,208

**11. Preferred Stock**

The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 15,000,000 shares of \$0.001 par value Preferred Stock. As of December 31, 2010, there were 4,357,885 shares of Series A Convertible Preferred Stock outstanding. There was no Preferred Stock issued or outstanding as of December 31, 2009.

The terms, rights, preference and privileges of the Company's Series A Convertible Preferred Stock are as follows:

**Voting Rights**

Holder of Series A Convertible Preferred Stock vote 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 is 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 Convertible Preferred Stock shall be 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.



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**Conversion**

Each share of Series A Convertible Preferred Stock will be voluntarily convertible into one share of Common Stock at the election of the holder. Additionally, each share of Series A Convertible Preferred Stock will 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.

As discussed in Note 17, in May 2011 the conversion feature was amended such that the Series A Convertible Preferred Stock will automatically convert to Common Stock on the effective date of the issuance of a registration statement.

**Dividends**

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

If the Series A Convertible Preferred Stock is automatically converted into Common Stock on April 26, 2012, the holders of Series A Convertible Preferred Stock shall, immediately prior to such automatic conversion, receive a special dividend per share (the "Special Dividend") payable in cash and/or shares of the Company's 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 the Company's Common Stock issued in payment of the Special Dividend shall be determined in the reasonable, good-faith discretion of the Company's board of directors at the time of payment.

The Special Dividend per share of Series A Convertible Preferred Stock will be paid in cash or in shares of common stock equal to 50% of the offering price, or \$4.20.

**Fully Paid and Nonassessable**

All of our outstanding shares of Series A Convertible Preferred Stock are fully paid and nonassessable.

In addition, under the Company's Certificate of Incorporation, the board of directors has 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 may

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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 Convertible Preferred Stock.

The Series A Convertible Preferred Stock is redeemable upon a liquidation event, including liquidation, winding up, and dissolution of the Company. Additionally, the preferred 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, the Series A Convertible Preferred Stock has been classified as mezzanine equity in the consolidated balance sheet.

During 2010, the Company issued 2,584,166 shares of its Series A Convertible Preferred Stock to investors for cash at a price of \$8.39 per share for total gross proceeds of \$21.7 million. As part of the issuance, PBC received \$2.1 million in commissions which were recorded as a reduction of the Series A Convertible Preferred Stock on the consolidated balance sheet. On April 26, 2010, holders of the Company's Senior Convertible Notes and Related Party Notes converted outstanding principle and accrued interest totaling \$10.5 million into 1,773,719 shares of the Company's Series A Convertible Preferred Stock.

## **12. 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. As of December 31, 2010, there were 4,791,102 shares of Common Stock outstanding.

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.

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**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 Equity Compensation Plan, for payment of par value (see Note 15). 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 15). 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, 2010, 2009, and 2008 and the period from inception to December 31, 2010 was \$2.0 million, \$39,000, \$25,000, 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.

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 was recorded as research and development expense in the consolidated statements of operations on the grant date.

**13. Warrants to Purchase Common Stock**

**Debt Placement Agent Warrants**

In connection with the issuance of the Company's 2008 and 2009 Senior Convertible Notes (see Note 11), the Company issued warrants to purchase shares of the Company's Common Stock to PBC as partial consideration for its services as the placement agent (the "Debt Placement Warrants"). 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 the Company's 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 warrants are exercisable for seven years.

The fair value of the warrants was measured on the date 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.

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In connection with the Series A Convertible Preferred 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 Convertible Preferred Stock offering, at an exercise price of 110% of the lowest price paid for securities in a qualified financing. Subsequent to the Series A Convertible Preferred Stock offering, PBC holds 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 of the warrants was reclassified from a liability to additional paid-in capital in the consolidated balance sheets.

The initial warrant fair values, which were not material, were recorded as debt issuance costs and amortized over the estimated life of the respective debt (see Note 10).

**PCP Warrants**

In connection with the issuance of the PCP Notes in 2009 (see Note 10), the Company also issued to PCP warrants to purchase shares of the Company's Common Stock (the "PCP Warrants"). The number of warrants and the exercise 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 the PCP Warrants to purchase shares of the Company's Common Stock 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 warrants are exercisable for five years.

The fair value of the warrants was measured on the date of issuance using a binomial option pricing model. The Company determined that the warrants would not be considered indexed to the Company's own 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 Convertible Preferred Stock offering on April 26, 2010, 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 Convertible Preferred Stock 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 was reclassified from a liability to additional paid-in capital in the consolidated balance sheets.

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**Coronado Biosciences, Inc. and Subsidiary**  
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The initial warrant fair values, which were not material, were recorded as a discount and were amortized over the estimated life of the related debt (see Note 11).

**Preferred Stock Placement Warrants**

In connection with the issuance of the Company's Series A Convertible Preferred offerings (see Note 11), the Company issued 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 "Preferred Stock Placement Warrants"). The warrants are exercisable for seven years.

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 Convertible Preferred Stock (see Note 12) with a corresponding increase to additional paid-in capital.

**Non-Employee Warrants**

On November 22, 2010, the Company issued 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 warrants were fully vested on the grant date and are exercisable for five years. 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.

**14. 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. Management believes that awards under the Plan may serve to broaden the equity participation of key employees and further link the long-term interests of management and stockholders. 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 3,649,280 were granted and 2,350,720 shares were available for issuance as of December 31, 2010.

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Incentive and nonstatutory stock options are granted pursuant to option agreements adopted by the plan administrator. Options generally have ten-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 own 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 Dividend Rate:* The Company has not paid and does not anticipate paying any dividends in the near future.

On October 5, 2010, the Company granted 790,235 options with an exercise price of \$1.37 per share to employees at a fair value of \$1.56 per share determined based on the following assumptions: a 92.7% volatility, a 1.52% risk-free rate of interest, an expected term of six years and an estimated fair value of the Company's Common Stock at the time of issuance of \$1.96 per share. The fair value of the awards was determined and fixed on the grant date.

On October 5, 2010, the Company granted 437,955 options with an exercise price of \$1.37 per share to non-employees at a fair value of \$1.77 per share determined based on the following assumptions: 95.2% volatility, a 2.50% risk-free rate of interest, a contractual life of ten years and an estimated fair value of the Company's Common Stock at the time of issuance of \$1.96 per share. The fair value of the awards was determined on the grant date and the unvested awards are remeasured each reporting period.

The Company uses public industry peer company's data to estimate volatility. Compensation expense is recorded for awards that are expected to vest, adjusted for actual share forfeitures. Compensation expense is recorded on a straight-line basis over the vesting period.

The following table summarizes the stock-based compensation expense from stock option and restricted Common Stock awards to employees and nonemployees for the years ended December 31, 2010, 2009 and 2008, and from the period June 28, 2006 (Date of Inception) to date:

(*\$ in thousands*)

	2010	2009	2008	Period from June 28, 2006 (Date of Inception) to December 31, 2010
Employee awards	\$ 215	\$—	\$—	\$ 215
Non-employee awards	2,114	39	25	2,190
Total compensation expense	<u>\$2,329</u>	<u>\$ 39</u>	<u>\$ 25</u>	<u>\$ 2,405</u>

**Coronado Biosciences, Inc. and Subsidiary**  
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The following table summarizes employee stock option activity:

	Outstanding Options			Weighted Average Remaining Contractual Life (in years)
	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	
<i>(\$ in thousands except per share amounts)</i>				
Outstanding at December 31, 2009	—	\$ —		
Options granted	790,235	1.37		
Options exercised	—	—		
Options forfeited	—	—		
Options expired	—	—		
Outstanding at December 31, 2010	<u>790,235</u>	<u>\$ 1.37</u>	\$ 466	9.8
Options vested and expected to vest	<u>761,787</u>	<u>\$ 1.37</u>	\$ 449	9.8
Options vested and exercisable	80,000	\$ 1.37	\$ 47	9.8

The following table summarizes non-employee stock option activity:

	Outstanding Options			Weighted Average Remaining Contractual Life (in years)
	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	
<i>(\$ in thousands except per share amounts)</i>				
Outstanding at December 31, 2009	—	\$ —		
Options granted	437,955	1.37		
Options exercised	—	—		
Options forfeited	(96,080)	1.37		
Options expired	—	—		
Outstanding at December 31, 2010	<u>341,875</u>	<u>\$ 1.37</u>	\$ 202	8.4
Options vested and expected to vest	<u>329,568</u>	<u>\$ 1.37</u>	\$ 194	8.4
Options vested and exercisable	48,040	\$ 1.37	\$ 28	0.3

As of December 31, 2010, the Company had unrecognized stock-based compensation expense related to all unvested stock options of \$1.4 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.8 years.

**15. License Agreements**

**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 the event that CNDO-109 is commercialized, the Company is obligated to pay to UCLB annual royalties 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.

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**Coronado Biosciences, Inc. and Subsidiary**  
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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.

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 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 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, to the scope of our license grant, 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 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.



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

<i>(\$ in thousands)</i>	<u>As of December 31,</u>	
	<u>2010</u>	<u>2009</u>
Deferred tax assets:		
Net operating loss carryforwards	\$ 6,308	\$ 3,122
Amortization of up-front fees	47	168
Stock compensation	60	9
Accruals and reserves	234	280
Total deferred tax assets	6,649	3,579
Valuation allowance	(6,649)	(3,579)
Net deferred tax assets	<u>\$ —</u>	<u>\$ —</u>

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

	<u>For the Year Ended December 31,</u>		
	<u>2010</u>	<u>2009</u>	<u>2008</u>
Percentage of pre-tax income			
U.S. federal statutory income tax rate	35%	35%	35%
Debt modification costs	-3%	0%	0%
Other	-1%	0%	0%
Change in valuation allowance	-31%	-35%	-35%
Effective income tax rate	<u>0%</u>	<u>0%</u>	<u>0%</u>

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 not likely to be realized and, accordingly, has provided a full valuation allowance.

As of December 31, 2010, the Company had \$6.3 million of federal net operating losses which expire beginning in 2024. 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.

As of December 31, 2010, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance as of December 31, 2010. 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, 2010. The tax years 2006 through 2010 remain open to examination by one or more major taxing jurisdictions to which the Company is subject.

## 17. Subsequent Events

In preparing the consolidated financial statements, in accordance with current accounting guidance, the Company has reviewed events that have occurred after December 31, 2010, through the date of issuance of the financial statements on July 15, 2011. During this period, the Company did not have any material subsequent events other than the events disclosed.

### **Asphelia Asset Purchase**

On January 7, 2011 (the "Closing Date") the Company purchased a sublicense and related agreements to an early-stage development asset and assumed certain liabilities from Asphelia Pharmaceuticals, Inc. ("Asphelia"), an affiliate of PBC. In exchange for the asset, the Company issued 2,525,677 shares of our Series B Convertible Preferred Stock at a stated value of \$5.59 per share, assumed promissory notes of \$750,000 due to Paramount Credit Partners, LLC 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, including \$61,000 to a related party. Under the terms of the sublicense agreement, the Company is required to make annual license payments to the original licensee, OvaMed GmbH, or directly to the licensor, the University of Iowa Research Foundation, of \$250,000. In addition, the Company may be required to make future payments totaling up to \$5.45 million upon the achievement of various milestones related to regulatory events for the first product. In the event that the compound is commercialized, the Company is obligated to pay to OvaMed annual royalties of 4% based upon net sales of the product and, if the Company further sublicenses the product, varying percentages of the amounts received by the Company from any such sublicense. We are also a party to a manufacturing and supply agreement with OvaMed, the exclusive supplier of the product.

The transaction was treated as an asset acquisition as it was determined that the assets acquired did not meet the definition of a business. The fair value of the cash, Series B Convertible Preferred Stock and the related debt assumed will be recorded as in-process research and development expense in January 2011.

### **Equity Issuances**

Subsequent to December 31, 2010 and through May 31, 2011, the Company issued 775,000 stock options at an exercise price ranging from \$1.37-\$1.93 per share.

On May 15, 2011, the Company entered into a definitive agreement with respect to the private placement of 4,612,624 shares of unregistered Series C Convertible Preferred Stock at \$5.59 per share to accredited investors. The Company completed the private placement in June 2011 resulting in approximately \$22.8 million in net proceeds to the Company. As compensation for services, the Company paid the placement agent of these securities 10% of the gross proceeds and issued to the placement agent warrants to purchase Series C Preferred Stock at \$5.59 per share equal to 10% of the aggregate number of shares sold in the offering. Following this Offering, the Company plans to become a reporting company by filing a registration statement on Form 10 ("Form 10") with U.S. Securities and Exchange Commission pursuant to Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The Company has agreed to use its commercially reasonable efforts to file the Form 10 within sixty (60) days following the Final Closing (the "Form 10 Filing Date"). In the event that the Form 10 is not filed by the Form 10 Filing Date, the Company will incur monthly liquidated damages, payable to investors in cash, in an amount equal to one (1.0%) percent of the purchase price of the shares issued in the Offering until the Form 10 is filed (the "Form 10 Liquidated Damages"), but in no event will the maximum aggregate Form 10 Liquidated Damages payable exceed ten (10%) percent. The Company has agreed to use its commercially reasonable efforts to file a Form S-1 within sixty (60) days following the effective date of a Form 10 registration statement (the "Post Effective Filing Date"). In the event that the Form S-1 is not filed by the Post-Effective Filing Date, the Company will incur monthly liquidated damages, payable to Investors in cash, in an amount equal to one (1.0%) percent of the purchase price of the shares issued in the Offering until the Form S-1 is filed (the "Form S-1 Liquidated Damages"), but in no event will the maximum aggregate Form S-1 Liquidated Damages payable exceed ten (10%) percent.

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**Coronado Biosciences, Inc. and Subsidiary**  
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**Notes to the Consolidated Financial Statements**

**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 Convertible Preferred Stock in satisfaction of the Series A Special Dividend that would have been due April 26, 2012 and in connection with such issuance (i) eliminated the provision for a Series A Special Dividend on April 26, 2012 and (ii) amended the event which will trigger an automatic conversion of shares of Series A Convertible Preferred and Series B Convertible Preferred into shares of Common Stock to be the effective date of a registration statement. The special dividend was paid in May 2011.

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

	As of June 30, 2011	As of December 31, 2010
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 29,647	\$ 14,862
Prepaid and other current assets	92	55
Total current assets	29,739	14,917
Computer equipment, net of accumulated depreciation	17	22
<b>Total Assets</b>	<b>\$ 29,756</b>	<b>\$ 14,939</b>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIT</b>		
Current Liabilities:		
Accounts payable	\$ 714	\$ 476
Accounts payable – related party	48	46
PCP Interest payable – related party	19	—
Accrued expenses	1,472	1,037
Warrant liability	1,286	—
Total current liabilities	3,539	1,559
PCP Notes payable – related party	750	—
Total Liabilities	4,289	1,559
Commitments and Contingencies		
Convertible Preferred Stock Series A, \$.001 par value, 5,000,000 shares authorized, 4,357,885 shares issued and outstanding as of June 30, 2011; 10,000,000 shares authorized 4,357,885 shares issued and outstanding as of December 31, 2010, net of issuance costs (liquidation value of \$54,844 at June 30, 2011 and December 31, 2010)	29,277	29,277
Convertible Preferred Stock Series B, \$.001 par value, 4,800,000 shares authorized, 2,525,677 shares issued and outstanding as of June 30, 2011 (liquidation value of \$21,178 at June 30, 2011); as of December 31, 2010 no shares authorized, issued or outstanding.	16,114	—
Convertible Preferred Stock Series C, \$.001 par value, 5,200,000 shares authorized, 4,612,624 shares issued and outstanding as of June 30, 2011 (liquidation value of \$38,677 at June 30, 2011); as of December 31, 2010 no shares authorized, issued or outstanding.	21,620	—
Stockholders' Deficit:		
Common Stock, \$.001 par value, 50,000,000 shares authorized, 7,028,059 shares issued and outstanding as of June 30, 2011; 4,791,102 shares issued and outstanding as of December 31, 2010;	7	5
Additional paid-in capital	4,939	4,312
Deficit accumulated during the development stage	(46,490)	(20,214)
Total Stockholders' Deficit	(41,544)	(15,897)
<b>Total Liabilities, Convertible Preferred Stock and Stockholders' Deficit</b>	<b>\$ 29,756</b>	<b>\$ 14,939</b>

See accompanying notes to condensed consolidated financial statements.

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Condensed Consolidated Statements of Operations**

(\$ in thousands except for per share amounts)

(Unaudited)

	For the six months ended June 30,		Period from June 28, 2006 (Date of Inception) to June 30, 2011
	2011	2010	
Operating expenses:			
Research and development	\$ 3,388	\$ 4,521	\$ 19,348
General and administrative	2,187	249	4,046
In-process research and development	20,706	—	20,706
Loss from operations	(26,281)	(4,770)	(44,100)
Interest income	41	8	120
Interest expense, net	(36)	(1,473)	(3,243)
Other income	—	—	733
Net loss	\$ (26,276)	\$ (6,235)	\$ (46,490)
Common Stock dividend to Series A Convertible Preferred Stockholders	(5,861)	—	(5,861)
Net loss attributed to Common Stock	\$ (32,137)	\$ (6,235)	\$ (52,351)
Basic and diluted net loss per common share	\$ (6.04)	\$ (1.51)	
Weighted average common shares outstanding – basic and diluted	5,322,793	4,124,805	

See accompanying notes to condensed consolidated financial statements.

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**  
(A development stage enterprise)  
**Condensed Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Deficit**  
**Period from June 28, 2006 (date of inception) through June 30, 2011**  
(\$ in thousands)  
(Unaudited)

	Preferred stock		Common stock		Additional paid-in capital	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	—	—	457,171	1	—	—	1
Stock-based compensation expense	—	—	—	—	13	—	13
Net loss	—	—	—	—	—	(2,645)	(2,645)
Balances at December 31, 2007	—	—	4,762,267	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	—	—	4,762,267	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	—	—	4,767,267	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 the fair value of Common Stock warrants	—	(2,912)	—	—	621	—	621
Reclassification of warrant liability at fair value	—	—	—	—	234	—	234
Change in fair value of embedded conversion feature related to the Related Party Notes and Senior Convertible Notes	—	—	—	—	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	4,791,103	\$ 5	\$ 4,312	\$ (20,214)	\$ (15,897)
Issuance of Convertible Preferred Stock Series B for purchase of CNDO-201 sublicense	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 warrants	—	(4,165)	—	—	—	—	—
Issuance of Common Stock dividend to Preferred Stock Series A stockholders	—	—	2,178,917	2	(2)	—	—
Exercise of stock options	—	—	58,040	—	80	—	80
Issuance of Common Stock warrants to non-employees for services	—	—	—	—	164	—	164
Stock-based compensation expense	—	—	—	—	365	—	365
Contribution of services by stockholder	—	—	—	—	20	—	20
Net loss	—	—	—	—	—	(26,276)	(26,276)
Balances at June 30, 2011	11,496,186	\$67,011	7,028,059	\$ 7	\$ 4,939	\$ (46,490)	\$ (41,544)

See accompanying notes to condensed consolidated financial statements

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**  
(A development stage enterprise)  
**Condensed Consolidated Statements of Cash Flows**  
*(\$ in thousands)*  
**(Unaudited)**

	For the six months Ended June 30,		Period from June 28, 2006 (Date of Inception) to June 30, 2011
	2011	2010	
<b>Cash flows from operating activities:</b>			
Net loss	\$(26,276)	\$ (6,235)	\$ (46,490)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	365	1,988	2,770
Acquired in-process research and development	20,706	—	20,706
Noncash interest	—	236	1,031
Noncash interest – related parties	—	34	286
Contribution of services by stockholder	20	20	120
Issuance of Common Stock to non-employee for services	—	82	82
Change in fair value of common stock warrant liability	—	234	234
Change in fair value of embedded conversion feature	—	831	831
Issuance of Common Stock warrants to non-employee for services	164	—	202
Amortization of deferred financing costs	—	157	737
Depreciation expense	4	3	23
Changes in operating assets and liabilities:			
Other current assets	(35)	(440)	(90)
Interest payable – related parties	19	—	19
Accounts payable and accrued expenses – related parties	2	5	49
Accounts payable and accrued expenses	673	817	2,186
Net cash used in operating activities	<u>(4,358)</u>	<u>(2,468)</u>	<u>(17,304)</u>
<b>Cash flows from investing activities:</b>			
Purchase of computer equipment	—	(5)	(41)
Purchase of in-process research and development	(3,843)	—	(3,843)
Net cash used in investing activities	<u>(3,843)</u>	<u>(5)</u>	<u>(3,884)</u>
<b>Cash flows from financing activities:</b>			
Proceeds from PCP notes payable – related party	—	—	570
Payment of PCP notes payable – related party	—	—	(570)
Proceeds from notes payable – related parties	—	302	2,221
Proceeds from issuance of Convertible Preferred Stock Series A	—	10,989	21,681
Payment of costs related to the issuance of Convertible Preferred Stock Series A	—	(1,454)	(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	(2,878)	—	(2,878)
Proceeds from borrowings under line of credit	—	—	80
Payment of line of credit	—	—	(80)
Proceeds from Senior Convertible Notes	—	—	7,570
Payment of debt issue costs	—	—	(737)
Payment of notes payable – related parties	—	—	(600)
Proceeds from issuance of Common Stock	80	—	85
Net cash provided by financing activities	<u>22,986</u>	<u>9,837</u>	<u>50,835</u>
<b>Increase / (decrease) in cash and cash equivalents</b>	<b>14,785</b>	<b>7,364</b>	<b>29,647</b>
Cash and cash equivalents – beginning of period	14,862	1,510	—
Cash and cash equivalents – end of period	<u>\$ 29,647</u>	<u>\$ 8,874</u>	<u>\$ 29,647</u>
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest	\$ 17	\$ 15	\$ 105
<b>Supplemental disclosure of non-cash financing and investing activities:</b>			
Issuance of Convertible Preferred Stock Series B for purchase of assets	\$ 16,114	\$ —	\$ 16,114
Assumed PCP note related to asset purchase	750	—	750
Issuance of warrants for Series C Preferred Stock related to the Convertible Preferred Stock Series C	1,286	—	1,286
Issuance of warrants for Common Stock related to the Convertible Preferred Stock Series A	—	366	621
Conversion of senior convertible notes principal and interest into Convertible Preferred Stock Series A	—	8,601	8,601
Conversion of related party notes principal and interest into Convertible Preferred Stock Series A	—	1,907	1,907

See accompanying notes to condensed consolidated financial statements.

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**  
(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements**  
(Unaudited)

**1. THE COMPANY AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES**

*Nature of Operations*

Coronado Biosciences, Inc. (the "Company"), incorporated in Delaware on June 28, 2006 (date of inception), is a development-stage biopharmaceutical company focused on novel immunotherapy agents for the treatment of cancer and autoimmune diseases. The Company focuses on in-licensing product candidates or technologies that have previously been tested for safety and biological activity in humans.

*Development-Stage Risks and Liquidity*

The Company is a development-stage enterprise. Activities to date include development of key compounds, obtaining regulatory approvals, establishing pre-commercial relationships, hiring qualified personnel and raising capital to fund operations. We continue to report as a development stage enterprise since planned principal operations have not yet commenced. Since inception, no revenue has been recognized and the Company has incurred net losses and negative cash flows from operations.

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit during the development stage of \$46.5 million as of June 30, 2011. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant revenue from its product candidates. To date, the Company's operations have been funded primarily by issuing equity securities and debt. During 2010, the Company issued 4,357,885 shares of Series A Convertible Preferred Stock resulting in gross proceeds to the Company of \$21.7 million. All debt obligations have either been repaid or converted into shares of Series A Convertible Preferred Stock as of December 31, 2010. On June 30, 2011, the Company completed an offering of 4,612,624 shares of Series C Convertible Preferred Stock resulting in net proceeds to the Company of approximately \$22.9 million. Management believes that cash and cash equivalents, including cash raised through the issuance of Series C Convertible Preferred Stock are sufficient to sustain operations through 2012 based on its existing business plan and given the ability to control the timing of significant expense commitments.

The Company expects to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its product candidates. The Company will require additional financing to obtain regulatory approvals, 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 could 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 may be required to delay, reduce or eliminate research and development programs, reduce or eliminate commercialization efforts and pursue merger or acquisition strategies.

There can be no assurance that the Company's research and development will be successfully completed, that adequate patent protection for the Company's technology will be obtained, that any products developed will obtain necessary government regulatory approval or that any approved products will be commercially viable. In addition, the Company operates in an environment of rapid change in technology and substantial competition from pharmaceutical and biotechnology companies, and is dependent upon the services of its employees and its consultants. Operations of the Company are subject to certain risks and uncertainties, including, among others,



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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

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 experience, 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 our business and financial results.

The Company sources certain critical components from single source suppliers. If we were required to purchase these components from an alternative source, it could adversely affect development of our product candidates.

***Summary of Significant Accounting Policies***

**Basis of Presentation and Principles of Consolidation**

The accompanying unaudited interim consolidated financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America, (“GAAP”), for interim financial information and the instructions to Form 10-Q and Rule 10-01 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by generally accepted accounting principles for complete financial statements. In the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of our balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company’s annual financial statements prepared in accordance with GAAP have been condensed or omitted. These consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The consolidated balance sheet at December 31, 2010 has been derived from the audited consolidated financial statements at that date. The consolidated financial statements and related disclosures have been prepared with the presumption that users of the consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these consolidated financial statements should be read in conjunction with the audited financial statements and notes thereto contained in this Form 10.

The Company’s unaudited consolidated financial statements include the accounts of the Company and its 100% owned subsidiary, Immune Limited. All intercompany balances and transactions have been eliminated.

The preparation of the Company’s unaudited consolidated financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the unaudited condensed consolidated financial statements and the reported amounts of expenses during the reporting period.

**Use of Estimates**

The Company’s unaudited 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 common and preferred stock, common 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 management’s estimates.

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

**Segment Reporting**

The Company operates as one business and 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.

**Cash and Cash Equivalents**

Cash and cash equivalents consist of cash and certain highly liquid investments with original maturities of less than three months. The Company maintains balances at financial institutions which may exceed Federal Deposit Insurance Corporation insured limits.

**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 considering estimated forfeiture rates. For stock-based compensation awards to nonemployees, the Company remeasures the fair value of the nonemployee 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 nonemployee 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. In the absence of a public trading market of the Company's Common Stock, the Company commenced periodic contemporaneous assessments of the valuation of the Company's Common Stock. These valuations were performed concurrently with the achievement of significant milestones or with major financing. The Company considered numerous objective and subjective factors, including but not limited to the following factors:

- Arms length private transactions involving the Company's Convertible 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 a result, if factors change and management uses different assumptions, stock-based compensation expense could be materially different for future awards.

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

**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.

**Recently Issued Accounting Standards**

In June 2011, the Financial Accounting Standards Board ("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.

In June 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.

**2. NET LOSS PER SHARE**

The Company calculates earnings per share using the two-class method, which is an earnings allocation formula that determines earnings per share for Common Stock and non-forfeitable participating securities according to dividends declared and 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 Convertible Preferred Stock are entitled to a dividend equal (on an as-if-converted to Common Stock basis) to the amount paid or set aside for each share of Common Stock. Additionally, holders of restricted Common Stock are entitled to all cash dividends, when 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 of the periods presented.

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of common shares 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 shares and common share 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.

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**  
(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

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

<i>(\$ in thousands except per share amounts)</i>	For the Six Months Ended June 30,	
	2011	2010
<b>Historical net loss per share:</b>		
<i>Numerator</i>		
Net loss	\$ (26,276)	\$ (6,235)
Common stock dividend to Series A Convertible Preferred stockholders	(5,861)	—
Net loss attributed to Common Stock	<u>\$ (32,137)</u>	<u>\$ (6,235)</u>
<i>Denominator</i>		
Weighted-average common shares outstanding- Denominator for basic and diluted net loss per share	<u>5,322,793</u>	<u>4,124,805</u>
Basic and diluted net loss per share attributed to common stockholders	<u>\$ (6.04)</u>	<u>\$ (1.51)</u>

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 securities would be antidilutive:

	For the Six Months Ended June 30,	
	2011	2010
Series A Convertible Preferred Stock	4,357,885	1,042,541
Series B Convertible Preferred Stock	2,441,953	—
Series C Convertible Preferred Stock	474,542	—
Unvested restricted Common Stock	—	651,152
Warrants to purchase Common Stock	494,222	156,867
Warrants to purchase Series C Convertible Preferred Stock	47,454	—
Options to purchase Common Stock	<u>1,267,626</u>	<u>—</u>
	<u>9,083,682</u>	<u>1,850,560</u>

### 3. DEBT

#### Paramount Credit Partners, LLC ("PCP") Promissory Notes (the "PCP Notes")

On January 7, 2011, as part of the Asphelia Asset Purchase, the Company assumed a 10% promissory note issued to PCP by Asphelia Pharmaceuticals, Inc. ("Asphelia"), an affiliate of Paramount Biosciences, LLC ("PBS"), on January 22, 2009 for \$750,000, which is classified as long-term debt in the consolidated balance sheets. All unpaid principal and accrued interest outstanding under the PCP Note is payable on the earlier of (i) December 31, 2013, (ii) the consummation of a merger, share 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 shareholders is greater than or equal to \$10 million.

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**  
(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

Interest expense consisted of the following:

<i>(\$ in thousands)</i>	For the Six Months Ended June 30,		Period from June 28, 2006 (Date of Inception) to June 30, 2011
	2011	2010	
Interest expense – senior convertible notes	\$ —	\$ 236	\$ 1,031
Interest expense – related parties	36	15	410
Amortization of embedded conversion feature related to the senior convertible and related party notes	—	831	831
Change in fair value of Common Stock warrant liability	—	234	234
Amortization of deferred financing fees related to the senior convertible notes	—	157	737
Total interest expense	\$ 36	\$ 1,473	\$ 3,243

**4. 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.

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

There were no assets or liabilities that were required to be remeasured at fair value as of December 31, 2010. During the second quarter of 2011, the Company issued preferred stock warrants that have been classified as a liability (level 3) and will be marked to market. The original fair value of the warrants was recorded as a reduction of the preferred stock and the mark to market as of June 30, 2011 was not material.

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, 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.

**5. COMPUTER EQUIPMENT, NET**

Computer equipment, net consists of the following:

<i>(\$ in thousands)</i>	As of June 30, 2011	As of December 31, 2010
Computer equipment	\$ 41	\$ 41
Less: Accumulated depreciation	<u>(24)</u>	<u>(19)</u>
Computer equipment, net	<u>\$ 17</u>	<u>\$ 22</u>

Depreciation expense for the three months ended June 30, 2011 and 2010 and for the period from June 28, 2006 (date of inception) through June 30, 2011 was \$4,000, \$3,000 and \$24,000, respectively.

**6. ACCRUED LIABILITIES**

Accrued liabilities consist of the following:

<i>(\$ in thousands)</i>	As of June 30, 2011	As of December 31, 2010
Salaries, bonuses and related benefits	\$ 723	\$ 553
Professional fees	441	309
Research and development expenses	299	143
Other	9	32
Total accrued expenses	<u>\$ 1,472</u>	<u>\$ 1,037</u>

**7. ASPHELIA ASSET PURCHASE**

On January 7, 2011, the Company entered into an asset purchase agreement with Asphelia (the "Asphelia Asset Purchase" or "Asphelia Agreement"). Pursuant to the terms of the Asphelia Agreement, the Company paid \$20.7 million for the purchase of Asphelia's assets relating to the CNDO-201 compound, an early stage developmental compound.

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

In exchange for the assets, the Company issued 2,525,677 shares of its Series B Convertible Preferred Stock at 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 shares of Series B Convertible Preferred Stock	\$16,114
Cash payment	3,809
Fair value of PCP Note	750
Other transaction costs	34
<b>Total purchase price</b>	<b><u>\$20,706</u></b>

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 the six months ended June 30, 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 CNDO-201, and additional milestone payments upon the achievement of regulatory milestones relating to subsequent indications. In the event that CNDO-201 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 expires in March 2013 and is subject to early termination by either party under certain customary conditions of breach. The OvaMed Supply Agreement will automatically renew for successive one-year periods, unless the Company gives 12 months prior notice of its election not to renew, and subject to the Company's right to terminate the agreement in the event of specified failures to supply or regulatory or safety failures.

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

**8. EQUITY**

**Series B Convertible Preferred Stock**

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

*Voting Rights*

Holder of Series B Convertible Preferred Stock vote 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 is 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 Convertible Preferred Stock shall 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 share of Series B Convertible Preferred Stock will be voluntarily convertible into one share of Common Stock at the election of the holder. Additionally, each share of Series B Convertible Preferred Stock will automatically convert into one share of Common Stock upon the effective date of a registration statement covering the resale of the underlying Common Stock.

*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 shares of Series B Convertible Preferred Stock are fully paid and nonassessable.

**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 Convertible Preferred Stock in satisfaction of the Series A Special Dividend that would have been due April 26, 2012. In connection with such issuance, the Company (i) eliminated the provision for a Series A Special Dividend on April 26, 2012 and (ii) amended the event which will trigger an automatic conversion of shares of Series A Convertible Preferred and Series B Convertible Preferred 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 fair value of the Common Stock was \$5.9 million and recorded as a liability and a reduction of additional paid in capital.



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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

**Series C Convertible Preferred Stock**

On June 30, 2011, the Company completed an offering of 4,612,624 shares of Series C Convertible Preferred Stock 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 Convertible Preferred Stock are as follows:

*Voting Rights*

Holder of Series C Convertible Preferred Stock vote 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 is 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 Convertible Preferred Stock shall 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 share of Series C Convertible Preferred Stock will be voluntarily convertible into one share of Common Stock at the election of the holder. Additionally, each share of Series C Convertible Preferred Stock will automatically convert into one share of Common Stock upon the effective date of a registration statement covering the resale of the underlying Common Stock.

*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 shares of Series C Convertible Preferred Stock are fully paid and nonassessable.

**Warrants for Common Stock**

**Non-Employee Warrants**

In February 2011, the Company issued fully vested warrants to purchase 50,000 shares of Common Stock at an exercise price of \$1.37 per share as compensation for consulting services provided by non-employees. The warrant expires on the fifth anniversary of its issuance date. The initial fair value of the warrant 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 interest 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 a warrant to purchase 60,000 shares of Common Stock at an exercise price of \$1.37 per share as compensation for consulting services provided by a non-employee. The warrant expires on the

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**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

tenth anniversary of its issuance date and vest over six months. The initial fair value of the warrant 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 interest 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 will be marked to market at each reporting date until it is fully vested.

**Warrants to Purchase Series C Convertible Preferred Stock**

In connection with the Company's Series C Convertible Preferred offering, the Company (i) paid to National Securities Corporation ("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 warrants to NSC to purchase an aggregate of 461,263 shares of the Company's Series C Convertible Preferred Stock at an exercise price of \$5.59 per share. The warrants are fully vested and exercisable for five years commencing May, 31, 2011.

The fair value of the warrants was \$1.3 million measured on the respective date of issuance and were recorded as a reduction in the carrying value of the Preferred Stock and a warrant liability. The warrants will be marked to market each reporting period. The fair values were determined using an option pricing model assuming 90.9% volatility, a 1.76% risk-free rate of interest, a term of five years and an estimated fair value of the Company's Series C Convertible Preferred Stock of \$5.59 per share.

**Stock-based Compensation***Stock-based Compensation Plans*

As of June 30, 2011, the Company has one active equity compensation plan, the Coronado Biosciences, Inc. 2007 Stock Incentive Plan (the "Plan"), for employees, non-employees and outside directors.

*Compensation Expense*

The following table summarizes the stock-based compensation expense from stock option and restricted Common Stock awards to employees and nonemployees for the six months ended June 30, 2011 and 2010, and from the period June 28, 2006 (Date of Inception) to date:

<i>(\$ in thousands)</i>	<u>2011</u>	<u>2010</u>	<u>Period from June 28, 2006 (Date of Inception) to June 30, 2011</u>
Employee awards	\$238	\$ —	\$ 453
Non-employee awards	127	1,988	2,317
Total compensation expense	<u>\$365</u>	<u>\$1,988</u>	<u>\$ 2,770</u>

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**  
(A development stage enterprise)

**Notes to Condensed Consolidated Financial Statements – (Continued)**  
**(Unaudited)**

The following table summarizes stock option activity as of June 30, 2011:

	Outstanding Options			Weighted Average Remaining Contractual Life (in years)
	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	
<i>(\$ in thousands except per share amounts)</i>				
At December 31, 2010	1,132,110	\$ 1.37		
Options granted	675,000	1.91		
Options exercised	(58,040)	1.37		
Options forfeited	(210,000)	1.37		
Options expired	(80,000)	1.37		
At June 30, 2011	<u>1,459,070</u>	\$ 1.62	\$ 1,941	9.1
Options vested and expected to vest	1,406,540	\$ 1.62	\$ 1,871	9.1
Options vested and exercisable	75,000	\$ 1.37	\$ 119	0.5

As of June 30, 2011, the Company had unrecognized stock-based compensation expense related to unvested stock options granted to employees of \$1.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.4 years.

**9. SUBSEQUENT EVENTS**

On July 15, 2011, the Company filed a registration statement on Form 10 ("Form 10") with the U.S. Securities and Exchange Commission pursuant to Section 12(g) of the Securities Exchange Act of 1934, as amended (the "Exchange Act") to become a public reporting company under the Exchange Act. Pursuant to its commitment to the Series C Preferred Stockholders, the Company has agreed to use its commercially reasonable efforts to file a Form S-1 within sixty (60) days following the effective date of the Form 10 (the "Filing Date"). In the event that the Form S-1 is not filed by the Filing Date, the Company will incur monthly liquidated damages, payable in cash to Series C Preferred Stock investors, in an amount equal to one (1.0%) percent of the purchase price of Series C Preferred Stock until the Form S-1 is filed up to a maximum of ten (10%) percent.

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

CORONADO BIOSCIENCES, INC.

Date: September 9, 2011

By /s/ Dale Ritter

Name: Dale Ritter

Title: Senior Vice President, Finance, Chief Accounting Officer  
and Acting Chief Financial Officer

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## EXHIBIT INDEX

<u>Exhibit</u>	<u>Description</u>
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)
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.
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.
10.11†	Manufacturing and Supply Agreement, dated March 29, 2006, by and among OvaMed GmbH and Collingwood Pharmaceuticals, Inc.
10.12†	License Agreement, dated November 5, 2007, by and between UCL Business PLC and the Registrant.

<u>Exhibit</u>	<u>Description</u>
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)
10.15†	Master Contract Services Agreement, dated April 1, 2010, by and between the Registrant and Progenitor Cell Therapy, LLC.
10.16†	Term Sheet in causa OvaMed/Asphelia, dated June 8, 2010, by and between OvaMed GmbH and Asphelia Pharmaceuticals, Inc.
10.17†	Amendment and Agreement, dated January 7, 2011, by and among Asphelia Pharmaceuticals, Inc., the Registrant and OvaMed GmbH.
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)
21.1	Subsidiaries of the Registrant.(1)

† Confidential Treatment Requested

\* Indicates management contract or compensatory plan

(1)Previously filed

THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, WHICH OPINION SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

No. \_\_\_\_\_-

\_\_\_\_\_, 2011

CORONADO BIOSCIENCES, INC.  
Series C Convertible Preferred Stock Purchase Warrant

THIS CERTIFIES THAT, for value received, National Securities Corporation (the "**Holder**"), is entitled to subscribe for and purchase from Coronado Biosciences, Inc., a Delaware corporation (the "**Company**"), at any time prior to May 31, 2016 (the "**Expiration Date**"), the Warrant Shares at the Exercise Price (each as defined in Section 1 below) and subject to the following terms and conditions.

This Warrant is being issued pursuant to that certain Placement Agency Agreement dated May 23, 2011, between the Company and National Securities Corporation (the "**Placement Agency Agreement**") and in connection with the Company's private offering to accredited investors of its securities in accordance with, and subject to, the terms and conditions described in that certain Confidential Private Placement Memorandum, dated May 23, 2011, as the same may be amended and supplemented from time to time (the "**Private Placement Memorandum**"). All warrants that are issued to the Placement Agent and its designees are referred to herein, collectively, as the "Warrants" and the holders of the Warrants (as well as any subsequent Permitted Transferees and Permitted Designees) along with the Holder named herein, the "**Holders**."

This Warrant is subject to the following terms and conditions:

1. **Shares.** The Holder has, subject to the terms set forth herein, the right to purchase, at any time at any time and from time to time on or after the date hereof to and including the Expiration Date, up to \_\_\_\_\_ (\_\_\_\_\_) shares (the "**Warrant Shares**") of the Company's Series C Convertible Preferred Stock, par value \$.001 per share ("**Series C Preferred**"), at a per share exercise price of \$5.59 (the "**Exercise Price**"). The Exercise Price is subject to adjustment as provided in Section 3 hereof. Notwithstanding the foregoing to the contrary, upon conversion of the Series C Preferred into shares of the Company's common stock (the "**Common Stock**") in accordance with the terms of the Certificate of Designation, Preferences and Rights of the Series C Preferred, as amended, this Warrant may only be

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exercised for shares of Common Stock and all Warrant Shares referred to hereunder shall be deemed to be shares of Common Stock.

2. Exercise of Warrant.

(a) Exercise. This Warrant may be exercised by the Holder at any time and from time to time on or after the date hereof to and including the Expiration Date. At 5:00 p.m., (New York City time) on the Expiration Date, the portion of this Warrant not exercised prior thereto shall be and become void and of no value and this Warrant shall be terminated and no longer be outstanding. The Holder may exercise this Warrant, in whole or in part, by delivering the notice of exercise attached as Exhibit A hereto (the “**Notice of Exercise**”), duly executed by the Holder to the Company at its principal office, or at such other office as the Company may designate, accompanied by payment, in cash or by wire transfer of immediately available funds or by check payable to the order of the Company, of the amount obtained by multiplying the number of Warrant Shares designated in the Notice of Exercise by the Exercise Price (the “**Purchase Price**”). For purposes hereof, “Exercise Date” shall mean the date on which all deliveries required to be made to the Company upon exercise of this Warrant pursuant to this Section 2(a) shall have been made.

(b) Exercise by Surrender of Warrant. In addition to the method of payment set forth in Section 2(a) and in lieu of any cash payment required thereunder, the Holder shall have the right at any time, at any time up to the Expiration Date, to exercise this Warrant, in whole or in part, by surrendering this Warrant in exchange for the number of shares of Series C Preferred computed by using the following formula:

$$X = \frac{Y(A - B)}{A}$$

Where X = the number of shares of Series C Preferred to be issued to the Holder pursuant to the net exercise.

Y = the number of shares of Series C Preferred subject to the Warrant being exercised or, if only a portion of such Warrant is being exercised, the portion of such Warrant being canceled (at the time of such calculation).

A = the Fair Market Value of one share of Series C Preferred (at the date of such calculation).

B = the Exercise Price (as adjusted to the date of such calculation).

For purposes of this Section 2(b), the “Fair Market Value” of one share of Series C Preferred shall mean:

- (i) If the Common Stock is traded Over-The-Counter or Nasdaq or on any other exchange, the per share Fair Market Value for the Series C Preferred Stock will be the average of the closing bid prices of the Common Stock quoted in the Over-The-



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Counter Market or the closing prices quoted on Nasdaq or any other exchange on which the Common Stock is listed, whichever is applicable, as published in the The Wall Street Journal for the ten (10) trading days prior to the date of determination of Fair Market Value multiplied by the number of shares of Common Stock into which each share of Series C Preferred Stock is then convertible; or

- (ii) In the event of an exercise in connection with a merger, acquisition or other consolidation in which the Company is not the surviving entity, the per share Fair Market Value for the Series C Preferred Stock shall be the value to be received per share of Series C Preferred Stock by all holders of the Series C Preferred Stock in such transaction as determined by the Board of Directors; or
- (iii) In any other instance, the per share Fair Market Value for the Series C Preferred Stock shall be as determined in good faith by the Company's Board of Directors.

For purposes of Rule 144 promulgated under the Securities Act, it is intended, understood and acknowledged that the Warrant Shares issued in a cashless exercise transaction shall be deemed to have been acquired by the Holder, and the holding period for the Warrant Shares shall be deemed to have commenced, on the date this Warrant was originally issued to the Holder (provided the U.S. Securities and Exchange Commission continues to take the position that such treatment is proper at the time of such exercise).

(c) Issuance of Certificates. As soon as practicable after the exercise of this Warrant, in whole or in part, in accordance with Section 2 hereof, the Company, at its expense, shall cause to be issued in the name of and delivered to the Holder (i) a certificate or certificates for the number of fully paid and non-assessable Warrant Shares to which the Holder shall be entitled upon such exercise and, if applicable, (ii) a new warrant of like tenor to purchase all of the Warrant Shares that may be purchased pursuant to the portion, if any, of this Warrant not exercised by the Holder. The Holder shall for all purposes hereof be deemed to have become the Holder of record of such Warrant Shares on the date on which the Notice of Exercise and payment of the Purchase Price in accordance with Section 2 hereof were delivered and made, respectively, irrespective of the date of delivery of such certificate or certificates, except that if the date of such delivery, notice and payment is a date when the stock transfer books of the Company are closed, such person shall be deemed to have become the holder of record of such Warrant Shares at the close of business on the next succeeding date on which the stock transfer books are open.

(d) Exercise Disputes. In the case of any dispute with respect to the number of Warrant Shares to be issued upon exercise of this Warrant, the Company shall cause its Transfer Agent to promptly issue such number of Warrant Shares that is not disputed and shall submit the disputed determinations or arithmetic calculations to the Holder via fax (or, if the Holder has not provided the Company with a fax number, by overnight courier) within five (5) Business Days of receipt of the Holder's election to purchase Warrant Shares. If the Holder and the Company are unable to agree as to the determination of the Exercise Price within five (5) Business Days of such disputed determination or arithmetic calculation being submitted to the Holder, then the Company shall in accordance with this Section, submit via facsimile the disputed determination to its independent auditor. The Company shall cause its independent

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auditor to perform the determinations or calculations and notify the Company and the Holder of the results promptly, in writing and in sufficient detail to give the Holder and the Company a clear understanding of the issue. The determination by the Company's independent auditor shall be binding upon all parties absent manifest error. If additional shares are required to be issued to the Holder based on the Company's independent auditor's determination, the Company shall then on the next Business Day instruct its Transfer Agent to issue certificate(s) representing the appropriate number of Warrant Shares in accordance with the independent auditor's determination and this Section.

(e) Taxes. The issuance of the Warrant Shares upon the exercise of this Warrant, and the delivery of certificates or other instruments representing such Warrant Shares, shall be made without charge to the Company for any tax or other charge of whatever nature in respect of such issuance, and the Holder shall bear any such taxes in respect of such issuance.

### 3. Adjustment of Exercise Price and Number of Warrant Shares.

(a) Adjustment for Reclassification, Consolidation or Merger. If while this Warrant, or any portion hereof, remains outstanding and unexpired there shall be (i) a reorganization or recapitalization (other than a combination, reclassification, exchange or subdivision of shares otherwise provided for herein), (ii) a merger or consolidation of the Company with or into another corporation or other entity in which the Company shall not be the surviving entity, or a reverse merger in which the Company shall be the surviving entity but the shares of the Company's capital stock outstanding immediately prior to the merger are converted by virtue of the merger into other property, whether in the form of securities, cash or otherwise, or (iii) a sale or transfer of the Company's properties and assets as, or substantially as, an entirety to any other corporation or other entity in one transaction or a series of related transactions, then, as a part of such reorganization, recapitalization, merger, consolidation, sale or transfer, unless otherwise directed by the Holder, all necessary or appropriate lawful provisions shall be made so that the Holder shall thereafter be entitled to receive upon exercise of this Warrant, during the period specified herein and upon payment of the Exercise Price then in effect, the greatest number of shares of capital stock or other securities or property that a holder of the Warrant Shares deliverable upon exercise of this Warrant would have been entitled to receive in such reorganization, recapitalization, merger, consolidation, sale or transfer if this Warrant had been exercised immediately prior to such reorganization, recapitalization, merger, consolidation, sale or transfer, all subject to further adjustment as provided in this Section 3; provided, however that notwithstanding the foregoing, if all of the Company's outstanding securities are acquired in an all-cash transaction, the Holder hereby agrees that it may be paid the net value of this Warrant in cash based on the per share value paid to the other security holders in such transaction, and in accordance with the provisions herein. If the per share consideration payable to the Holder for Warrant Shares in connection with any such transaction is in a form other than cash or marketable securities, then the value of such consideration shall be determined in good faith by the Company's Board of Directors (the "Board of Directors"). The foregoing provisions of this paragraph shall similarly apply to successive reorganizations, recapitalizations, mergers, consolidations, sales and transfers and to the capital stock or securities of any other corporation that are at the time receivable upon the exercise of this Warrant. In all events, appropriate adjustment shall be made in the application of the provisions of this Warrant with respect to the rights and interests of the Holder after the transaction, to the end that the provisions of this

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Warrant shall be applicable after that event, as near as reasonably may be, in relation to any shares or other property deliverable or issuable after such reorganization, recapitalization, merger, consolidation, sale or transfer upon exercise of this Warrant.

(b) Adjustments for Split, Subdivision or Combination of Shares. If the Company shall at any time subdivide (by any stock split, stock dividend, recapitalization, reorganization, reclassification or otherwise) the shares of Series C Preferred subject to acquisition hereunder, then, after the date of record for effecting such subdivision, the Exercise Price in effect immediately prior to such subdivision will be proportionately reduced and the number of shares of Series C Preferred subject to acquisition upon exercise of the Warrant will be proportionately increased. If the Company at any time combines (by reverse stock split, recapitalization, reorganization, reclassification or otherwise) the shares of Series C Preferred subject to acquisition hereunder, then, after the record date for effecting such combination, the Exercise Price in effect immediately prior to such combination will be proportionately increased and the number of shares of Series C Preferred subject to acquisition upon exercise of the Warrant will be proportionately decreased.

(c) Adjustments for Dividends in Stock or Other Securities or Property. If while this Warrant, or any portion hereof, remains outstanding and unexpired, the holders of any class of securities as to which purchase rights under this Warrant exist at the time shall have received or, on or after the record date fixed for the determination of eligible stockholders, shall have become entitled to receive, without payment therefor, other or additional stock or other securities or property (other than cash) of the Company by way of dividend, then and in each case, this Warrant shall represent the right to acquire, in addition to the number of shares of such class of security receivable upon exercise of this Warrant, and without payment of any additional consideration therefor, the amount of such other or additional stock or other securities or property (other than cash) of the Company that such holder would hold on the date of such exercise had it been the holder of record of the class of security receivable upon exercise of this Warrant on the date hereof and had thereafter, during the period from the date hereof to and including the date of such exercise, retained such shares and/or all other additional stock available to it as aforesaid during said period, giving effect to all adjustments called for during such period by the provisions of this Section 3.

(d) Notice of Adjustments. Upon any adjustment of the Exercise Price and any increase or decrease in the number of Warrant Shares purchasable upon the exercise of this Warrant, then, and in each such case, the Company, within thirty (30) days thereafter, shall give written notice thereof to the Holder at the address of such Holder as shown on the books of the Company, which notice shall state the Exercise Price as adjusted and, if applicable, the increased or decreased number of Warrant Shares purchasable upon the exercise of this Warrant, setting forth in reasonable detail the method of calculation of each.

(e) Calculations. All calculations under this Section 3 shall be made to the nearest cent or the nearest share, as applicable.

(f) Notice of Corporate Events. If the Company (i) declares a dividend or any other distribution of cash, securities or other property in respect of its Series C Preferred Stock, including without limitation any granting of rights or warrants to subscribe for or purchase any

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capital stock of the Company, (ii) authorizes or approves, or enters into any agreement contemplating or solicits stockholder approval for any merger or consolidation or (iii) authorizes the voluntary dissolution, liquidation or winding up of the affairs of the Company, then the Company shall deliver to the Holder a notice describing the material terms and conditions of such transaction, at least ten calendar days prior to the applicable record or effective date on which a person would need to hold Series C Preferred Stock in order to participate in or vote with respect to such transaction, and the Company will take all steps reasonably necessary in order to insure that the Holder is given the practical opportunity to exercise this Warrant prior to such time so as to participate in or vote with respect to such transaction; provided, however, that the failure to deliver such notice or any defect therein shall not affect the validity of the corporate action required to be described in such notice.

4. Notices. All notices, requests, consents and other communications required or permitted under this Warrant shall be in writing and shall be deemed delivered (i) three business days after being sent by registered or certified mail, return receipt requested, postage prepaid or (ii) one business day after being sent via a reputable nationwide overnight courier service guaranteeing next business day delivery, in each case to the intended recipient as set forth below:

If to the Company to:

Coronado Biosciences, Inc.  
45 Rockefeller Plaza, Suite 2000  
New York NY 10111  
Attention: Bobby W. Sandage, Jr., Ph.D., CEO  
Fax: (212) 554-4355

With a copy (that shall not constitute notice) to:

Cooley LLP  
500 Boylston Street  
Boston, MA 02116-3736  
Attention: Marc Recht  
Fax: (617) 937-2400.

If to the Holder at its address as furnished in the Subscription Agreement.

Either party may give any notice, request, consent or other communication under this Warrant using any other means (including personal delivery, messenger service, telecopy, first class mail or electronic mail), but no such notice, request, consent or other communication shall be deemed to have been duly given unless and until it is actually received by the party for whom it is intended. Either party may change the address to which notices, requests, consents or other communications hereunder are to be delivered by giving the other party notice in the manner set forth in this Section 4.

5. Legends. Each certificate evidencing the Warrant Shares issued upon exercise of this Warrant shall be stamped or imprinted with a legend substantially in the following form:

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THE SECURITIES REPRESENTED BY THIS CERTIFICATE HAVE NOT BEEN REGISTERED UNDER THE SECURITIES ACT OF 1933, AS AMENDED (THE "ACT"), OR THE SECURITIES LAWS OF ANY STATE AND MAY NOT BE SOLD OR TRANSFERRED IN THE ABSENCE OF AN EFFECTIVE REGISTRATION STATEMENT UNDER APPLICABLE FEDERAL AND STATE SECURITIES LAWS OR PURSUANT TO AN APPLICABLE EXEMPTION FROM, OR IN A TRANSACTION NOT SUBJECT TO, THE REGISTRATION REQUIREMENTS OF THE ACT AND IN ACCORDANCE WITH APPLICABLE STATE SECURITIES LAWS AS EVIDENCED BY A LEGAL OPINION OF COUNSEL TO THE TRANSFEROR TO SUCH EFFECT, WHICH OPINION SHALL BE REASONABLY ACCEPTABLE TO THE COMPANY.

6. Removal of Legend. Upon request of a holder of a certificate with the legends required by Section 5 hereof, the Company shall issue to such holder a new certificate therefor free of any transfer legend, if, with such request, the Company shall have received an opinion of counsel satisfactory to the Company in form and substance to the effect that any transfer by such holder of the Warrant Shares evidenced by such certificate will not violate the Act or any applicable state securities laws.

7. Fractional Shares. No fractional Warrant Shares will be issued in connection with any exercise hereunder. Instead, the Company shall round up, as nearly as practicable to the nearest whole Warrant Share, the number of Warrant Shares to be issued.

8. Rights of Stockholders. Except as expressly provided in Section 3(c) hereof, the Holder, as such, shall not be entitled to vote or receive dividends or be deemed the holder of the Warrant Shares or any other securities of the Company that may at any time be issuable on the exercise hereof for any purpose, nor shall anything contained herein be construed to confer upon the Holder, as such, any of the rights of a stockholder of the Company or any right to vote for the election of directors or upon any matter submitted to stockholders at any meeting thereof, or to give or withhold consent to any corporate action (whether upon any recapitalization, issuance of stock, reclassification of stock, change of par value, consolidation, merger, conveyance, or otherwise) or to receive notice of meetings, or otherwise until this Warrant shall have been exercised and the Warrant Shares purchasable upon the exercise hereof shall have been issued, as provided herein.

9. Reservation of Warrant Shares. The Company covenants that it will at all times reserve and keep available out of the aggregate of its authorized but unissued and otherwise unreserved Series C Preferred, solely for the purpose of enabling it to issue Warrant Shares upon exercise of this Warrant as herein provided, the number of Warrant Shares which are then issuable and deliverable upon the exercise of this entire Warrant, free from preemptive rights or any other contingent purchase rights of persons other than the Holder (after giving effect to the adjustments and restrictions of Section 3, if any). The Company covenants that all Warrant Shares so issuable and deliverable shall, upon issuance and the payment of the applicable Exercise Price in accordance with the terms hereof, be duly and validly authorized, issued and fully paid and nonassessable. The Company will take all such action as may be necessary to assure that such shares of Series C Preferred may be issued as provided herein without violation

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of any applicable law or regulation, or of any requirements of any securities exchange or automated quotation system upon which the Series C Preferred may be listed.

10. Replacement of Warrant. If this Warrant is mutilated, lost, stolen or destroyed, the Company shall issue or cause to be issued in exchange and substitution for and upon cancellation hereof, or in lieu of and substitution for this Warrant, a new Warrant, but only upon receipt of evidence reasonably satisfactory to the Company of such loss, theft or destruction, or surrender of any mutilated Warrant, and customary and reasonable bond or indemnity, if requested. Applicants for a new Warrant under such circumstances shall also comply with such other reasonable regulations and procedures and pay such other reasonable third-party costs as the Company may prescribe.

11. Miscellaneous.

(a) Restrictions on Transfers. This Warrant may not be transferred at any time without (i) registration under the Securities Act or (ii) an exemption from such registration and a written opinion of legal counsel addressed to the Company that the proposed transfer of the Warrant may be effected without registration under the Securities Act, which opinion will be in form and from counsel reasonably satisfactory to the Company.

(b) Permitted Transfers and Assignments. Notwithstanding any provision to the contrary in this Section 11, the Holder may transfer, with or without consideration, this Warrant or any of the Warrant Shares (or a portion thereof) to the Holder's Affiliates (as such term is defined under Rule 144 of the Securities Act) without obtaining the opinion from counsel that may be required by Section 11(a) above), provided, that the Holder delivers to the Company and its counsel certification, documentation, and other assurances reasonably required by the Company's counsel to enable the Company's counsel to render an opinion to the Company's Transfer Agent that such transfer does not violate applicable securities laws.

(c) Permitted Designees. Notwithstanding anything contained herein, the Company shall, upon written instructions from the Holder to be delivered to the Company within ninety (90) calendar days following the date of the issuance of this Warrant, transfer all or a portion of this Warrant to officers, directors, employees and other associated persons of the Holder and other registered dealers, agents and finders (collectively, "**Permitted Designees**"). Such transfer shall be effective upon delivery of this Warrant and the form of assignment attached hereto.

(d) Amendments and Waivers. The Company may, without the consent of the Holders (but with written notice to the Holders), by supplemental agreement or otherwise, (i) make any changes or corrections in this Warrant that are required to cure any ambiguity or to correct or supplement any provision herein which may be defective or inconsistent with any other provision herein or (ii) add to the covenants and agreements of the Company for the benefit of the Holders (including, without limitation, reduce the Exercise Price or extend the Expiration Date), or surrender any rights or power reserved to or conferred upon the Company in this Warrant; provided that, in the case of (i) or (ii), such changes or corrections shall not adversely affect the interests of Holders of then outstanding Warrants. This Warrant may also be amended

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or waived with the written consent of the Company and the Holders holding a majority of the then outstanding Warrants.

(e) Governing Law; Venue; Waiver of Jury Trial. This Warrant shall be governed by and construed exclusively in accordance with the internal laws of the State of New York regard to the conflicts of laws principles thereof. The parties hereto hereby expressly and irrevocably agree that any suit or proceeding arising directly and/or indirectly pursuant to, arising out of or under this Warrant, shall be brought solely and exclusively in a federal or state court located in New York. By its execution hereof, the parties hereby expressly covenant and irrevocably submit to the in personam jurisdiction of the federal and state courts located in New York and agree that any process in any such action may be served upon any of them personally, or by certified mail or registered mail upon them or their agent, return receipt requested, with the same full force and effect as if personally served upon them in New York. The parties hereto expressly and irrevocably waive any claim that any such jurisdiction is not a convenient forum for any such suit or proceeding and any defense or lack of in personam jurisdiction with respect thereto. In the event of any such action or proceeding (including, but not limited to, any motions made), the party prevailing therein shall be entitled to payment from the other party hereto of its reasonable counsel fees and disbursements. The Company and Holders hereby waive all rights to a trial by jury.

(f) Partial Invalidity. In case any one or more of the provisions of this Warrant shall be invalid or unenforceable in any respect, the validity and enforceability of the remaining terms and provisions of this Warrant shall not in any way be affected or impaired thereby and the parties will attempt in good faith to agree upon a valid and enforceable provision which shall be a commercially reasonable substitute therefor, and upon so agreeing, shall incorporate such substitute provision in this Warrant.

(g) Headings. The headings herein are for convenience only, do not constitute a part of this Warrant and shall not be deemed to limit or affect any of the provisions hereof.

[Signature Page Follows]

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IN WITNESS WHEREOF, the Company has caused this Warrant to be signed by its duly authorized officer.

CORONADO BIOSCIENCES, INC.

By \_\_\_\_\_  
Name:  
Title:



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**Exhibit A**  
**FORM OF EXERCISE NOTICE**

(To be executed by the Holder to exercise the right to purchase shares of Series C Preferred Stock under the foregoing Warrant)

To: CORONADO BIOSCIENCES, INC.

The undersigned is the Holder of Warrant No. \_\_\_\_\_ (the "Warrant") issued by Coronado Biosciences, Inc., a Delaware corporation (the "Company"). Capitalized terms used herein and not otherwise defined have the respective meanings set forth in the Warrant.

The Warrant is currently exercisable to purchase a total of \_\_\_\_\_ Warrant Shares.

- (b) The undersigned Holder hereby exercises its right to purchase \_\_\_\_\_ Warrant Shares pursuant to the Warrant.
- (c) The holder shall make payment of the Exercise Price as follows (check one):
  - \_\_\_\_\_ "Cash Exercise" under Section 2(a).
  - \_\_\_\_\_ "Cashless Exercise" under Section 2(b).
- (d) If the holder is making a Cash Exercise, the holder shall pay the sum of \$ \_\_\_\_\_ to the Company in immediately available funds in accordance with the terms of the Warrant.
- (e) Pursuant to this exercise, the Company shall deliver to the holder \_\_\_\_\_ Warrant Shares in accordance with the terms of the Warrant.
- (f) Following this exercise, the Warrant shall be exercisable to purchase a total of \_\_\_\_\_ Warrant Shares.

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(g) The Holder represents that, as of the date of exercise:

- i. the Warrant Shares being purchased pursuant to this Exercise Notice are being acquired solely for the Holder's own account and not as a nominee for any other party, for investment, and not with a view toward distribution or resale; and
- ii. the Holder is an "accredited investor" as such term is defined in Rule 501(a)(1) of Regulation D promulgated by the U.S. Securities and Exchange Commission under the Securities Act.

(h) If the Holder cannot make the representations required in Section (h)(ii) above because it is factually incorrect, it shall be a condition to the exercise of the Warrant that the Company receive such other representations as the Company considers necessary, acting reasonably, to assure the Company that the issuance of securities upon exercise of this Warrant shall not violate any United States or other applicable securities laws.

Dated: \_\_\_\_\_, \_\_\_\_

Name of Holder: \_\_\_\_\_

(Print)

By: \_\_\_\_\_

Name: \_\_\_\_\_

Title: \_\_\_\_\_

(Signature must conform in all respects to name of holder as specified on the face of the Warrant)

FORM OF ASSIGNMENT

[To be completed and signed only upon transfer of Warrant]

FOR VALUE RECEIVED, the undersigned hereby sells, assigns and transfers unto \_\_\_\_\_ the right represented by the within Warrant to purchase \_\_\_\_\_ shares of Series C Preferred Stock of Coronado Biosciences, Inc. to which the within Warrant relates and appoints \_\_\_\_\_ attorney to transfer said right on the books of Coronado Biosciences, Inc. with full power of substitution in the premises.

The undersigned transferee agrees to be bound by the covenants of the Warrant Holder during the term of the Warrant.

The undersigned transferee agrees represents and warrants that:

- i. the Warrant Shares being purchased pursuant to this Assignment are being acquired solely for the transferee’s own account and not as a nominee for any other party, for investment, and not with a view toward distribution or resale; and
- ii. the undersigned transferee is an “accredited investor” as such term is defined in Rule 501(a)(1) of Regulation D promulgated by the Securities and Exchange Commission under the Securities Act.

If the undersigned transferee cannot make the representations required in clause (ii) above because it is factually incorrect, it shall be a condition to the transfer of the Warrant that the Company receive such other representations as the Company considers necessary, acting reasonably, to assure the Company that the transfer of this Warrant shall not violate any United States or other applicable securities laws.

Dated: \_\_\_\_\_, \_\_

\_\_\_\_\_  
(Signature must conform in all respects to name of holder as specified on the face of the Warrant)

\_\_\_\_\_  
Address of Transferee

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

\_\_\_\_\_  
Signature of Transferee

In the presence of:

\_\_\_\_\_

(Signature and Date)

**CONFIDENTIAL TREATMENT REQUESTED.  
INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN  
REQUESTED IS OMITTED AND MARKED WITH “[\*\*\*\*\*]” OR OTHERWISE  
CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS  
ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

**EXCLUSIVE SUBLICENSE AGREEMENT**

This Exclusive Sublicense Agreement (hereinafter referred to as this “Agreement”), effective as of this December 12, 2005 (the “Effective Date”), is entered into by and between Ovamed GbmH & Co KG, a corporation duly incorporated under the laws of Germany and having a principal place of business at Kiebitzhörn 33-35, 22885 Barsbüttel, Germany (“Ovamed”) and Collingwood Pharmaceuticals, Inc., a corporation duly organized and existing under the laws of the State of Delaware having a principal place of business at 787 Seventh Avenue, 48<sup>th</sup> Floor, New York, New York 10019 (the “Company”).

**WHEREAS**, under the patent policy of The University of Iowa (“UI”), all inventions and technology arising during the normal course of research and teaching at the UI are assigned and entrusted to the University of Iowa Research Foundation (“URIF”) to obtain patent or other appropriate intellectual property protection and license said technology;

**WHEREAS**, UIRF is, therefore, owner by assignment from Joel Weinstock and David Elliott of their entire right, title and interest in United States Patent 6,764,838 and United States Patent Application Numbers 09/362,598; 10/715,659; 10/779,249; Canada Patent Application Number 2,315,790; Japanese Patent Application Number 2000-526233; Australia Patent Number 740776, all titled “Use of Parasitic Biological Agents for Prevention and Control of Autoimmune Diseases”;

**WHEREAS**, Ovamed has entered into an Exclusive License Agreement with URIF under which Ovamed has obtained an exclusive license to the research, development and commercialization of intellectual property relating to the use of parasitic biological agents for the prevention and control of autoimmune diseases (the “Technology”) as claimed in the Patent Rights (as defined below) in the Field (as defined below) in the Territory (as defined below) (the “License Agreement”);

**WHEREAS**, the Company is interested in obtaining rights to the research, development and commercialization of intellectual property relating to the Technology as claimed in the Patent Rights (as defined below) in the Field (as defined below) in the Territory (as defined below);

**WHEREAS**, Ovamed is willing to grant such rights to the Company so that the Technology may be developed and the benefits enjoyed by the public;

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**NOW, THEREFORE**, it is agreed as follows:

**ARTICLE 1 – DEFINITIONS**

For the purposes of this Agreement, the following words and phrases shall have the following meanings:

**1.1** “Affiliate” shall mean, with respect to any Entity (as hereinafter defined), any Entity that directly or indirectly controls, is controlled by, or is under common Control with such Entity.

1.1.1 “Control” shall mean, for this purpose, direct or indirect control of more than fifty percent (50%) of the voting securities of an Entity or, if such Entity does not have outstanding voting securities, more than 50% of the directorships or similar positions with respect to such Entity.

1.1.2 “Entity” shall mean any corporation, association, joint venture, partnership, trust, university, business, individual, government or political subdivision thereof, including an agency, or any other organization that can exercise independent legal standing.

**1.2** “Field” shall mean the prevention, treatment, cure or diagnosis of human diseases, with the exception of gastroenterology (*e.g.*, inflammatory bowel disease) and hepatology in Europe.

**1.3** “Know-how” shall mean all tangible or intangible information (other than those contained in the Patent Rights) whether patentable or not (but which have not been patented) and physical objects related to the Licensed Product, including but not limited to formulations, biological samples, tissues, animals, organisms, compounds, intermediates, in vitro, preclinical or clinical design, other proprietary materials, processes, including but not limited to manufacturing processes, data, drawings and sketches and designs owned or controlled by Ovamed or which Ovamed has the right to disclose and license to the Company.

**1.4** “Licensed Product(s)” shall mean any product that cannot be manufactured, used or sold, in whole or in part, without infringing one or more claims under Patent Rights in the country in which the product is made, used, leased, imported, offered for sale or sold.

**1.5** “Licensed Process(es)” shall mean processes which, in the course of being practiced would, in the absence of this Agreement, infringe one or more claims of the Patent Rights.

**1.6** “Net Sales” shall mean the total gross receipts for sales of Licensed Products or practice of Licensed Processes by or on behalf of the Company or its Affiliates or Company Sublicensees (as applicable), whether invoiced or not, less only the sum of the following: (a) usual trade discounts to customers; (b) sales, tariff duties and/or taxes directly imposed and with reference to particular sales; (c) amounts allowed or credited on returns or rejections; (d) bad debt deductions actually written off during the accounting period; (e) outbound transportation prepaid or allowed and transportation insurance; (f) sales commissions; and (g) packaging and freight charges.

1.6.1 Notwithstanding anything to the contrary in this Article 1.6, Net Sales does not include sales of Licensed Product at or below the fully burdened cost of manufacturing solely for non-profit research or clinical testing or for indigent or similar public support or compassionate use programs. If (i) the end user is a Company Sublicensee or an Affiliate or (ii) if Licensed Product or Licensed Process is sold for consideration other than money, then Net Sales shall be calculated based on the final gross selling price of comparable Licensed Products sold in arm’s length transactions by Company to an end user.

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1.6.2 For purposes of determining Net Sales, Licensed Product shall be deemed to be sold when shipped or to be the subject of a sale upon the delivery of Licensed Product to the purchaser or a common carrier at the risk of the purchaser and the transfer of title thereto to the purchaser.

1.6.3 Sales between or among the Company, Company Sublicensee and their Affiliates shall be excluded from the computation of Net Sales provided such parties are not the end-user of the products, but sales by such entities to their non-affiliated customers shall be included in such computation.

**1.7** "Patent Rights" shall mean (a) United States Patent Number 6,764,838 and United States Patent Application Numbers 09/362,598; 10/715,659; 10/779,249; Canada Patent Application Number 2,315,790; Japanese Patent Application Number 2000-526233; and Australia Patent Number 740776, all entitled "Use of Parasitic Biological Agents for Prevention and Control of Autoimmune Diseases", patents issuing thereon or reissues thereof; any and all foreign patents and patent applications corresponding thereto; any divisional, continuation in part, continuation and reexamination applications; and any extensions thereof; (b) any and all US or foreign patents, patent applications, or other rights issuing from, or filed subsequent to the date of this Agreement, based on or claiming priority to or from the applications and rights listed in 1.1(a); and (c) any foreign counterpart to any of (a or b) not otherwise listed therein. All such Patent Rights shall be set forth in Appendix A, attached to this Agreement and made part thereof.

**1.8** Non-Royalty Sublicensing Income ("NRSI") shall mean any and all consideration received from a Company Sublicensee in consideration for grant of a sublicense under the Patent Rights, which shall include upfront and milestone payments, but expressly excludes all royalty payments; payments resulting from the sale of one or more Licensed Products; research and development funding; equity exchanges; and investment.

**1.9** Company Sublicensee means any other third party that has entered into a sublicense agreement with the Company to make, have made, use, have used, lease, offer to sell, sell and/or have sold the Licensed Products and to practice and have practiced the Licensed Processes.

**1.10** "Territory" shall mean the world, to the extent Ovamed possesses a license to practice the Patent Rights in specific countries and/or territories in the world.

## **ARTICLE 2 – GRANT**

**2.1** Ovamed hereby grants to the Company and the Company accepts, subject to the terms and conditions of this Agreement, an exclusive license in the Field to practice under the Patent Rights and to utilize the Know-how in the Territory, and (a) to make, have made, use, have used, lease, import, offer to sell, sell and/or have sold the Licensed Products and to practice and have practiced the Licensed Processes, to the full end of the term for which the Patent Rights are granted, unless sooner terminated as hereinafter provided and (b) to sublicense to third parties, in accordance with Article 2.2 below, the rights granted under subsection (a) of this Article 2.1.

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**2.2** In accordance with 2.1 above, Ovamed hereby grants to the Company the right to grant sublicenses to third parties under the license granted hereunder in the sole discretion of the Company. Upon termination of this Agreement other than by expiration in accordance with paragraph 9.9, any and all sublicenses shall survive such termination, provided, however, Ovamed shall not be obligated to incur any obligation or duties to any former Company Sublicensee of the Company not already incurred or delegated to the Company by Ovamed in this Agreement. Notwithstanding the foregoing, if Company believes that Ovamed has terminated this Agreement for the primary purpose of doing business directly with the Company Sublicensee, the termination may be disputed.

**2.3** Unless otherwise prohibited by law, Ovamed shall provide Company with and give Company access to the following: (i) copies of all regulatory submissions, (ii) copies of all patient records, (iii) any communications and the minutes of any meetings with the FDA or other regulatory authority relating to the Licensed Product; (iv) trial master files relating to any regulatory submission; (v) copies of all case report forms; (vi) all results of clinical trials conducted prior to and as of the Effective Date of this agreement relating to the Licensed Products, including without limitation, clinical data, hard copy CRFs and reports; patient samples (such as blood samples, microbiology samples, and tissue samples) and access to (yarned personnel with relevant expertise to explain the foregoing (vii) copies of all computer data and reports pertaining to clinical trials, (viii) copies of all adverse event reports, (ix) copies of all preclinical evaluations, (x) any clinical trial material that has not expired, (xi) storage of and access permission to biological samples, (xii) access to physicians, CROs and health care administrators involved in trials; (xiii) copies of an access to records and reports of any CMC related activities; (xiv) all drug manufacture files along with the right to use manufacturing process and the manufacturing source, (xv) remaining quantities of any API (active pharmaceutical ingredient) and intermediates and (xvi) all other information that Company may reasonably request regarding clinical trials and regulatory approvals. All costs related to the duplication of such materials will be borne by Company. In addition, Ovamed shall cross-reference or assign all regulatory filings, at Company's option. From time to time during the term of this Agreement, at the request of Company, Ovamed shall execute and deliver to Company such documents and take such other action as Company may reasonably request to consummate more effectively the transactions contemplated hereby. Ovamed shall reasonably cooperate with Company and provide Company with such assistance as reasonably may be requested by Company, including with respect to the transfer of clinical data and filings with the FDA or other regulatory authorities.

### **ARTICLE 3 – COMMERCIALIZATION**

**3.1** The Company shall use all commercially reasonable efforts or shall cause its Affiliates or Company Sublicensees to use commercially reasonable efforts, to bring a Licensed Product to market through a thorough, vigorous and diligent program for exploitation

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of the Technology as timely and efficiently as possible. Such program shall include the preclinical and clinical development of Licensed Products, including research and development, manufacturing, laboratory and clinical testing and marketing. The Company shall continue active, diligent marketing efforts for a Licensed Product throughout the term of this Agreement.

**3.2** Following the execution of this Agreement, Ovamed and the Company shall negotiate in good faith the terms of a Manufacturing and Supply Agreement under which, subject to the terms of such agreement, Ovamed shall supply the Company with Licensed Product in amounts sufficient to satisfy the Company's clinical and commercial requirements.

#### **ARTICLE 4 – ROYALTIES AND OTHER CONSIDERATION**

**4.1** Within ninety (90) days after the pre-IND meeting to be held at the United States Food and Drug Administration ("FDA") on December 13, 2005 ("The pre-IND Meeting"), the Company shall pay to Ovamed or directly to UIRF (at the Company's option) the following:

4.1.1 a non-refundable license fee of One Hundred Ten Thousand Dollars (\$110,000) upon execution of this Agreement;

4.1.2 One Hundred Percent (100%) of all monies paid by Ovamed to UIRF for costs incurred as of the effective date of the License Agreement relating to the preparation, filing, prosecution and maintenance of the Patent Rights where such costs as of July 20, 2005 were One Hundred Ninety Thousand Six Hundred Thirty Three Dollars and Ninety Three Cents (\$190,633.93) plus any costs incurred by UIRF between July 20, 2005 and the Effective Date of this Agreement;

**4.2** The Company agrees to pay to Ovamed or directly to UIRF (at the Company's option) the royalties set forth below, to the end of the term of this License Agreement or until this Agreement shall be terminated as hereinafter provided.

4.1.1 During the term of the License Agreement, the Company shall pay Ovamed or directly to UIRF (at the Company's option) royalties equal to: four percent (4%) of Net Sales by the Company, Affiliates or Company Sublicensees;

4.1.2 The Company shall also pay to Ovamed thirty percent (30%) of any NRSI received by the Company as a result of the sublicensing of any of the Patent Rights prior to the pre-IND meeting in the United States or a foreign equivalent; twenty percent (20%) of NRSI subsequent to the pre-IND but prior to commencement of clinical trials; fifteen percent (15%) of NRSI after commencement of clinical trials, but prior to the completion of enrollment of a phase II clinical trial; and ten percent (10%) of any NRSI subsequent to enrollment of a Phase II clinical trial.

**4.3** As further consideration for the license granted hereunder, the Company will make the following one-time milestone payments (each a "Milestone Payment") to Ovamed.



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- 4.3.1 One Million Five Hundred Thousand] Dollars (\$1,500,000) upon acceptance by the FDA of a Company-, Affiliate- or Company Sublicensee- sponsored Investigational New Drug Application (an “IND”) for a Licensed Product;
- 4.3.2 One Million Five Hundred Thousand Dollars (\$1,500,000) upon the one year anniversary of the acceptance by the FDA of a Company-, Affiliate- or Company Sublicensee- sponsored IND for a Licensed Product;
- 4.3.3 Two Hundred Thousand Dollars (\$200,000) upon completion by the Company of the issuance of the Company’s debt or equity securities to qualified investors in exchange for aggregate cash proceeds equal to or in excess of Five Million Dollars (\$5,000,000);
- 4.3.4 Six Hundred Thousand Dollars (\$600,000) upon the acceptance for review by the FDA of the first Company-, Affiliate- or Company Sublicensee- sponsored New Drug Application (“NDA”) for a Licensed Product;
- 4.3.5 One Million Seven Hundred Fifty Thousand Dollars (\$1,750,000) upon the final approval by the FDA of the first Company-, Affiliate- or Company Sublicensee-sponsored NDA for a Licensed Product;
- 4.3.6 One Million Two Hundred Fifty Thousand Dollars (\$1,250,000) upon the final approval by the FDA of each subsequent Company-, Affiliate- or Company Sublicensee-sponsored NDA for a Licensed Product having an indication other than the indication on which the milestone of 4.3.5 is based;
- 4.3.7 Two Hundred Thousand Dollars (\$200,000) upon the acceptance for review of the first Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in the European Union by the European Agency for Evaluation of Medicinal Products (the “EMA”) or its successor organization;
- 4.3.8 Four Hundred Thousand Dollars (\$400,000) upon the final approval by the EMA or its equivalent of the first Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in the European Union;
- 4.3.9 Four Hundred Thousand Dollars (\$400,000) upon the final approval by the EMA or its equivalent for each subsequent Company-, Affiliate- or Company Sublicensee-sponsored application for the commercial sale of a Licensed Product having an indication other than the indication on which the milestone of 4.3.8 is based;
- 4.3.10 Two Hundred Thousand Dollars (\$200,000) upon the acceptance for review of the first Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Japan by the Ministry of Health, Labor, and Welfare or its equivalent (“MHLW”);
- 4.3.11 Four Hundred Thousand Dollars (\$400,000) upon the final approval of a Company-, Affiliate- or Company Sublicensee-sponsored application for the commercial sale of a Licensed Product in Japan by MHLW;

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4.3.12 Four Hundred Thousand Dollars (\$400,000) upon the final approval of each subsequent Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Japan by MHLW having an indication other than the indication on which the milestone of 4.3.11 is based;

4.3.13 Two Hundred Thousand Dollars (\$200,000) upon the acceptance for review of the first Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Canada by Health Canada or its equivalent;

4.3.14 Four Hundred Thousand Dollars (\$400,000) upon the final approval of a Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product by Health Canada or its equivalent;

4.3.15 Three Hundred Fifty Thousand Dollars (\$350,000) upon the final approval of each subsequent Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Canada by Health Canada or its equivalent having an indication other than the indication on which the milestone of 4.3.14 is based;

4.3.16 One Hundred Fifty Thousand Dollars (\$150,000) upon acceptance for review of the first Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Australia by the Pharmaceutical Benefits Advisory Committee or its equivalent ("PBAC");

4.3.17 Three Hundred Fifty Thousand Dollars (\$350,000) upon final approval of a Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Australia by the PBAC; and;

4.3.18 Three Hundred Fifty Thousand Dollars (\$350,000) upon final approval of each subsequent Company-, Affiliate- or Company Sublicensee- sponsored application for the commercial sale of a Licensed Product in Australia by the PBAC having an indication other than the indication on which the milestone of 4.3.17 is based.

**4.4** No multiple royalties shall be payable because the use, lease or sale of any Licensed Product or Licensed Process is, or shall be, covered by more than one valid and unexpired claim contained in the Patent Rights.

**4.5** In the event that a Licensed Product or Licensed Process is sold in the form of a combination product/process containing one or more products or technologies which are themselves not a Licensed Product or Licensed Process, the Net Sales for such combination product/process shall be calculated by multiplying the sales price of such combination product by the fraction  $A/(A+B)$  where A is the invoice price of the Licensed Product/Licensed Process or the Fair Market Value of the Licensed Product/Licensed Process if sold to an Affiliate and B is the total invoice price of the other products or technologies or the Fair Market Value of the other products or technologies if purchased from an Affiliate.

**4.6** Royalty payments shall be paid in United States dollars at such place as Ovamed may reasonably designate consistent with the laws and regulations controlling in the United States and if applicable in any foreign country. Any taxes which the Company, its Affiliate or

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any Company Sublicensee shall be required by law to withhold on remittance of the royalty payments shall be deducted from such royalty payment to Ovamed. The Company shall furnish Ovamed with the original copies of all official receipts for such taxes. If any currency conversion shall be required in connection with the payment of royalties hereunder, such conversion shall be made by using the exchange rate prevailing at Citibank, N.A. in New York, New York on the last business day of the calendar quarterly reporting period to which such royalty payments relate.

**4.7** Royalties payable to Ovamed shall be paid semi-annually on or before June 30 and December 31 of each calendar year. Each such payment shall be for unpaid royalties which accrued within or prior to the Company's two most recently completed fiscal quarters.

**4.8** Commencing on the fourth anniversary of the execution date of this Agreement, the Company shall remit to Ovamed or to UIRF (at the Company's option) an annual license maintenance fee payment of Two Hundred Fifty Thousand Dollars (\$250,000). Notwithstanding the limitations of this Article 4.8, annual license maintenance fees paid hereunder shall be reduced by the total amount of any milestones and royalties accrued to the Company, an Affiliate or a Company Sublicensee solely during the relevant agreement year but shall not be reduced by (a) any royalties accruing in any other agreement year or (b) contract research funding payable to the University of Iowa or UIRF pursuant to the terms of any research or development agreement.

**4.9** No payment obligations shall be due with respect to any sale or sublicense covering any Licensed Product in a country if there are no issued Patent Rights underlying such Licensed Product in such country.

**4.10** To the extent that the Company, its Affiliate, or its Company Sublicensee is required (i) in its sole discretion after appropriate legal analysis, or (ii) by order or judgment of any court in any jurisdiction, to obtain a license from a third party in order to practice the rights purported to be granted to the Company by Ovamed hereunder under Patent Rights in such jurisdiction, then up to [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the royalties payable under such license in such jurisdiction may be deducted from royalties otherwise payable to Ovamed hereunder, provided that in no event shall the aggregate royalties payable to Ovamed in any semi-annual period in such jurisdiction be reduced by more than [\*\*\*\*\*] percent ([\*\*\*\*\*]%) as a result of any such deduction, provided further that any excess deduction remaining as a result of such limitation may be carried forward to subsequent periods.

**4.11** Should the Company fail to make any payments due to Ovamed pursuant to Articles 4.1, 4.2, 4.3, 4.8 and 6.1 of this Agreement, Paramount Biosciences, LLC ("Paramount") shall make such payments to Ovamed on the Company's behalf (such payments may be made directly to UIRF, at the Company's option). In return for such payments, Paramount will receive promissory notes from the Company in amounts equal to those amounts remitted by Paramount to Ovamed (or UIRF as applicable) pursuant to the preceding sentence (the "Notes") that will accrue interest at [\*\*\*\*\*] percent ([\*\*\*\*\*]%) per annum, compounded [\*\*\*\*\*], and [\*\*\*\*\*] percent ([\*\*\*\*\*]%) upon default. The Notes will become due and payable in [\*\*\*\*\*] months from the date of payment by Paramount of the applicable fund to Ovamed (or UIRF as applicable). The Notes will also convert into shares of [\*\*\*\*\*], at Paramount's option, at a per share price representing a [\*\*\*\*\*] Dollars

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(\$[\*\*\*\*\*]) valuation of the Company, should the Company fail to repay any outstanding Note when due. Paramount's obligation to Ovamed and the Company under this Article 4.11 shall terminate upon such time as the Company has received in excess of [\*\*\*\*\*] Dollars (\$[\*\*\*\*\*]) in gross proceeds as a result of the sale of its equity securities.

#### **ARTICLE 5 – REPORTS AND RECORDS**

**5.1** The Company shall report to Ovamed the date of first sale of Licensed Products (or results of Licensed Processes) in each country within thirty (30) days of occurrence.

**5.2** The Company agrees to submit to Ovamed within [\*\*\*\*\*] days after the calendar quarters ending March 31, June 30, September 30, and December 31, reports setting forth for the preceding three (3) month period at least the following information:

- (i) the number of the Licensed Products sold by the Company, its Affiliates and its Company Sublicensees in each country;
- (ii) total billings for such Licensed Products;
- (iii) an accounting for all Licensed Processes used or sold;
- (iv) deductions applicable to determine the Net Sales thereof;
- (v) the amount of royalty due thereon;

and with each such royalty report to pay the amount of royalty due. Such report shall be certified as correct by an officer of the Company and shall include a detailed listing of all deductions from royalties as specified herein. If no royalties are due to Ovamed for any reporting period, the written report shall so state. All such reports shall be maintained in confidence under Article 15 of this Agreement.

#### **ARTICLE 6 – FILING, PROSECUTION AND MAINTENANCE**

**6.1** Pursuant to Article 4.1.2, the Company shall reimburse Ovamed or may reimburse UIRF directly (at the Company's option) for all reasonable expenses Ovamed has paid to UIRF under the License Agreement in connection with the preparation, filing, prosecution and maintenance of Patent Rights and the Company shall reimburse Ovamed for monies Ovamed has paid to UIRF under the License Agreement for all such future expenses upon receipt of invoices from Ovamed and/or UIRF. It is understood that UIRF shall take responsibility for the preparation, filing, prosecution and maintenance of any and all patent applications and patents included in Patent Rights.

**6.2** Ovamed and the Company shall cooperate fully in the preparation, filing, prosecution and maintenance of Patent Rights and of all patents and patent applications licensed to the Company hereunder, executing all papers and instruments or causing members of UIRF to execute such papers and instruments as to enable UIRF to apply for, to prosecute and to maintain

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patent applications and patents in UIRF's name in any country. Each party shall provide to the other prompt notice as to all matters which come to its attention and which may affect the preparation, filing, prosecution or maintenance of any such patent applications or patents.

**6.3** If the Company elects to no longer pay the expenses of a patent application or patent included with Patent Rights, the Company shall notify Ovamed not less than sixty (60) days prior to such action and shall thereby surrender its rights and extinguish its obligations under such patent or patent application.

**6.4** Notwithstanding anything to the contrary herein, Ovamed and/or UIRF will provide the Company with ample time in which to review and comment on any communication for which submission to any patent office is intended, including but not limited to responses to official actions, amendments, affidavits, declarations and patent applications. In no event shall Ovamed provide the Company with less than seven (7) business days in which to review an intended patent office submission prior to such submission. Ovamed shall use best efforts, and shall cause UIRF to use best efforts, to accommodate the Company's requests to (a) enter and/or amend a claim in a pending patent application under the Patent Rights or (b) file additional patent applications as reasonably needed to advance the purposes of this Agreement or to protect the rights and licenses granted hereunder. Ovamed further agrees to cause UIRF to retain patent counsel to prosecute and maintain the Patent Rights that is reasonably acceptable to the Company with respect to quality of work and responsiveness. Within [\*\*\*\*\*] days of the Effective Date of this Agreement, Ovamed and the Company shall develop, in good faith, a budget for controlling all costs associated with the preparation, filing, prosecution and maintenance of the Patent Rights. Ovamed and/or UIRF shall obtain the Company's prior written consent for any such costs that exceed the budget by more than [\*\*\*\*\*] percent ([\*\*\*\*\*]%).

**6.5** Notwithstanding anything to the contrary herein, Ovamed shall cause UIRF to authorize UIRF's patent counsel to communicate directly with the Company on the same basis that said patent counsel communicates with UIRF with respect to the prosecution of Patent Rights.

#### **ARTICLE 7 – MARKING**

**7.1** If a licensed patent has been or is subsequently issued to UIRF covering any feature or features of the Licensed Products, the Company agrees to mark each and every package or container in which the Licensed Products are used or sold by or for the Company with marking complying with the provisions of Title 35, U.S. Code, Section 287, if required, or any future equivalent provisions of the United States relating to the marking of patented devices, or with marking complying with the law of the country where the Licensed Products are shipped, used or sold.

#### **ARTICLE 8 – INFRINGEMENT**

**8.1** The Parties shall promptly provide written notice to each other of any alleged infringement or any challenge or threatened challenge to the validity, enforceability or priority of any of the Patent Rights, and provide each other with any available evidence of such infringement, challenge or threatened challenge by a third party of the Patent Rights and provide such other party with any available evidence of such infringement.

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**8.2** During the term of this Agreement, the Company shall have the right, but not the obligation, to institute such action as it deems appropriate at its own expense and utilizing counsel of its choice, to terminate the infringement of, and/or challenge to, the Patent Rights in the Territory in the Field through negotiation, litigation and/or alternative dispute resolution means, provided that the Company shall not act in any arbitrary or capricious manner and shall not act in contravention or breach of the licenses granted to the Company hereunder. Ovamed shall reasonably cooperate in any such action, and shall cause UIRF to reasonably cooperate in any such action in accordance with the terms of the License Agreement. Pursuant to the License Agreement, UIRF may join the Company as a party in any such suit (and will join at Ovamed's request), provided that the Company and/or Ovamed pay all of UIRF's reasonable out-of-pocket expenses. Any recovery of damages pursuant to this Article 8.2 shall be retained entirely by the Company and allocated pursuant to 8.4 below.

**8.3** In the event that a claim or suit is asserted or brought against the Company alleging that the manufacture or sale of any Licensed Product or Licensed Process by the Company, an Affiliate, or Company Sublicensee, or the use of such Licensed Product or Licensed Process by any customer of any of the foregoing, infringes proprietary rights of a third party, the Company shall give written notice thereof to Ovamed. The Company may, in its sole discretion, modify such Licensed Product or such Licensed Process to avoid such infringement and/or may settle on terms that it deems advisable in its sole discretion, subject to paragraph 8.2. Otherwise, the Company shall have the right, but not the obligation, to defend any such claim or suit. In the event the Company elects not to defend such suit, Ovamed shall have the right, but not the obligation to do so at its sole expense.

**8.4** Any recovery of damages by the Company, in any such suit under Article 8.2 and 8.3, shall be applied first in satisfaction of any unreimbursed expenses and legal fees of the Company relating to the suit. The balance remaining from such suit shall be allocated accordingly: (a) amounts relating to lost sales shall be allocated in their entirety to the Company, provided however, that Company shall pay Ovamed royalties due for such lost sales pursuant to Article 4 of this Agreement; and (b) any amounts remaining after the allocation of amounts pursuant to 8.4(a) shall be divided equally between the Company and Ovamed.

**8.5** The Company may credit the cost of any litigation costs incurred by the Company in any country in the Territory pursuant to this Article 8 including all amounts paid in judgment or settlement of litigation within the scope of this Article 8 against royalties or other fees thereafter payable to Ovamed hereunder for such country. If the costs of such litigation in such country exceeds the royalties payable to Ovamed in any year in which such costs are incurred then the amount of such costs, expenses and amounts paid in judgment or settlement, in excess of the royalties payable shall be carried over and credited against royalty payments in future years for such country.

**8.6** If within [\*\*\*\*\*] months after receiving notice of any alleged infringement of the Patent Rights, the Company shall have been unsuccessful in persuading the alleged infringer to desist, or shall not have brought and shall not be diligently prosecuting an infringement action, or

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if the Company shall notify Ovamed, at any time prior thereto, of its intention not to bring suit against the alleged infringer, then, and in those events only, the Company shall have the right, but not the obligation, to prosecute, at its own expense and utilizing counsel of its choice, any infringement of the Patent Rights, and the Company may, for such purposes, join Ovamed and/or IMF as a party plaintiff. The total cost of any such infringement action commenced solely by Ovamed shall be borne by Ovamed and Ovamed shall keep any recovery or damages for infringement or otherwise derived therefrom and such shall not be applicable to any royalty obligation of the Company.

**8.7** In any suit to enforce and/or defend the Patent Rights pursuant to this Agreement, the party not in control of such suit shall, at the request and expense of the controlling party, cooperate in all respects and, to the extent possible, have its employees testify when requested and make available relevant records, papers, information, samples, specimens, and the like.

**8.8** If the Company, its Affiliate or Company Sublicensee elects to commence an action as described above, the Company may reduce, by up to [\*\*\*\*\*] percent ([\*\*\*\*\*]%), the royalty due to Ovamed earned under the patent subject to suit by [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the amount of the expenses and costs of such action, including attorney fees. In the event that such [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of such expenses and costs exceed the amount of royalties withheld by the Company for any calendar year, the Company may to that extent reduce the royalties due to Ovamed from the Company in succeeding calendar years, but never by more than [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the royalty due in any one year.

#### **ARTICLE 9 – TERMINATION OF AGREEMENT**

**9.1** Upon any termination of this Agreement, and except as provided herein to the contrary, all rights and obligations of the Parties hereunder shall cease, except as follows:

- (a) Ovamed's right to receive or recover and the Company's obligation to pay royalties accrued or accruable for payment at the time of any termination;
- (b) Ovamed's obligation to maintain records and the Company's right to conduct a final audit as provided in Article 5 of this Agreement; and
- (c) Any cause of action or claim of by either party, accrued or to accrue because of any breach or default by the Company.

**9.2** In the event the Company fails to make payments due hereunder which is not subject to a bona fide good faith dispute, Ovamed shall provide the Company with [\*\*\*\*\*] days written notice of such failure. The Company shall then have [\*\*\*\*\*] days from the date of such written notice in which to make the payment due. If payments are not so made within the time limit, Ovamed may immediately terminate this Agreement by written notice.

**9.3** In the event that the Company shall be in default in the performance of any material obligations under this Agreement (other than as provided in 9.2 above which shall take precedence over any other default), and if the default has not been remedied within [\*\*\*\*\*] days after the date of notice in writing of such default, Ovamed may terminate this Agreement immediately by written notice.

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**9.4** If the Company shall become bankrupt, or shall file a petition in bankruptcy and such petition is not dismissed within [\*\*\*\*\*] days after it has been filed, or if the business of the Company shall be placed in the hands of a receiver, assignee or trustee for the benefit of creditors, whether by the voluntary act of the Company or otherwise, this Agreement shall automatically terminate.

**9.5** In the event that this Agreement is terminated due to the Company's breach, Company Sublicensee shall have at least [\*\*\*\*\*] days in which to bring this Agreement back into good standing. Should the nature of the activity associated with bringing this Agreement back into good standing reasonably require more than [\*\*\*\*\*] days, then Ovamed shall grant Company Sublicensee additional time in which to bring this Agreement back into good standing.

**9.6** The Company shall have the right to terminate this Agreement by giving thirty (30) days advance written notice to Ovamed to that effect. Upon termination, a final report shall be submitted and any royalty payments and unreimbursed patent expenses due to Ovamed become immediately payable.

**9.7** The Company shall have the right during a period of six (6) months following the effective date of such termination to sell or otherwise dispose of the Licensed Product existing at the time of such termination, and shall make a final report and payment of all royalties related thereto within sixty (60) days following the end of such period or the date of the final disposition of such inventory, whichever first occurs,

**9.8** Upon termination of this Agreement for any reason, nothing herein shall be construed to release either party from any obligation that matured prior to the effective date of such termination or obligations under Articles 4, 5, 12 and 16, for the exception of obligations under Articles 4.1.1 and 4.1.2. Ovamed hereby acknowledges and agrees that, should the Company terminate this Agreement within [\*\*\*\*\*] days after The pre-IND Meeting, then the Company shall have no obligation to pay any amounts pursuant to Articles 4.1.1 and 4.1.2. The Company and/or any Company Sublicensee thereof may, however, after the effective date of such termination and continuing for a period not to exceed [\*\*\*\*\*] months thereafter, sell all completed Licensed Products, and any Licensed Products in the process of manufacture at the time of such termination, and sell the same, provided that the Company shall pay or cause to be paid to Ovamed the royalties thereon as required by Article 4 of this Agreement and shall submit the reports required by Article 5 hereof on the sales of Licensed Products.

**9.9** If not terminated sooner, this Agreement shall terminate on the date of the last to expire valid claim contained in the Patent Rights in accordance with Section 2.1.

**9.10** Force Majeure: Neither party is responsible for delays resulting from causes beyond its reasonable control, including without limitation fire, explosion, flood, war, strike, or riot, provided that the non-performing party uses commercially reasonable efforts to avoid or remove those causes of nonperformance and continues performance under this Agreement with reasonable dispatch whenever the causes are removed.



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## **ARTICLE 10 – ASSIGNMENT**

**10.1** This Agreement and the rights and duties appertaining hereto may not be assigned by either party without first obtaining the written consent of the other which consent shall not be unreasonably withheld. Any such purported assignment, without the written consent of the other party, shall be null and of no effect. Notwithstanding the foregoing, the Company may assign this Agreement without the consent of Ovamed (i) to a purchaser, merging or consolidating corporation, or acquirer of substantially all of the Company's assets or business and/or pursuant to any reorganization qualifying under section 368 of the Internal Revenue Code of 1986 as amended, as may be in effect at such time, or (ii) to an Affiliate.

## **ARTICLE 11 – LIMITATION OF LIABILITY, INDEMNITY**

EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, OVAMED MAKES NO REPRESENTATIONS AND EXTENDS NO WARRANTIES OF ANY KIND, EITHER EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, WARRANTY OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND VALIDITY OF PATENTED RIGHTS CLAIMS, ISSUED OR PENDING.

## **ARTICLE 12 – INDEMNIFICATION & INSURANCE**

**12.1** The Company agrees to defend, indemnify and hold Ovamed harmless from and against all liability, demands, damages, including without limitation, expenses or losses including death, personal injury, illness or property damage arising directly or indirectly: (a) out of use by the Company or its transferees of inventions licensed or information furnished under this Agreement or (b) out of any use, sale or other disposition by the Company or its transferees of Patent Rights, Licensed Products or Licensed Processes, in each case which are not the result of Licensor's breach of any representation or warranty, negligence or willful misconduct.

**12.2** Beginning at the time as any such product, process or service is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by the Company its Affiliate, or a Company Sublicensee, the Company shall, at its sole cost and expense procure and maintain comprehensive general liability insurance in amounts not less than \$[\*\*\*\*\*] per incident and \$[\*\*\*\*\*] annual aggregate and naming UIRF as an additional insured. During clinical trials of any such product, process or service the Company shall, at its sole cost and expense, procure and maintain comprehensive general liability insurance in such equal or lesser amounts as required by the License Agreement, naming UIRF as an additional insured. Such comprehensive general liability insurance shall provide (i) product liability coverage and (ii) liability coverage consistent with the Company's indemnification obligations under this Agreement. If the Company elects to self-insure all or part of the limits described above (including deductibles or retentions which are in excess of \$[\*\*\*\*\*] annual aggregate) such self-insurance program must be acceptable to UIRF. The minimum amounts of insurance coverage required shall not be construed to create a limit of the Company's liability with respect to its indemnification under this Agreement.

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**12.3** The Company shall provide Ovamed and/or UIRF (at the Company's option) with written evidence of such insurance upon request of Ovamed. The Company shall provide Ovamed and/or UIRF (at the Company's option) with written notice at least [\*\*\*\*\*] days prior to the cancellation, non-renewal or material change in such insurance; if the Company does not obtain replacement insurance providing comparable coverage within such [\*\*\*\*\*] day period, the Company shall have the right to terminate this Agreement effective at the end of such [\*\*\*\*\*] day period upon written notice.

**12.4** The Company shall maintain such comprehensive general liability insurance beyond the expiration or termination of this Agreement during (i) the period that any product, process, or service, relating to, or developed pursuant to, this Agreement is being commercially distributed or sold by the Company, its Affiliate or a Company Sublicensee, and (ii) a reasonable period after the period referred to in (i) above which in no event shall be less than [\*\*\*\*\*].

### **ARTICLE 13 – PAYMENT OF FEES AND EXPENSES**

Each of the Company and Ovamed shall be responsible for their own expenses relating to the preparation and consummation of this Agreement and the agreements and transactions contemplated hereby.

### **ARTICLE 14 – USE OF NAMES AND PUBLICATION**

**14.1** Nothing contained in this Agreement shall be construed as granting any right to the Company or its Affiliates to use in advertising, publicity, or other promotional activities any name, trade name, trademark, or other designation of Ovamed or any of its units (including contraction, abbreviation or simulation of any of the foregoing) without the prior, written consent of Ovamed; provided, however, that Ovamed acknowledges and agrees that the Company may use the name of Ovamed in various documents used by the Company for capital raising and financing without such prior written consent and where the use of such names may be required by law.

**14.2** Nothing herein shall be deemed to establish a relationship of principal and agent between Ovamed and the Company, nor any of their agents or employees for any purpose whatsoever.

**14.3** In the event that Ovamed desires to publish or disclose, by written, oral or other presentation, Patent Rights, Know-how, or any material information related thereto then Ovamed shall notify the Company and in writing by facsimile where confirmed by the receiving party, and/or by certified or registered mail (return receipt requested) of their intention at least [\*\*\*\*\*] days prior to any speech, lecture or other oral presentation and at least [\*\*\*\*\*] days before any written or other publication or disclosure. Ovamed shall include with such notice a description of any proposed oral presentation or, in any proposed written or other disclosure, a current draft of such proposed disclosure or abstract. The Company may request that Ovamed, no later than [\*\*\*\*\*] days following the receipt of such notice, delay such presentation, publication or disclosure for up to an additional [\*\*\*\*\*] days in order to enable the Company

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to file, or have filed on their behalf, a patent application, copyright or other appropriate form of intellectual property protection related to the information to be disclosed or request that Ovamed do so. Upon receipt of such request to delay such presentation, publication or disclosure, Ovamed shall arrange for a delay of such presentation, publication or disclosure until such time as the Company or Ovamed have filed, or had filed on its behalf, such patent application, copyright or other appropriate form of intellectual property protection in form and in substance reasonably satisfactory to the Company and Ovamed. If Ovamed does not receive any request from the Company to delay such presentation, publication or disclosure, Ovamed may submit such material for presentation, publication or other form of disclosure.

#### **ARTICLE 15 – PAYMENTS, NOTICES AND OTHER COMMUNICATIONS**

Any payment, notice or other communication required or permitted to be given pursuant to this Agreement shall be in writing and sent by certified first class mail, postage prepaid, by hand delivery or by facsimile if confirmed in writing, in each case effective upon receipt, at the addresses below or as otherwise designated by written notice given to the other party:

In the case of Ovamed:  
Ovamed GbmH & Co KG  
Attention: Mr. Detlev Goj, General Manager  
Kiebitzhörn 33-35, 22885  
Barsbüttel, Germany  
Tel: 49-40-67105710

In the case of the Company:  
Collingwood Pharmaceuticals, Inc.  
787 Seventh Avenue, 48<sup>th</sup> Floor  
New York, NY 10036  
Attn: President  
Tel: (212) 554-4300  
Fax: (212) 554-4490

#### **16. CONFIDENTIALITY**

**16.1** Any proprietary or confidential information exchanged under this agreement (including, but not limited to, information relating to the Patent Rights and royalty reports submitted pursuant to Article 5) constitute the “Confidential Information.” The Company and Ovamed agree that they will not use the Confidential Information for any purpose unrelated to this Agreement, and will hold it in confidence during the term of this Agreement and for a period of [\*\*\*\*\*] years after the termination or expiration date of this Agreement. The parties shall exercise with respect to such the Confidential Information the same degree of care as the parties exercise with respect to their own confidential or proprietary information of a similar nature, and shall not disclose it or permit its disclosure to any third party (except to those of its employees, consultants, or agents who are bound by the same obligation of confidentiality as the parties bound by pursuant to this Agreement). However, such undertaking of confidentiality by the parties shall not apply to any information or data which:

16.1.1 The receiving party receives at any time from a third-party lawfully in possession of same and having the right to disclose same;

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16.1.2 Is, as of the date of this Agreement, in the public domain, or subsequently enters the public domain through no fault of the receiving party;

16.1.3 Is independently developed by the receiving party as demonstrated by written evidence without reference to information disclosed by the disclosing party;

16.1.4 Is disclosed pursuant to the prior written approval of the disclosing party; and

16.1.5 Is required to be disclosed pursuant to law or legal process (including, without limitation, to a governmental authority) provided, in the case of disclosure pursuant to legal process, reasonable notice of the impending disclosure is provided to the disclosing party and the disclosing party has agreed to such disclosure in writing or has exhausted its right to contest such disclosure.

#### **ARTICLE 17 – REPRESENTATIONS AND WARRANTIES**

##### **17.1** Ovamed represents and warrants that:

17.1.1 Ovamed has all right and interest in and to the Patent Rights and Know-how, including the exclusive right and interest thereto, free and clear of all liens, charges, encumbrances or other restrictions or limitations of any kind whatsoever.

17.1.2 There are no licenses, options, restrictions, liens, rights of third parties, disputes, royalty obligations, proceedings or claims relating to, affecting, or limiting Ovamed's rights or the rights of the Company under this Agreement, or which may lead to a claim of infringement or invalidity regarding, any part or all of the Patent Rights or Know-how or their use.

17.1.3 There is no claim, pending or threatened, of infringement, interference or invalidity regarding any part or all of the Patent Rights or Know-how or their use.

17.1.4 The patent applications and patents itemized on Exhibit A set forth all of the patents and patent applications relating to or useful for practicing the Technology in the Field of Use owned by or licensed by Ovamed on the Effective Date.

17.1.5 There are no inventors of Patent Rights other than those listed as inventors on Exhibit A.

17.1.6 The Patent Rights and Know-how were not supported in whole or part by funding or grants by any federal or state agency.

17.1.7 Ovamed has provided the Company with copies of all documents reflecting support or funding for all or part of the research leading to Patent Rights and Know-how, and has listed all such funding agencies on Exhibit B.

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## **ARTICLE 18 – MISCELLANEOUS PROVISIONS**

**18.1** This Agreement shall be construed, governed, interpreted and applied in accordance with the Republic of Germany, without regard to principles of conflicts of laws.

**18.2** The parties hereto acknowledge that this Agreement, including the Appendices and documents incorporated by reference, sets forth the entire agreement and understanding of the parties hereto as to the subject matter hereof, and shall not be subject to any change of modification except by the execution of a written instrument subscribed to by the parties hereto and shall supersede all previous communications, representations or understandings, either oral or written, between the parties relating to the subject matter hereof.

**18.3** The provisions of this Agreement are severable, and in the event that any provision of this Agreement shall be determined to be invalid or unenforceable under any controlling body of law, such invalidity or unenforceability shall not in any way affect the validity or enforceability of the remaining provisions hereof.

**18.4** The failure of either party to assert a right hereunder or to insist upon compliance with any term or condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. Any waiver of any rights or failure to act in a specific instance relates only to that instance and is not an agreement to waive any rights or fail to act in any other instance.

**18.5** The headings of the several articles are inserted for convenience of reference only and are not intended to be a part of or to affect the meaning or interpretation of this Agreement.

**18.6** This Agreement will not be binding upon the parties until it has been signed below on behalf of each party, in which event, it shall be effective as of the date recited on page one. As of the Effective Date, this Agreement is binding upon and inures to the benefit of the parties and their respective permitted successors and assigns.

**18.7** Each party hereto shall be excused from any breach of this Agreement which is proximately caused by governmental regulation, act of war, strike, act of God or other similar circumstance normally deemed outside the control of the parties.

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IN WITNESS WHEREOF, the parties hereto have executed this Agreement by proper persons thereunto duly authorized.

**Collingwood Pharmaceuticals, Inc.**

**OVAMED GbmH & Co KG**

By: /s/ J. Jay Lobell

By: /s/ Detlev Goj

Name: J. Jay Lobell

Name: Detlev Goj

Title: President

Title: Chief Executive Officer

Date: December 12, 2005

Date: December 12, 2005

Agreed as to Article 4.11:

**Paramount Biosciences, LLC**

By: /s/ Lindsay A. Rosenwald, M.D.

Name: Lindsay A. Rosenwald, M.D.

Title: Managing Member

Date: December 12, 2005

Acknowledged

**University of Iowa Research Foundation**

By: /s/ Pamela K. York

Name: Pamela K. York

Title: Executive Director

Date: December 12, 2005

*[EXECUTION PAGE TO THE EXCLUSIVE SUBLICENSE AGREEMENT DATED DECEMBER \_\_, 2005]*

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**Appendix A**

The following comprise PATENT RIGHTS:

United States Patent Number 6,764,838

United States Patent Application Numbers 09/362,598; 10/715,659; 10/779,249

Canada Patent Application Number 2,315,790

Japanese Patent Application Number 2000-526233

Australia Patent Number 740776

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**Appendix B**

National Institutes of Health / DHHS grant Identification Numbers [\*\*\*\*\*]

21.



**CONFIDENTIAL TREATMENT REQUESTED.  
INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN  
REQUESTED IS OMITTED AND MARKED WITH “[\*\*\*\*\*]” OR OTHERWISE  
CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS  
ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

MANUFACTURING AND SUPPLY AGREEMENT

by and among

COLLINGWOOD PHARMACEUTICALS, INC.,

and

OVAMED GMBH

March 29, 2006

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#### SCHEDULES AND EXHIBITS

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Exhibit C	Raw Materials Index
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## MANUFACTURING AND SUPPLY AGREEMENT

This Manufacturing and Supply Agreement (the "Agreement") is entered into this \_\_ day of December, 2005 (the "Effective Date"), by and between Collingwood Pharmaceuticals, Inc., a corporation organized and existing under the laws of Delaware and having a principal place of business at 787 Seventh Avenue, 48<sup>th</sup> Floor, New York, New York 10019 ("Collingwood"), and Ovamed GmbH, a corporation organized and existing under the laws of Germany and having a principal place of business at Kiebitzhörn 33-35, 22885 Barsbüttel, Germany ("Ovamed"). Collingwood and Ovamed may each be referred to herein individually as a "Party" and collectively as the "Parties."

### Recitals

A. Collingwood wishes to engage Ovamed to manufacture Products (as defined below) and supply them to Collingwood as an active pharmaceutical ingredient and drug product for preclinical, clinical and commercial use.

B. Ovamed desires to manufacture Products and supply them to Collingwood and Collingwood desires to purchase Products from Ovamed for such use as further described and in accordance with the terms and conditions of this Agreement.

C. Ovamed has obtained an exclusive license (the "License") from the University of Iowa Research Foundation ("UIRF") to practice certain patent rights in the United States, Canada, Japan, and Australia;

D. Collingwood and Ovamed have entered an Exclusive Sublicense Agreement (the "Sublicense"), under which Ovamed granted to Collingwood an exclusive right to practice the patent rights discussed in the License in connection with the prevention, treatment, cure or diagnosis of human diseases, with the exception of gastroenterology (*e.g.*, inflammatory bowel disease) and hepatology in Europe (the "Field of Use").

### Agreement

NOW THEREFORE, the parties agree as follows:

#### **1. DEFINITIONS**

Capitalized terms used but not defined in this Agreement have the meanings given to them as set forth below.

"Acceptance" has the meaning given to it in Section 3.2.1.

"Approved Subcontractor" means, at any time, any member of the Ovamed Group or other subcontractor engaged by Ovamed for the manufacture or supply of a principal component necessary for the manufacture of Product reasonably acceptable to Collingwood.

"Affiliate" of any person shall mean any general or limited partner of any such person that is a partnership, member of any such person that is a limited liability company or any person or entity that, directly or indirectly, through one or more intermediaries, controls, or is controlled by, or is under common control with, such person.

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“CGMP” means Current Good Manufacturing Practices, as defined in a regulation in 21 CFR § 210, 211, or 600 or, as applicable, the applicable European Agency for the Evaluation of Medicinal Products (“EMA”) Guidelines, or any other rules or regulations which may be applicable in any jurisdiction in which Ovamed manufactures the Product pursuant to this Agreement.

“Change Request” means a written request for a change to a Specification.

“Competing Party” means any third party manufacturing, developing, or commercializing a product approved or intended to be approved by a Regulatory Authority for use within the Field of Use which includes the use of TSO.

“Confidential Information” means all information relating to a Party, its business or prospects (including, without limitation, data, know-how, trade secrets, business plans), disclosed by such Party from time to time to the other Party in any manner, whether orally, visually or in tangible form (including, without limitation, documents, devices and computer readable media) and all copies thereof, created by either party.

“Developments” has the meaning given to it in Section 11.1.

“Disclosing Party” has the meaning given to it in Section 12.1.

“FDA” means the United States Food and Drug Administration.

“Field of Use” has the meaning given to it in the Recitals.

“IND Milestone Payments” has the meaning given to it in Section 7.2.

“Intellectual Property Rights” means patents, copyrights, design rights, trademarks, service marks, trade names, trade secrets, know-how, and other intellectual property rights of any kind and nature.

“Late Delivery Credit” has the meaning given to it in Section 3.3.

“Liabilities” means any liability, loss, damage, claim, cost or expense (including reasonable fees of attorneys and other professionals and court costs).

“License” has the meaning given to it in the Recitals.

“Minimum Batch Size” will be mutually agreed to by the parties in writing in the event of changes to the Product pursuant to Article 6 below. There will be no Minimum Batch Size prior to any such entered agreement.

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“Ovamed Competitor” means any direct competitor of Ovamed that (i) sells TSO and (ii) sells a product that directly competes with a product sold by Ovamed that constitutes [\*\*\*\*\*]% or more of Ovamed’s net revenues.

“Ovamed Group” means Ovamed and its Affiliates.

“Products” means initially TSO manufactured in accordance with the Specifications, or as otherwise mutually agreed by the Parties in the event changes are made to the Product pursuant to Article 6 below.

“Purchase Order” means a written purchase order submitted to Ovamed by Collingwood or one of its affiliates under this Agreement for delivery of Products; *provided* that any terms and conditions contained or incorporated by reference in any such purchase order that conflict with the terms and conditions of this Agreement or the attachments made a part hereof shall be of no force or effect whatsoever concerning the subject matter of this Agreement, and Ovamed’s failure to object thereto shall not be deemed a waiver of Ovamed’s rights hereunder.

“Receiving Party” has the meaning given to it in Section 12.1.

“Regulatory Approval” means with respect to a nation or multinational jurisdiction any approvals, licenses, registrations or authorizations necessary for the manufacture, marketing and sale of the Product in such nation or jurisdiction.

“Regulatory Authority” means any federal, state or foreign government authority.

“Regulatory Information” means the following information (or the equivalent in any relevant non-United States jurisdiction): IND Safety Reports & Follow-ups (21 CFR §312.32(c)&(d)), Post-marketing 15-day Alert Reports & Follow-ups (21 CFR §314.80(c)1), Periodic Adverse Drug Experience Reports (21 CFR §314.80(c)2), Field Alert Reports (21 CFR §314.81(b)(1)), Product Complaints (21 CFR §211.198), IND Annual Reports (21 CFR §312.33(b)) and Post-marketing Annual Reports (21 CFR §314.81(b)(2)(i),(iv)&(v)).

“Specifications” means the finished product specifications for the Products and testing standards and procedures to be employed in determining compliance therewith attached hereto as Exhibit A, as amended from time to time in accordance with this Agreement.

“Sublicense” has the meaning given to it in the Recitals.

“Term” has the meaning given to it in Section 8.1.

“Territory” means the entire world, to the extent Ovamed possesses a license to practice the Patent Rights (as defined in the Sublicense) in specific countries and/or territories in the world.

“Transfer Assistance” has the meaning given to it in Section 8.3.

“TSO” means *Trichuris suis ova*.

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“UIRF” has the meaning given to it in the Recitals.

“Unit” means approximately [\*\*\*\*\*], or such other final dose as approved by the relevant Regulatory Authority, on the basis that a treatment dose will require [\*\*\*\*\*] Units per year and maintenance dose will require [\*\*\*\*\*] Units per year.

“Withdrawal Notice Date” has the meaning given to it in Section 8.2.5.

## **2. MANUFACTURING AND SUPPLY AND PURCHASE.**

### **2.1 Manufacturing.**

Ovamed agrees to manufacture and supply, and Collingwood agrees to purchase, Product solely for non-clinical, clinical and commercial use in the Field of Use in the Territory, according to the terms of this Agreement. Ovamed also agrees to engage in development with Collingwood in connection with the Products as part of a Change Request pursuant to the terms and conditions as set forth in Section 6.1.1 of this Agreement.

### **2.2 Manufacturing Facilities.**

In addition to the existing manufacturing facility in Germany, Ovamed shall establish at least two (2) more manufacturing facilities located in the United States, which will be in compliance with CGMP and the first of which will be completed and operational upon [\*\*\*\*\*]. Ovamed will establish a second manufacturing facility located in the United States, which will be completed and operational prior to the [\*\*\*\*\*]. Upon the establishment of the United States manufacturing facilities and any others, and on each twelve-month anniversary thereof, Ovamed will provide to Collingwood written certification that all manufacturing facilities in the United States at which Product is manufactured are in compliance with CGMP and that all manufacturing facilities existing outside of the United States at which Product is manufactured are in compliance with the relevant regulations of such jurisdiction.

### **2.3 Third Party Manufacturers.**

Ovamed shall remain responsible for its obligations under this agreement notwithstanding any delegation hereunder.

### **2.4 Purchase Orders.**

All orders placed by Collingwood for the Products require a Purchase Order. Collingwood shall submit to Ovamed a [\*\*\*\*\*] month rolling supply forecast in writing and a firm Purchase Order for the purchase of any Products at least [\*\*\*\*\*] days prior to the specified delivery date in writing, and Ovamed shall accept such Purchase Order in writing, subject to the adherence of such Purchase Order to the terms and conditions of this Agreement. Each Purchase Order shall be signed by an employee of Collingwood and specify the quantity of Products ordered, the purchase price, the requested delivery date or dates, and delivery locations. Ovamed reserves the right to cancel, suspend, refuse or delay any orders if Collingwood fails to make any payment when due, and such failure continues after [\*\*\*\*\*] days notice of such non-payment

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from Ovamed. At the reasonable request of Ovamed, Collingwood will cooperate and submit to Ovamed any information required for Ovamed to obtain "accounts receivable insurance" from a bona fide third party carrier (such information will be restricted to information that is customarily required for such types of insurance).

## 2.5 Inspection and Notifications.

2.5.1 Inspections. During regular business hours and upon reasonable advance notice, Ovamed shall permit, and upon reasonable notice and coordination of schedules shall use reasonable efforts to cause each of its Approved Subcontractors to permit, Collingwood, its consultants and/or contractors reasonably acceptable to Ovamed (or if not reasonably acceptable to Ovamed, Ovamed will supply a list of appropriately qualified consultants acceptable to it for Collingwood to use) and government personnel (including without limitation personnel from the FDA, for whom advance notice is not required, or any other Regulatory Authority in the Territory) to inspect the facilities of Ovamed and each of its Approved Subcontractors and to review manufacturing activities related to the Products solely to the extent necessary for, and for the purpose of assessing Ovamed's regulatory and quality compliance with, CGMP and for the purpose of determining compliance with the Specifications; *provided that*, (i) Collingwood shall not be permitted to exercise its right of inspection under this Section more than [\*\*\*\*\*] times in any twelve month period (ii) such restriction on the number of inspections shall not apply to governmental inspections, (iii) each party conducting an inspection, other than governmental, shall execute with Ovamed a nondisclosure agreement containing a conventional penalty in case of breach not less than € [\*\*\*\*\*], reasonably acceptable to Ovamed with regard to all materials inspected. Ovamed shall permit, and use reasonable efforts, to cause each of its Approved Subcontractors to permit, Collingwood and government personnel, to review and make copies of all relevant documents related to the Products that might reasonably be requested for such purposes. The costs of Ovamed's reasonable expenses incurred in connection with such inspections, shall be borne by Collingwood.

2.5.2 Notification. Ovamed shall promptly provide Collingwood notice of all inspections of Ovamed's facilities by any Regulatory Authority reasonably related to Ovamed's performance hereunder or the subject matter of this Agreement, and each Party shall promptly provide the other Party with notice of all (A) written claims and allegations, and (B) claims and allegations made orally that reasonably appear to warrant investigation or response, in either case of which Ovamed or Collingwood is aware, that Ovamed is not complying with CGMP or with the relevant Specifications. The obligations of this Section apply equally to any such notices provided to Ovamed's Approved Subcontractors to Ovamed's knowledge.



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2.5.3 Records. Ovamed shall maintain all of its manufacturing and analytical records, all records of shipments of Products and all reasonable validation data relating to Products for a minimum of five (5) years from Product shipment. Collingwood shall maintain all of its sales, and analytical records, all records of shipments of Products and all reasonable validation data relating to Products for a minimum of two (2) years from Product shipment. Each Party agrees that, in response to any complaint, or in the defense by the other Party of any litigation, hearing, regulatory proceeding or investigation relating to any Products, it shall make available to the other Party, at the other Party's cost and expense, such employees and records reasonably necessary to permit the effective response to, defense of, or investigation of such matters, subject to appropriate confidentiality protections and such records shall be deemed Confidential Information of the disclosing party hereunder.

2.6 Semi-Annual Relationship Review.

The Parties will meet or speak by telephone during the last month of each semi-annual period following the Effective Date and at such other times as mutually agreed upon by the parties, to review their relationship and performance under this Agreement, including but not limited to, review of the Specifications. This review will not give rise to any amendment to the Agreement other than pursuant to Section 13.8 hereunder.

2.7 Documentation. Ovamed will supply all reasonable documentation related to the Products to support Collingwood's effort to obtain and maintain Regulatory Approval for the Sale of Products that is required to comply with guidance documents and regulations of Regulatory Authorities that is relevant to biological agents for human use (the "Documentation"). To the extent that the Documentation required to be supplied by Ovamed under this Section is documentation, or is substantially the same as documentation, that Ovamed has, at the time, in its possession, then Ovamed shall supply such Documentation without any additional charge to Collingwood; otherwise, Collingwood shall pay to Ovamed an amount equal to Ovamed's fully burdened costs, including, but not limited to, overhead, incurred in performing the work required to prepare such Documentation.

**3. DELIVERY, ACCEPTANCE, REJECTIONS.**

3.1 Delivery.

3.1.1 Delivery. Ovamed shall deliver all Products ordered under this Agreement corresponding to the quantities, delivery dates and delivery locations set forth in each Purchase Order provided to Ovamed pursuant to and in accordance with Section 2.3. All Products shipped pursuant to the terms of this Agreement shall be manufactured not more than [\*\*\*\*\*] months preceding the shipment date, labeled and packed for shipment in accordance with the Specifications set forth on Exhibit A, and shall be marked for shipment to the designated location specified in the Purchase Order. All deliveries of Products will be to the designated location specified in the Purchase Order. Ovamed will have no further responsibility for Products after, and all risk of damage to or loss or delay of Products will pass to Collingwood upon, delivery by Ovamed to the designated carrier. The prices of the Products include all palletizing, packing, crating and storage charges at Ovamed facility, other than as set forth in Section

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3.1.2 below. Collingwood will pay for all freight, insurance and other shipping expenses incurred during shipment to the designated location and Ovamed shall be responsible for clearing the Product for import, export and for other customs matters. Both parties (Ovamed and Collingwood) shall consult with each other in advance of each shipment and shall cooperate with each other to permit Ovamed to make suitable shipping, insurance, customs and related arrangements. Ovamed shall obtain all appropriate approvals and consents of any governmental authority in the United States or other relevant jurisdictions, as applicable, necessary for the manufacture (including packaging), and exportation from the place of manufacture of the Products to Collingwood and Ovamed shall comply with all applicable laws and regulations pertaining thereto.

3.1.2 Except to the extent resulting from Ovamed's failure to comply with its obligations under this Agreement, Collingwood will bear the actual and reasonable costs (including storage) resulting from Collingwood's failure to receive Products at scheduled times.

### 3.2 Acceptance and Rejection.

3.2.1 Acceptance. Ovamed will provide Collingwood with a certificate of analysis for each invoiced Product substantially in the form of Exhibit D. Each shipment of Product will be deemed accepted by 5:00 p.m. EST on the [\*\*\*\*\*] day after receipt by Collingwood unless Collingwood notifies Ovamed prior to such time that the shipment (i) contains any discrepancy between the actual quantity of Product supplied and the quantity of Product quoted in the supply documents delivered with the applicable Products, (ii) is incorrectly invoiced, or (iii) does not contain a certificate of analysis showing conformity of the Product with the Specifications. The shipment will be deemed rejected upon delivery of such notice by Collingwood; provided, however, if the original shipment of the Product is found to be conforming, then Collingwood shall pay to Ovamed any due amount plus interest in the amount of [8]% per year of the unpaid amount. Each shipment of Product(s) accepted by Collingwood under this Agreement will be subject to inspection and performance testing by Collingwood within a period of [\*\*\*\*\*] days after receipt of a particular shipment of Product(s) (as applicable, the "Inspection Period") to determine whether the Product(s) in such shipment complied at the time of delivery to the carrier at Ovamed's facilities with the Specifications and any applicable warranties under this Agreement. Collingwood shall promptly, but in no event more than [\*\*\*\*\*] days after the Inspection Period (the "Notice Period"), notify Ovamed if any particular shipment did not so comply with the Specifications or applicable warranties at the time of delivery to the carrier. Upon request by Collingwood, during the Inspection Period, Ovamed will promptly provide copies of completed batch records (including deviations and corrective actions), and Collingwood shall pay for the actual costs of copying and sending such batch records on a cost basis. If Collingwood and Ovamed reasonably determine that the Product(s) did not comply with the Specifications or the applicable warranties under this Agreement at the time of delivery to the carrier, Collingwood shall promptly notify Ovamed

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of such non-compliance, but in no event more than the later of (x) [\*\*\*\*\*] days after Collingwood's receipt of all such completed batch records or (y) the expiration of the Notice Period. If the Parties are unable to agree on whether such non-compliance has occurred within [\*\*\*\*\*] days, then the Parties shall promptly engage a third party testing laboratory, mutually agreed upon and that shall enter into a confidentiality Agreement with Ovamed and Collingwood, to determine whether such non-compliance has occurred prior to the delivery of Product(s) to the carrier. The costs of such third party testing laboratory shall be borne by Collingwood, unless such third party testing laboratory determines that the particular shipment of Product was non-compliant at Ovamed's facilities at the time of delivery to the carrier, in which case such costs shall be borne by Ovamed. If Collingwood does not deliver written notice to Ovamed during the Notice Period that Collingwood rejects such shipment because of a non-compliance at the time of delivery to the carrier at Ovamed's facilities, Collingwood will be deemed to have accepted the shipment, subject to any right it may have under law or this Agreement.

**3.2.2 Replacement; Expenses.** If a Product shipment is rejected by Collingwood under Section 3.2.1(iii) or because such shipment did not comply at the time of delivery to the carrier with the Specifications and any applicable warranties under this Agreement as set forth in Section 3.2.1 above (subject to the dispute resolution procedure set forth therein), then Collingwood may, at its discretion, either (i) obtain a credit or refund, in [\*\*\*\*\*]'s sole discretion, for the amount paid by Collingwood for the non-conforming Product or (ii) require Ovamed to correct or replace, in [\*\*\*\*\*]'s sole discretion, the non-conforming Product so that it complies. If Collingwood requests, Ovamed agrees to correct or replace any such Product as soon as is practicable but no later than [\*\*\*\*\*] days after Collingwood's request for such correction, and will bear all reasonable expenses of making such corrections. If Ovamed is unable to so correct or replace the Product within such [\*\*\*\*\*] day period, it will so notify Collingwood no later than [\*\*\*\*\*] days after the end of such [\*\*\*\*\*] day period, whereupon Collingwood will have the option, at its sole discretion, to (x) require Ovamed to credit Collingwood for the amount paid by Collingwood for such Product or (y) require Ovamed to use all commercially reasonable efforts to promptly replace the Product at Ovamed's expense. Upon Ovamed's request and at Ovamed's expense Collingwood shall return or dispose of the non-conforming Products. Without limiting the foregoing, Ovamed will reimburse or credit Collingwood for any costs or expenses paid by Collingwood at the instructions of Ovamed or as required by relevant regulations related to the return, repair or destruction of the non-conforming Product(s). Notwithstanding the foregoing, if the original shipment of Product is found to be conforming, then Collingwood shall pay for the replacement shipment in accordance with the terms of this Agreement plus interest as applicable to late payment. Any credit or refund due under this Section will bear interest, which shall accrue at an annual percentage rate equal to the lesser of [\*\*\*\*\*] percent ([\*\*\*\*\*]%) per month or the maximum rate allowable by law at the date of such credit or refund is due until such refund is paid or such credit is used.

3.3 Late Delivery Credit.

3.3.1 Credit. Subject to a Force Majeure Event, if Ovamed fails to deliver any Products within [\*\*\*\*\*] days after the delivery date specified in an accepted Purchase Order to the designated location specified in the Purchase Order, Ovamed will give Collingwood a credit to be applied to the purchase price owed for such Product(s) (a "Late Delivery Credit"); provided, that (a) such credit shall be applied to future payments due by Collingwood under this Agreement, if any; and (b) except as set forth in Section 8.2.1 and 8.2.2, such Late Delivery Credit shall be Collingwood's sole and exclusive remedy for any such delay. The amount of the Late Delivery Credit will vary based on the number of days a delivery follows the date specified in the accepted Purchase Order, and will equal the following percentage of the purchase price for the Product(s) that is delivered late:

<u>Number of Days Late</u>	<u>Late Delivery Credit</u>
[*****]	[*****]% of the purchase price for late Product
[*****]	[*****]% of the purchase price for late Product
[*****]	[*****]% of the purchase price for late Product

Collingwood may apply the Late Delivery Credit to reduce the amount due to Ovamed under the invoice for late-delivered Product. In the event that Ovamed knows that any Product being shipped to Collingwood will be delivered more than [\*\*\*\*\*] after the delivery date specified in the accepted Purchase Order for such Product due to reasons that are within Ovamed's control, Ovamed will note the Late Delivery Credit that applies to that Purchase Order in the invoice for that Purchase Order.

**4. RECALLS, ADVERSE EVENT REPORTING, COMPLAINTS; REGULATORY.**

4.1 Recalls.

4.1.1 Recalls of Product. Collingwood shall promptly notify Ovamed of any recall, product withdrawal, or field correction to the Product, and provide copies of all press releases related to such action, whether or not effected voluntarily or requested or ordered by any federal or state agency or government agency. Ovamed may recommend a recall, product withdrawal or field correction, however, subject to Ovamed's obligation to adhere to all applicable laws and regulations, the decision to conduct such an activity shall be Collingwood's alone. Ovamed shall reasonably cooperate with Collingwood as necessary to effectuate any such recall, withdrawal or correction, at Collingwood's sole cost and expense. Subject to applicable law, regulation or Regulatory Authority request, Collingwood or its designee shall make all contacts with the FDA and any other regulatory agencies, shall be responsible for coordinating all of the necessary activities in connection with such recall, product withdrawal, or field correction and shall make any statements to the media,

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including, but not limited to, press releases and interviews for publication or broadcast related to such recall, product withdrawal, or field correction; *provided* that, Collingwood will provide Ovamed written notice concurrently or as soon as practicable after Collingwood makes any statement to the FDA, regulatory agency, media and/or to the public related to a recall, product withdrawal, or field correction that specifically refers to Ovamed or is reasonably related to any of the Products, which sets forth such statement. Ovamed will reasonably cooperate with Collingwood in the conduct of such activities. Collingwood shall keep Ovamed fully informed of progress and shall consult with Ovamed in relation to all material decisions or actions as may reasonably relate to a recall, product withdrawal, or field correction of the Products.

4.1.2 Recall Expense. Ovamed shall bear the full expense of both Parties incurred in any recall, withdrawal or correction of the Product resulting from (i) failure of any Product to meet the Specifications at the time of delivery of such Product by Ovamed to the carrier, or (ii) Ovamed's failure to manufacture any Product in accordance with CGMP and all other applicable laws, and Collingwood shall bear the full expense of both Parties incurred in any other recall, withdrawal or correction of the Product. Any dispute between the Parties as to which Party is responsible for a defect will be made by an independent arbitrator, mutually satisfactory to the Parties, and having sufficient scientific and manufacturing skills necessary to adjudicate upon the matter in dispute. The costs of such arbitrator will be borne by the Party against whom the arbitrator rules. Such expenses of recall shall include, without limitation, the expenses of notification and destruction or return of the recalled Product and the sum paid by a third party for the recalled Product. In the event, however, that a recall is partially caused by reasons as set forth in subsections (i) and/or (ii) of this Section 4.1.2 and partially for other reasons, then each Party shall be responsible for its proportionate share of the recall expenses based on its proportionate share of causation.

#### 4.2 Adverse Experience Reporting.

Each Party shall cooperate with the other Party and provide all assistance reasonably requested by the other Party for the other Party to respond in a timely fashion to Regulatory Authorities in the event of product complaints, Field Alert Reports, SUSARs, or Adverse Event reports which require submission to Regulatory Authorities as expedited reports, e.g., 15-day Alert Reports or in other regulatory submissions including but not limited to IND Annual Reports and NDA/BLA Annual Reports or Periodic Safety User reports, each as defined by the applicable Section of the U.S. Code of Federal Regulations, in accordance with current FDA and any other applicable guidance and regulations, including without limitation providing to the other Party all Regulatory Information in its possession reasonably required for FDA compliance. Each Party may use such information to meet its respective legal and regulatory obligations. The capitalized terms used in this Section but not defined in this Agreement shall have the customary meaning under current FDA and European Union guidance and regulations.

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#### 4.3 Complaints.

Unless otherwise required by law, Collingwood shall have sole responsibility and authority to respond to any customer or other complaints with respect to the Products or other aspects of the Product; provided, however, Collingwood will provide Ovamed written notice concurrently with or as soon as practicable after Collingwood makes any statement to such complaining party, the FDA, regulatory agency, media and/or to the public in response to any complaint that may be reasonably related to the Products that specifically refers to Ovamed or any of the Products, which sets forth such statement. Except as otherwise provided herein, Ovamed will not be liable or made responsible for any act or cost incurred or committed by Collingwood in connection with any action taken by Collingwood under this Section. Each Party shall promptly advise the other Party of all relevant details if it receives any complaints pertaining to the Product. Collingwood shall promptly advise Ovamed of all relevant details if it receives any significant complaints pertaining to the Product (except that any complaints pertaining to the Product that require a report to a Regulatory Authority shall be deemed to be significant), and Ovamed shall promptly advise Collingwood of all relevant details if it receives any significant complaints pertaining to the Product (except that any complaints pertaining to the Product that require a report to a Regulatory Authority shall be deemed to be significant). Subject to the foregoing, Ovamed shall provide reasonable cooperation and assistance to Collingwood in responding to complaints with respect to the Products.

#### 4.4 Regulatory Approvals.

The Parties shall fully cooperate in good faith, and shall provide all reasonable assistance and information, in a timely manner, to each other, to obtain and maintain all Regulatory Approvals that are required to manufacture, distribute, use or sell the Products, including without limitation the preparation, filing and maintenance of any U.S. Biological License Application or European Marketing Authorization (or equivalent in other jurisdictions). If there are incremental regulatory filing fees that are applicable to the Products, Collingwood will bear such regulatory fees. The parties shall also reasonably assist each other in responding to requests and inquiries from applicable Regulatory Authorities prior to, during and after regulatory review periods, including without limitation, providing all data, records and reports required in order to comply with the regulatory Authority request.

### **5. QUALITY AND CAPACITY.**

#### 5.1 Ovamed Representations, Warranties and Covenants.

Ovamed hereby represents, warrants and covenants to Collingwood that the Products [\*\*\*\*\*]: (a) shall be manufactured in compliance with CGMP and all other applicable regulatory and governmental regulations, as applicable; (b) shall conform to the certificates of analysis supplied with each shipment pursuant to Section 5.2; and (c) shall be free and clear of any lien or encumbrance and Ovamed will have all rights necessary to transfer title to the Products to Collingwood. The foregoing warranty shall not apply to the extent that the Product has been subject to use or other conditions not in accordance with the applicable Specifications, or has otherwise been the subject of mishandling, misuse, neglect, alteration or damage by the carrier or Collingwood.

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## 5.2 Testing of Product for Conformance with Specifications.

Ovamed will test each batch of the Products supplied to Collingwood under this Agreement and provide Collingwood with a written certificate of analysis (in the form set forth in Exhibit D) along with each batch of Products that confirms that such Product meets the Specifications and warranties under this Agreement. Collingwood may retest each batch of Products and perform other performance measurements in accordance with Section 3.2.1 of this Agreement to confirm that such batch meets the applicable Specifications and warranties in accordance with this Agreement.

## **6. CHANGES IN SPECIFICATIONS OR MANUFACTURING PROCEDURES.**

### 6.1 Sponsored Changes.

6.1.1 Changes Sponsored by Collingwood. Collingwood shall notify Ovamed in writing of a Change Request proposed by Collingwood no less than 180 days prior to the proposed effective date for the Change Request. The notification shall include a description of the proposed changes, information regarding medical, clinical, and regulatory factors and the proposed implementation date. Notification shall also include the reasonably appropriate documentation to support Ovamed's investigation of the impact of this proposal. Ovamed may review the feasibility of the implementation and any other aspect of the proposed Change Request. Ovamed shall use commercially reasonable efforts to advise Collingwood of its decision with respect to the proposed Change Request as soon as practicable but in any case no later than within 120 days after receipt of Collingwood's written notification. No Change Request shall be made by Collingwood without Ovamed's prior written approval, which approval may be provided or withheld in Ovamed's reasonable discretion. Until a Change Request has been agreed to in writing by both Parties, the Change Request shall not be effective, and the Parties shall continue to perform their obligations under the then-effective Specifications. Any change that is in connection with the Minimum Batch Size and in connection with a mandatory change resulting from a Regulatory Authority communication, shall not be considered a Change Request sponsored by Collingwood.

6.1.2 Changes Sponsored by Ovamed. Ovamed shall notify Collingwood in writing of a Change Request proposed by Ovamed no less than 180 days prior to the proposed effective date for the Change Request. If so proposed, Ovamed will provide Collingwood with samples of Product that incorporates or is a result of the Change Request. The notification shall include a description of the proposed changes, information regarding medical, clinical, and regulatory factors and the proposed implementation date. Notification shall also include the reasonably appropriate documentation to support Collingwood's investigation of the impact of this proposal. Collingwood may review the feasibility of the implementation and any other aspect of the proposed Change Request. Collingwood shall use commercially reasonable efforts to advise Ovamed of its decision with respect to the proposed Change Request as soon as

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practicable but in any case no later than within 120 days after receipt of Ovamed's written notification. No Change Request shall be made by Ovamed without Collingwood's prior written approval, which approval may be provided or withheld in Collingwood's reasonable discretion. Until a Change Request has been agreed to in writing, the Change Request shall not be effective, and the Parties shall continue to perform their obligations under the then-effective Specifications. Any change that is in connection with the Minimum Batch Size and in connection with a mandatory change resulting from a Regulatory Authority communication, shall not be considered a Change Request sponsored by Ovamed.

6.1.3 FDA Agreement. To the extent that a Change Request accepted or proposed by Collingwood will require any filing with any Regulatory Authority or the granting of any Regulatory Approval for the Product, each Party shall reasonably cooperate with each other and take all reasonable actions and provide all information as may be reasonably requested by Collingwood or Ovamed in connection with preparing such filings and obtaining such Regulatory Approval. Costs incurred by Ovamed in connection with the above will be subject to the terms of Sections 6.1.1 and 6.1.2 above. Without limiting any other provision of this Article 6, Ovamed will not change any aspect of the Product or the process by which the Product is manufactured that requires the FDA approval if the FDA does not provide written confirmation, prior to making the change, that the change will not terminate or otherwise impair any Regulatory Approval for the Product. Collingwood will support and assist Ovamed in any communications with the FDA that may be required as described above in order to achieve such FDA confirmation.

6.2 Impact on Inventory.

Any agreed modification following a Change Request shall only take effect once all Product manufactured pursuant to the previous Specifications and already scheduled for delivery has been delivered under the terms of this Agreement.

**7. PAYMENT.**

7.1 Price.

In consideration of Ovamed's manufacture and supply of Products hereunder, Collingwood shall pay to Ovamed an amount equal to the total number of Units delivered in each calendar quarter (the "Actual Amount") multiplied by the corresponding Price (per Unit), as defined in the following sentence, minus any Late Delivery Credit owed to Collingwood under Section 3.3 of this Agreement (the "Interim Amount"). On the Effective Date of this Agreement, the "Price" shall be \$[\*\*\*\*\*] per Unit for clinical supplies and \$[\*\*\*\*\*] per Unit for commercial supplies. During the Term, Ovamed will use commercially reasonable efforts to decrease the cost of goods sold to Collingwood (as determined in accordance with generally accepted accounting principles, consistently applied). Ovamed will promptly notify Collingwood of any such decreases and the Price shall be decreased by [\*\*\*\*\*]% of any such decrease in cost of goods sold. In case the FDA or other official Regulatory Authority mandates that more than [\*\*\*\*\*] Units



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to be dosed to the patient Collingwood shall not be required to pay an amount greater than: (i) [\*\*\*\*\*] Dollars (\$[\*\*\*\*\*]) per patient per year for total commercial supplies of Units in the first year in which Units are administered to a patient; and (ii) [\*\*\*\*\*] Dollars (\$[\*\*\*\*\*]) per patient per year for total commercial supplies of Units in any subsequent year following the first year in which Units are administered to a patient.

7.2 Milestone Credit.

So long as Collingwood makes the milestone payments to Ovamed which are set forth in Sections 4.3.1 and 4.3.2 of the Sublicense (the “IND Milestone Payments”), Ovamed will give Collingwood a credit, said credit not to exceed [\*\*\*\*\*] Dollars (\$[\*\*\*\*\*]), to be applied to the purchase price owed for any Units purchased for clinical supplies of Products up to the aggregate amount of the IND Milestone Payments. To the extent that the aggregate amount of IND Milestone Payments exceeds the aggregate purchase price of clinical supplies, any excess will be applied as a credit against the purchase price of any commercial supplies of Products.

7.3 Payment.

Ovamed will invoice Collingwood for Products upon delivery. Amounts owed under invoices shall be due and payable in U.S. currency within [\*\*\*\*\*] days after date of such invoice, subject to the offset described in Section 7.1. A late payment charge calculated from the date such payment was due at the [\*\*\*\*\*] or the highest interest rate allowed by applicable law shall be charged upon all unpaid amounts due hereunder. All payments due hereunder shall be made by wire transfer from a bank in the United States in immediately available funds to a bank designated by Ovamed, or such other bank upon prior written notice.

7.3 Overdue Amounts; Disputes.

Subject to Section 3.2.1, in the event that [\*\*\*\*\*] disputes in good faith any amount that Ovamed claims to be due under this Agreement [\*\*\*\*\*] may so notify Ovamed at the time such payment is made, and if any disputed amount is ultimately determined to not be due hereunder Ovamed will refund promptly [\*\*\*\*\*] or the highest rate allowable by law at the date of such decision.

**8. TERM AND TERMINATION.**

8.1 Term.

Unless terminated in accordance with Section 8.2, the term (the “Term”) of this Agreement shall commence on the Effective Date and shall continue until the fifth anniversary of the Effective Date, unless earlier terminated pursuant to the terms of this Agreement, provided that Collingwood may extend the Term for successive one (1) year periods by providing written notice of such extension to Ovamed not later than 12 months prior to the then expiration date of the Term.

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## 8.2 Termination.

8.2.1 Termination for Cause. Either Party may terminate this Agreement immediately without penalty or further obligation to the other, upon written notice to the other Party if (i) the other Party makes a general assignment for the benefit of creditors, or a receiver or similar officer is appointed to take charge of all or substantially all of the other Party's assets; (ii) the other Party ceases to carry on its business; (iii) a bankruptcy or similar petition is filed by the other Party or a final insolvency order is issued against the other Party, and in the case of an involuntary petition, the proceeding is not dismissed within 120 days; or (iv) the other Party is in material breach of any material representation, warranty, covenant or obligation under this Agreement, and such breach is not cured within 60 days of receiving written notice thereof. Without limiting the foregoing, Collingwood shall have the right to terminate this Agreement as provided in any of Sections 8.2.2 through 8.2.6. The Parties agree that a "material breach of a material obligation" includes but is not limited to any failure by Ovamed to deliver (x) at least [\*\*\*\*\*]% of the amount of Product in any particular order pursuant to Section 3.1 within [\*\*\*\*\*] days of the required delivery date, (y) [\*\*\*\*\*]% of the amount of Product in any particular order pursuant to Section 3.1 within [\*\*\*\*\*] days of the required delivery date or (z) certification reasonably satisfactory to Collingwood pursuant to Section 2.2.

8.2.2 Failure to Supply. The parties will agree about the quantity to be delivered in forecasts that will be determined by the parties each year. In the event that Ovamed fails (i) to satisfactorily supply at least [\*\*\*\*\*]% of the amount of Product in any particular order within [\*\*\*\*\*] days of the required delivery date or at least [\*\*\*\*\*]% of the amount of Product in any particular order within [\*\*\*\*\*] days of the required delivery date, (ii) to substantially perform its obligations in connection with United States or other relevant Regulatory Approval of the Products and such failure has continued for more than [\*\*\*\*\*] days, or such longer period as reasonably necessary to cure such failure or such period required by the relevant Regulatory Approval authority, or (iii) to have adequate operational manufacturing facilities such that it is unable to manufacture Product, or unable to manufacture product in accordance with Specifications, for a period of [\*\*\*\*\*] days or more ((i), (ii) and (iii) individually or collectively referred to herein as the "Manufacturing Failure"), and (x) Ovamed does not, at the time, have the right to terminate this Agreement under Section 8.2.1 and (y) Collingwood has not, at the time, developed a commercial second source (on commercially reasonable terms) for a product that can be substituted for the Product and that can meet the supply shortage resulting from Ovamed's failure to supply, then, upon notice of such failure from Collingwood, Collingwood may terminate this Agreement and receive a worldwide, royalty-free, perpetual, non-transferable (except as set forth in Section 13.3 below), non-exclusive, fully paid license, with the right to grant sublicenses for the sole purpose of manufacturing the Product on behalf of Collingwood (provided each such sublicensee signs a confidentiality agreement with Ovamed on terms consistent with the confidentiality obligations under this Agreement), under all intellectual property

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owned by Ovamed or for which Ovamed has the right to grant a license or sublicense pursuant to this Section and which is reasonably necessary or useful to manufacture and sell the Product in the Field of Use (the “Manufacturing IP”) (collectively, the “Manufacturing Failure License”), and such license shall be effective immediately upon notice of such election by Collingwood, and (b) Ovamed shall provide all assistance reasonably requested by Collingwood to assist Collingwood or a third party acting on behalf of Collingwood in the manufacturing of the Product in accordance with the Specifications, *provided however*, that Collingwood shall reimburse Ovamed for any reasonable expenses it incurs in relation to its rendering of such assistance; Notwithstanding anything to the contrary herein, if Ovamed delivers to Collingwood a remediation plan reasonably acceptable according to which full remediation of any Manufacturing Failure will be achieved within [\*\*\*\*\*] months from the first date of such Manufacturing Failure, then this Agreement shall remain in effect, *provided however*, that Collingwood shall have the right to use and have used all Manufacturing IP to manufacture or have manufactured Product during such period that Ovamed is engaged in such remediation. Such plan shall be delivered to Collingwood within 30 days after the failure occurred. Collingwood may terminate this Agreement immediately, without penalty or further obligation to Ovamed, if Ovamed fails to achieve remediation within such [\*\*\*\*\*] month period and Collingwood shall immediately be entitled to the Manufacturing Failure License.

8.2.3 Failure to Obtain Regulatory Approval for the Product. Collingwood may terminate this Agreement immediately, without penalty or further obligation to Ovamed, if Collingwood fails to obtain Regulatory Approval for the Product in the United States, provided that Collingwood will be obligated to: (i) purchase such quantity of Products that is already scheduled for delivery in the three (3) month period following the date Collingwood notifies Ovamed of such withdrawal requirement (“Withdrawal Notice Date”), and (ii) pay for costs actually incurred by Ovamed, as of the date of termination pursuant to this Section, in performing the work required under an Collingwood sponsored Change Request.

8.2.4 Early Failure in Clinical Trials. Collingwood may terminate this Agreement immediately, without penalty or further obligation to Ovamed, if the Product fails (i) preclinical pharmacology and toxicology studies or (ii) any clinical trial (or the results from a clinical trial are such that, in Collingwood’s good faith judgment, it would not be commercially reasonable to continue development of the Product) within 12 months of the Effective Date, provided however, that Collingwood will pay for costs actually incurred by Ovamed, as of the date of termination pursuant to this Section, in performing the work required under an Collingwood sponsored Change Request.

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8.2.5 Withdrawal from US or Other Market. In the event FDA or any other Regulatory Authority requires that the Product be withdrawn from the applicable market, or in the event that Collingwood at any time determines that it is not, or will not be, commercially feasible to market the Product in the United States or other relevant market, then Collingwood shall have the right, on each such occurrence, to terminate this Agreement immediately, without penalty or further obligation to Ovamed, provided however, that if such withdrawal arises as a result of a component other than the Product, Collingwood will be obligated to: (i) purchase such quantity of Products that is already scheduled for delivery in the three (3) month period following the date Collingwood notifies Ovamed of such withdrawal requirement (“Withdrawal Notice Date”), and (ii) pay for costs actually incurred by Ovamed, as of the date of termination pursuant to this Section, in performing the work required under an Collingwood sponsored Change Request.

8.2.6 Termination of Sublicense. This Agreement will terminate immediately upon the termination of the Sublicense.

### 8.3 Survival.

The Parties agree that any provisions which by their nature should survive termination or expiration of this Agreement to give effect to their intent, shall survive, including without limitation, Articles 4 (Recalls, Adverse Event Reporting, Complaints), 7 (Payment), 9 (Indemnification and Insurance), 10 (Liability), 11 (Intellectual Property), 12 (Confidential Information), and Sections 8.4 (Survival), 13.1 (Correspondence and Notices), 13.5 (Use of Name), 13.9 (Waiver), 13.10 (Severability), 13.12 (Governing Law), and 13.13 (Jurisdiction; Venue; Service of Process).

## 9. INDEMNIFICATION AND INSURANCE.

### 9.1 Ovamed Indemnification of Collingwood.

Ovamed will defend, indemnify, and hold Collingwood, its officers, directors, employees, and agents (each an “Indemnified Party”) harmless against any and all third party Liabilities to the extent arising from (i) any asserted infringement or other violation of any third party Intellectual Property Rights arising from Ovamed’s manufacture or supply to Collingwood of the Products under this Agreement; or (ii) any third party claim arising from personal injury caused by a defect in the manufacture or workmanship of the Product (including claims arising from the Products not meeting the Specifications at the time of delivery).

### 9.2 Collingwood Indemnification of Ovamed.

Collingwood will defend, indemnify, and hold Ovamed, its officers, directors, employees, and agents harmless (each an “Indemnified Party”) against any and all third party Liabilities to the extent arising from (i) any third party claim against Ovamed asserting infringement or other violation of any third party Intellectual Property Rights arising from the Product (but only to the extent the claim does not arise from the manufacture, use or sale of the Products); or (ii) any third party claim arising from a personal injury caused by a defect in the Product (but only to the extent the claim does not arise from the Products not meeting the Specifications at the time of delivery).

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### 9.3 Procedure.

Each Party will promptly notify the other Party in writing in the event it becomes aware of a claim for which indemnification may be sought hereunder. In case any proceeding (including any governmental investigation) shall be instituted involving any Party in respect of which indemnity may be sought pursuant to this Article 9, such Party will promptly notify the other Party (the "Indemnifying Party") in writing. The Indemnifying Party shall have sole control of any such claim. The Indemnified Party will reasonably cooperate with the Indemnifying Party in defense of such matter. In any such proceeding, the Indemnified Party will have the right to retain its own counsel, but the fees and expenses of such counsel shall be at the expense of the Indemnified Party. The Indemnifying Party shall not be liable for any settlement of any proceeding effected without its written consent, but, if settled with such consent or if there be a final judgment for the plaintiff, the Indemnifying Party agrees to pay any such settlement or final judgment. The Indemnifying Party shall not, without the written consent of the Indemnified Party, effect any settlement of any pending or threatened proceeding in respect of which the Indemnified Party is, or arising out of the same set of facts could have been, a party and indemnity could have been sought hereunder by the Indemnified Party, unless such settlement includes a release of the Indemnified Party from all liability on claims that are the subject matter of such proceeding.

### 9.4 Insurance.

Ovamed agrees to maintain during the Term and for three (3) years thereafter, at its own expense, insurance from a reputable and financially secure insurance company, providing \$[\*\*\*\*\*] of protection per any one occurrence and for the insurance period against Ovamed's legal liability deriving from claims, suits, losses and damages arising out of alleged defects in the Products. Collingwood will be named as an additional insured under such policy and Ovamed will provide, at Collingwood's request, a certificate of insurance evidencing its obligations hereunder. Such certificate shall provide Collingwood with thirty (30) days written notice of cancellation, modification or termination of such insurance. All such insurance policies will provide a worldwide coverage territory including suits brought within the United States, its territories and possessions.

Collingwood agrees to maintain during the Term and for three (3) years thereafter, at its own expense, insurance from a reputable and financially secure insurance company, providing at least \$[\*\*\*\*\*] of protection per any one occurrence and for the insurance period against Collingwood's legal liability deriving from claims, suits, losses and damages arising out of alleged defects in the Product. Ovamed will be named as an additional insured under such policy and Collingwood will provide, at Ovamed's request, a certificate of insurance evidencing its obligations hereunder. Such certificate shall provide Ovamed with thirty (30) days written notice of cancellation, modification or termination of such insurance. All such insurance policies will provide a worldwide coverage territory including suits brought within the United States, its territories and possessions.

Each Party hereby waives any claims against the other (whether founded upon the indemnification provisions contained in this Agreement or otherwise) to the extent any such claim is covered by such waiving Party's insurance carrier, and loss proceeds are paid to and

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received by such waiving Party, and provided such waiver (i) is not in violation of the policies of insurance under which such loss proceeds are so paid; (ii) does not invalidate such insurance and (iii) does not disproportionately increase the premiums thereof.

#### **10. LIABILITY.**

IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER FOR ANY INCIDENTAL, CONSEQUENTIAL, SPECIAL OR PUNITIVE DAMAGES OF ANY KIND OR NATURE ARISING OUT OF THIS AGREEMENT, WHETHER SUCH LIABILITY IS ASSERTED ON THE BASIS OF CONTRACT, TORT (INCLUDING THE POSSIBILITY OF NEGLIGENCE OR STRICT LIABILITY), OR OTHERWISE, EVEN IF THE PARTY HAS BEEN WARNED OF THE POSSIBILITY OF ANY SUCH LOSS OR DAMAGE, AND EVEN IF ANY OF THE LIMITED REMEDIES IN THIS AGREEMENT FAIL OF THEIR ESSENTIAL PURPOSE.

#### **11. INTELLECTUAL PROPERTY.**

11.1 Ownership of Intellectual Property. All Intellectual Property Rights developed or conceived by either party in connection with this Agreement (“Developments”) shall be owned by the party who invented such Development (where inventorship is defined based on concept of inventorship set forth by the patent laws of the United States). Ovamed has the worldwide, fully paid, perpetual exclusive right to fully exploit such Developments as required to perform its obligations under this Agreement. As long as Collingwood purchases products — fully paid - from Ovamed under this agreement, Collingwood has the worldwide, fully paid, perpetual license to fully utilize any Developments owned by Ovamed. Collingwood agrees to reasonably cooperate when requested by Ovamed, at Ovamed’s expense, in enforcing Ovamed’s Intellectual Property Rights embodied in the Developments, including without limitation prosecuting and maintaining patent applications and patents and being joined as a party to an action brought by Ovamed to enforce such rights. Ovamed agrees to reasonably cooperate when requested by Collingwood, at Collingwood’s expense, in enforcing Collingwood’s Intellectual Property Rights embodied in the Developments, including without limitation prosecuting and maintaining patent applications and patents and being joined as a party to an action brought by Collingwood to enforce such rights.

11.2 Cooperation. Each Party shall promptly notify the other Party of the development or conception of any subject matter arising under and in the performance of this Agreement prior to filing a patent application that discloses such subject matter. Notwithstanding the foregoing, the Parties acknowledge that the provisions of Article 12 will continue to apply to any proposed disclosure that includes Confidential Information of the other Party.

11.3 License of Ovamed Intellectual Property Rights. Subject to the terms and conditions of this Agreement, Ovamed hereby grants to Collingwood and its Affiliates a license under any Ovamed Intellectual Property Rights in order to sell the Product either by Collingwood directly or through third parties.

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## 12. CONFIDENTIAL INFORMATION.

### 12.1 Confidentiality.

Except to the extent expressly authorized by this Agreement or otherwise agreed in writing, the Parties agree that, for the term of this Agreement and for [\*\*\*\*\*] years thereafter, each Party (the "Receiving Party") receiving any Confidential Information of the other Party (the "Disclosing Party") hereunder will keep such Confidential Information confidential and will not publish or otherwise disclose or use such Confidential Information for any purpose other than as provided for in this Agreement, except for Confidential Information that the Receiving Party can establish:

- (a) was already known by the Receiving Party (other than under an obligation of confidentiality) at the time of disclosure by the Disclosing Party and the Receiving Party has documentary evidence to that effect;
- (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the Receiving Party;
- (c) became generally available to the public or otherwise part of the public domain after its disclosure or development, as the case may be, other than through any act or omission of the Receiving Party or any of its Affiliates;
- (d) was disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party who had no obligation to the Disclosing Party not to disclose such information to others; or
- (e) was independently discovered or developed by or on behalf of the Receiving Party without the use of any Confidential Information belonging to the Disclosing Party and the Receiving Party has documentary evidence to that effect.
- (f) is necessary to prepare and/or conduct litigation

### 12.2 Authorized Disclosure.

Notwithstanding the foregoing provisions of Section 12.1, each Party may disclose Confidential Information belonging to the other Party (i) to employees or Approved Subcontractors of the disclosing Party to the extent such disclosure is necessary for the disclosing Party to perform its obligations under this Agreement, or (ii) to the extent such disclosure is necessary, in the reasonable opinion of such Party's legal counsel, to prosecute or defend litigation or to comply with applicable governmental laws or regulations (including, but not limited to, securities laws and regulations), or (iii) to the extent such disclosure is necessary for any financing or corporate partnering activity of either parties provided that disclosure will be done under a signed CDA in a form substantially in accordance with the provisions of this

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clause. In the event a Party deems it necessary to disclose to a third party any Confidential Information belonging to the other Party, pursuant to this Section 12.2, the Disclosing Party will to the extent possible give reasonable advance notice of such disclosure to the other Party and take reasonable measures to ensure, including without limitation redacting portions of this Agreement prior to disclosure, as reasonably requested by the other Party, and ensuring that such third party is bound by and complies with the confidentiality terms of this Agreement.

12.3 No Confidential Information of Other Parties.

Each Party represents and warrants to the other that it has not used and will not use in the course of its performance hereunder, and will not disclose to the other, any confidential information of any third party, unless it is expressly authorized in writing by such third party to do so.

12.4 Equitable Relief.

Each Party agrees that the other Party would be irreparably injured by a material breach of the confidentiality and nonuse provisions of this Agreement by the breaching Party or by other parties to whom such Party has disclosed Confidential Information, that monetary remedies would be inadequate to protect the other Party against any actual or threatened material breach of the provisions of this Article 12 by the breaching Party or by such other authorized third parties, without prejudice to any other rights and remedies otherwise available to the other Party, the breaching Party agrees, upon proof of any such actual or threatened material breach, to the granting of equitable relief, including injunctive relief and specific performance. It is further understood and agreed that no failure or delay by either Party in exercising any right, power or privilege hereunder shall operate as a waiver thereof, nor shall any single or partial exercise thereof preclude any other or further exercise thereof or the exercise of any other right, power or privilege hereunder.

**13. MISCELLANEOUS.**

13.1 Correspondence and Notices.

All notices or other communications to a Party required or permitted hereunder will be in writing and will be delivered personally or by facsimile (receipt confirmed) to such Party (or, in the case of an entity, to an executive officer of such party) or will be given by certified mail, postage prepaid with return receipt requested, addressed as set forth below in this Section 13.1. Each Party may change its respective above-specified recipient and/or mailing address by notice to the other Party given in the manner herein prescribed. All notices will be deemed given on the day when actually delivered as provided above (if delivered personally or by facsimile) or on the day shown on the return receipt (if delivered by mail).

All correspondence to Collingwood shall be addressed as follows:

Collingwood Pharmaceuticals, Inc.  
787 Seventh Avenue  
New York, NY 10019  
Attn: Frank Taffy  
Tel: (212) 554-4385  
Fax: (212) 554-4355



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With a copy to:

Hemie Chang, Esq.  
Ropes & Gray LLP  
One International Place  
Boston, MA 02110  
Tel: (617) 951-7317  
Fax: (617) 951-7050

All correspondence to Ovamed shall be addressed as follows:

Ovamed GmbH  
Kiebitzhörn 33-35  
22885 Barsbüttel  
Germany  
Attention: Detlev Goj  
Tel: +49-40-67 50 95-0

With a copy to:  
Klaus Lodigkeit  
c/o Vorberg Rechtsanwälte  
Rappstraße 16  
20146 Hamburg  
Germany

### 13.2 Compliance with the Laws, Permits and Licenses.

Each Party agrees that it will, in fulfilling its obligations under this Agreement, materially comply with all applicable laws including, but not limited to statutes, codes, rules, regulations, ordinances, judgments and decrees, now or hereafter in effect. Collingwood agrees that it will materially comply with all applicable laws including, but not limited to statutes, codes, rules, regulations, ordinance, judgments and decrees, now or hereafter in effect related to the development, manufacture and marketing of the Product. Collingwood also represents and warrants that it has all governmental and regulatory licenses and permits necessary to operate its facilities and fulfill its obligations under this Agreement. Ovamed also represents and warrants that it has all United States and any other governmental and regulatory licenses and permits necessary to operate its facilities and fulfill its obligations under this Agreement. Failure to comply with this Section 13.2 will be a material breach of the Agreement.

### 13.3 Assignment.

This Agreement and the rights and duties appertaining hereto may not be assigned by either Party without first obtaining the written consent of the other, which consent shall not be unreasonably withheld. Any such purported assignment, without the written consent of the other Party, shall be null and of no effect. Notwithstanding the foregoing, Collingwood may assign

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this Agreement without the consent of Ovamed (i) to a purchaser, merging or consolidating corporation, or acquirer of substantially all of Collingwood's assets or business and/or pursuant to any reorganization qualifying under section 368 of the Internal Revenue Code of 1986 as amended, as may be in effect at such time, or (ii) to an Affiliate.

#### 13.4 Force Majeure.

Neither Party shall be liable to the other for delay or failure in the performance of the obligations on its part contained in this Agreement if and to the extent that such failure or delay is due to circumstances beyond its control that it could not have avoided by the exercise of reasonable diligence, including without limitation, acts of God or of the public enemy, acts of the government in either its sovereign or contractual capacity, acts of terrorism, fires, floods, war, earthquakes, epidemics, quarantine restrictions, strikes, freight embargoes, unusually severe weather, the failure of Ovamed's suppliers or carriers to meet their contractual obligations, or if necessary raw material is unavailable (each a "Force Majeure Event"). The Party relying on this Section will notify the other Party promptly in the event such circumstances arise, giving an indication of the likely extent and duration thereof, and will use all commercially reasonable efforts to resume performance of its obligations as soon as practicable; provided, however, that neither Party shall be required to settle any labor dispute or disturbance. During the period that the performance by one of the Parties of its obligations under this Agreement has been suspended by reason of an event of Force Majeure, the other Party may likewise suspend the performance of all or part of its obligations hereunder to the extent that such suspension is commercially reasonable.

#### 13.5 Use of Name.

Except as required by law, neither Party will use any trade name, trademark or service mark of the other Party, or of any of the other Party's Affiliates, in any advertising, promotional or sales literature, offering materials, business plan or any other form of publicity without the other Party's prior written consent.

#### 13.6 Language of the Agreement.

The language of this Agreement shall be English and the parties hereby waive, and agree that this Agreement shall be valid and enforceable notwithstanding, any requirement that it be written in or translated into any language other than English. If, for any reason, this Agreement is translated into a language other than English, the English language version shall be controlling for all purposes.

#### 13.7 UN Convention on Contracts for Sale of Goods.

The parties expressly agree that the United Nations Convention on Contracts for the International Sale of Goods shall not apply to this Agreement.

#### 13.8 Amendment.

No amendment, modification or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

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### 13.9 Waiver.

No provision of the Agreement shall be waived by any act, omission or knowledge of a Party or its agents or employees except by an instrument in writing expressly waiving such provision and signed by a duly authorized officer of the waiving Party.

### 13.10 Severability.

If any clause or portion thereof in this Agreement is for any reason held to be invalid, illegal or unenforceable, the same shall not affect any other portion of this Agreement, as it is the intent of the Parties that this Agreement shall be construed in such fashion as to maintain its existence, validity and enforceability to the greatest extent possible. In any such event, this Agreement shall be construed as if such clause or portion thereof had never been contained in this Agreement, and there shall be deemed substituted therefore such provision as will most nearly carry out the intent of the Parties as expressed in this Agreement to the fullest extent permitted by applicable law.

### 13.11 Descriptive Headings.

The descriptive headings of this Agreement are for convenience only and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement.

### 13.12 Governing Law.

This Agreement, the rights of the Parties and all claims arising under or in connection herewith, shall be governed by and interpreted in accordance with the substantive laws of Germany, without regard to conflict of law principles thereof that would cause the application of the laws of any other jurisdiction.

### 13.13 Jurisdiction; Venue; Service of Process.

13.13.1. Jurisdiction. Each Party by its execution hereof, (a) hereby irrevocably submits to the jurisdiction of the courts of Germany for the purpose of any claim, controversy, action, cause of action, suit or litigation ("Action") between the parties arising in whole or in part under or in connection with this Agreement, (b) hereby waives to the extent not prohibited by applicable law, and agrees not to assert, by way of motion, as a defense or otherwise, in any such Action, any claim that it is not subject personally to the jurisdiction of the above-named courts, that its property is exempt or immune from attachment or execution, that any such Action brought in one of the above-named courts should be dismissed on grounds of forum non conveniens, should be transferred or removed to any court other than one of the above-named courts, or should be stayed by reason of the pendency of some other proceeding in any other court other than one of the above-named courts, or that this Agreement or the subject matter hereof may not be enforced in or by such court and (c) hereby agrees not to commence any such Action other than before one of the above-named courts. Notwithstanding the previous sentence a Party may commence any Action in a court other than the above-named courts solely for the purpose of enforcing an order or judgment issued by one of the above-named courts or in connection with injunctive relief.

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13.13.2 . Venue. Each Party agrees that for any Action between the parties arising in whole or in part under or in connection with this Agreement, any Action brought shall be brought in Germany.

13.14 Entire Agreement.

This Agreement and the Exhibits attached hereto constitutes and contains the complete, final and exclusive understanding and agreement of the Parties and cancels and supersedes any and all prior negotiations, correspondence, understandings and agreements, whether oral or written, between the Parties respecting the subject matter hereof and thereof.

13.15 Conflicts.

The Parties agree that, to the extent there is an inconsistency between the terms of this Agreement and the terms of the Sublicense, the terms of the Sublicense shall govern.

13.16 Independent Contractors.

Both Parties are independent contractors under this Agreement. Nothing herein contained shall be deemed to create an employment, agency, joint venture or partnership relationship between the Parties hereto or any of their agents or employees, or any other legal arrangement that would impose liability upon one Party for the act or failure to act of the other Party. Neither Party shall have any express or implied power to enter into any contracts or commitments or to incur any liabilities in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.

13.17 Counterparts.

This Agreement may be executed in any number of counterparts, each of which need not contain the signature of more than one Party but all such counterparts taken together shall constitute one and the same agreement.

*[Signature page follows.]*

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IN WITNESS WHEREOF, the parties hereto have as of the Effective Date duly executed this Agreement, including the attached Exhibits that are incorporated herein and made a part hereof.

COLLINGWOOD PHARMACEUTICALS, INC.

By: /s/ J. Jay Lobell

Name: J. Jay Lobell

Title: President

OVAMED GMBH

By: \_\_\_\_\_

Name:

Title:

**Specifications for TSO**

Parameters	TSO specification

**Vial**

Name and address of manufacturer:

\_\_\_\_\_

Physical description: \_\_\_\_\_

Size: \_\_\_\_\_

**Closure System**

Product name: \_\_\_\_\_

Name and address of manufacturer:

\_\_\_\_\_

Physical description: \_\_\_\_\_

Size: \_\_\_\_\_

**Development and regulatory work to be performed by Ovamed**

**Raw Materials Index**



**TSO US- Specification**

Parameters	Specification

**Clinical Plan for Product**

**CONFIDENTIAL TREATMENT REQUESTED.  
INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN  
REQUESTED IS OMITTED AND MARKED WITH “[\*\*\*\*\*]” OR OTHERWISE  
CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS  
ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

**Licence Agreement**

**between**

**UCL BUSINESS PLC**

**and**

**CORONADO BIOSCIENCES, INC**

**Dated November 5, 2007**



**PATENT AND KNOW-HOW LICENCE AGREEMENT**

**This Agreement** dated November 5, 2007 is between:

- (1) **UCL Business PLC**, whose registered office is The Network Building, 97 Tottenham Court Road, London W1T 4TP United Kingdom (“UCLB”); and
- (2) **Coronado Biosciences, Inc** (the “Licensee”) a Delaware corporation whose principal place of business is at 4365 Executive Dr. Ste 1500, San Diego, CA, 92121, United States of America.

**Recitals:**

- A. UCLB has developed certain technology and owns certain intellectual property rights relating to Tumour Activated Natural Killer Cells (“TANKS”) technology including the Patents and the Know-how.
- B. The Licensee wishes to acquire rights under the Patents and to use the Know-how for the development and commercialisation of Licensed Products in the Field and in the Territory, all in accordance with the provisions of this Agreement.

**It is agreed as follows:**

**1. Definitions**

In this Agreement, the following words shall have the following meanings:

<b>Affiliate</b>	In relation to a Party, means any entity or person that Controls, is Controlled by, or is under common Control with that Party.
<b>Claims</b>	All demands, claims, actions and other proceedings (whether criminal or civil, in contract, tort or otherwise) by any third party (that is not an Affiliate) for Losses.
<b>Commencement Date</b>	5 <sup>th</sup> November 2007.
<b>Competing Product</b>	A product that has the same chemical composition as a Licensed Product.
<b>Completion</b>	With respect to a specified human clinical trial, the achievement (as determined by the sponsor of such trial) of the primary clinical endpoint identified in the protocol for such trial.
<b>Confidential Information</b>	<ol style="list-style-type: none"> <li>(a) All Know-how; and</li> <li>(b) All other technical or commercial information that: <ol style="list-style-type: none"> <li>(i) in respect of information provided in documentary or by way of a model or in other tangible form, at the time of provision is marked or otherwise designated to show expressly or by necessary implication that it is imparted in confidence; and</li> <li>(ii) in respect of information that is imparted orally or other intangible form, any information that the Disclosing Party or its representatives informed the Receiving Party at the time of disclosure was imparted in confidence, and reasonable efforts are taken to summarise such information in writing, marked as confidential, within 30 days after the time of disclosure; and</li> </ol> </li> </ol>

- (iii) is a copy of any of the foregoing; and
- (iv) is not the subject of a Confidentiality Exception.

<b>Confidentiality Exception</b>	Has the meaning given in Clause 3.4.
<b>Control</b>	Direct or indirect beneficial ownership of 50% (or, outside a Party's home territory, such lesser percentage as is the maximum, permitted level of foreign investment) or more of the share capital, stock or other participating interest carrying the right to vote or to distribution of profits of that Party, as the case may be.
<b>Diligent and Reasonable Efforts</b>	Exerting such efforts and employing such resources as would normally be exerted or employed by a reasonable third party biotechnology company for a product of similar market potential at a similar stage of its product life, when utilizing sound and reasonable scientific, medical and business practice and judgment in order to attempt to develop and commercialize the product in a timely manner.
<b>Disclosing Party</b>	Has the meaning given in Clause 3.3.
<b>EMEA</b>	European Agency for the Evaluation of Medicinal Products.
<b>Field</b>	The prevention, treatment, diagnosis, detection, monitoring, and predisposition testing of all diseases, states or conditions in humans or other animals.
<b>FDA</b>	Food and Drug Administration (USA).
<b>Generic Equivalent</b>	In relation to a Licensed Product in a country of the Territory, means a product that (a) has the same chemical composition as that Licensed Product, (b) does not infringe a Valid Claim in that country, and (c) has obtained all requisite Regulatory Approval to be marketed or sold in that country.
<b>Indemnitees</b>	Has the meaning given in Clause 7.5.
<b>Indication</b>	A recognized disease, state or condition for a specific tissue or cell type
<b>Investigational New Drug application (IND)</b>	An Investigational New Drug application, or similar application to commence human clinical testing of a Licensed Product for use in the Field submitted to the FDA.
<b>Know-how</b>	Technical information in the Field developed in the Laboratory on or prior to the date of this Agreement under the supervision of the Principal Investigator, and within the definition of the Technology set out below and within the description set out in the attached Schedule 1 Part B, in each case that is not the subject of a Confidentiality Exception.

<b>Laboratory</b>	The laboratory of the Principal Investigator within University's Department of Haematology.
<b>Licensed Products</b>	Any and all products for use in the Field that (a) if made, used, sold, offered for sale or imported absent the license granted hereunder would infringe a Valid Claim, or (b) otherwise uses or incorporates, or their development makes use of, any of the Know-how.
<b>Losses</b>	All losses, liabilities, damages, legal costs and other expenses of any nature whatsoever and all costs and expenses (including without limitation legal costs) incurred in connection therewith.
<b>MHLW</b>	Ministry of Health, Labour and Welfare (Japan; formerly Ministry of Health and Welfare, MHW).
<b>Net Receipts</b>	With respect to any Licensed Product, the aggregate cash royalties received by Licensee or its Affiliates in consideration for the sublicense under the Patents or Know-how by Licensee or its Affiliates to a third party sublicensee with respect to such Licensed Product that are calculated solely on the basis of sales of such Licensed Product.
<b>Net Sales Value</b>	<p>The invoiced price of Licensed Products sold by the Licensee or its Affiliates (or, for the purpose of calculating the minimum royalty payable under Clause 4.4(d) or 4.6 only, the invoiced price of Licensed Products sold by the sub-licensee) to independent third parties in arm's length transactions, after deduction of all documented:</p> <ul style="list-style-type: none"><li>(a) cash, quantity and trade discounts, rebates and other price reductions given under price reduction programs;</li><li>(b) credits, allowances, discounts and rebates to, and chargebacks from the account of, customers for nonconforming, damaged, out-dated and returned Licensed Product;</li><li>(c) packaging, carriage, freight and insurance costs of transporting Licensed Products;</li><li>(d) sales, use, value-added and other direct taxes; (e) customs duties, tariffs, surcharges and other governmental charges for exporting or importing;</li><li>(e) sales commissions; and</li><li>(f) an allowance for uncollectible or bad debts determined in accordance with generally accepted accounting principles;</li></ul> <p>In each case, provided that such deductions do not exceed reasonable and customary amounts in the markets in which such sales occurred. Sales between any of the Licensee, its Affiliates and Sub-licensees shall not be considered for the purposes of this definition unless there is no subsequent sale to a person who is not the Licensee, its Affiliate or Sub-licensee in an arm's length transaction exclusively for money.</p>
<b>New Drug Application (NDA)</b>	A New Drug Application, or similar application for marketing approval of a Licensed Product for use in the Field submitted to the FDA.

<b>Parties</b>	UCLB and the Licensee, and “Party” shall mean either of them.
<b>Patents</b>	(a) Any and all of the patents and patent applications referred to in Schedule 1 Part A; (b) all divisions, continuations, continuations-in-part, that are based on, or claim priority to or common priority with, the patent applications described in clause (a) above; and (c) all patents that have issued or in the future issue from any of the foregoing patent applications, including utility, model and design patents and certificates of invention, together with any reissues, renewals, extensions or additions thereto.
<b>Phase I Studies</b>	A controlled human clinical trial in any country involving the administration of Licensed Product for the first time in human patients, the results of which could be used to establish the safety of a Licensed Product.
<b>Phase II Studies</b>	A controlled human clinical trial in any country involving the administration of Licensed Product in patients with the disease or condition of interest, the results of which could be used to initially establish the safety and efficacy of a Licensed Product.
<b>Phase III Studies</b>	A controlled human clinical trial in any country involving the administration of Licensed Product in patients with the disease or condition of interest, the results of which could be used to establish the safety and efficacy of a Licensed Product in a manner sufficient to obtain Regulatory Approval to market and sell such Licensed Product.
<b>Principal Investigator</b>	Dr Mark Lowdell.
<b>Receiving Party</b>	Has the meaning given in Clause 3.3.
<b>Regulatory Approval</b>	Means formal approval for commercial marketing, sale or use of the Licensed Product by the relevant government agency responsible for any such product in any such country.
<b>Royalty Term</b>	With respect to each Licensed Product in each country, the period equal to the longer of (a) if, at the time of the first commercial sale of such Licensed Product in such country, the use, offer for sale, sale or import of such Licensed Product in such country would infringe a Valid Claim (if such Valid Claim were in an issued patent), the term for which such Valid Claim remains in effect and would be infringed (if such Valid Claim were in an issued patent), and (b) ten (10) years following the date of the first commercial sale of a Licensed Product in the Territory; provided, however that the Royalty Term for a Licensed Product in a country shall terminate immediately three (3) months after the first commercial sale of a Generic Equivalent of such Licensed Product in such country.
<b>Technology</b>	All compositions, methods, data, information and other discoveries, inventions, innovations, improvements and technology regarding or relating to natural killer (“NK”) cells, methods of activating NK cells and methods of producing or testing, or uses of any of the foregoing.

<b>Territory</b>	Worldwide.
<b>Valid Claim</b>	Either (a) a claim of an issued and unexpired patent included within the Patents, which has not been held permanently revoked, unenforceable or invalid by a decision of a court or other governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been admitted to be invalid or unenforceable through reissue or disclaimer or otherwise or (b) a claim of a pending patent application included within the Patents, which claim was filed in good faith, is being actively prosecuted and has not been abandoned or finally disallowed without the possibility of appeal or refiling of such application.

## 2. Grant of rights

2.1 *Licences.* UCLB hereby grants to the Licensee, subject to the provisions of this Agreement:

- (a) an exclusive licence under the Patents, with the right to sub-licence through multiple tiers, subject to clause 2.3 below, to develop, manufacture, have manufactured, import, use, offer for sale and sell Licensed Products only in the Field in the Territory; and
- (b) An exclusive licence to use the Know-how, with the right to sub-licence through multiple tiers, subject to clause 2.3 below, to develop, manufacture, have manufactured, import, use, offer for sale and sell Licensed Products only in the Field in the Territory.

2.2 *Formal licences.* The Parties shall execute such formal licences as may be necessary or appropriate for registration with Patent Offices and other relevant authorities in particular territories. In the event of any conflict in meaning between any such licence and the provisions of this Agreement, the provisions of this Agreement shall prevail wherever possible. Prior to the execution of the formal licence(s) (if any) referred to in this Clause 2.2, the Parties shall so far as possible have the same rights and obligations towards one another as if such licence(s) had been granted. The Parties shall use reasonable endeavours to ensure that, to the extent permitted by relevant authorities, this Agreement shall not form part of any public record.

2.3 *Sub-licensing.*

The Licensee shall be entitled to grant sub-licences of its rights under this Agreement to any person, provided that:

- (a) the sub-licence shall include obligations on the sub- licensee which are equivalent to the obligations on the Licensee under this Agreement and limitations of liability that are equivalent to those set out in this Agreement;
- (b) without the prior written consent of UCLB (such consent not to be unreasonably delayed or withheld), the Licensee shall not enter into any agreement with a sub- licensee that provides for the payment of any consideration that would be fairly attributable to the grant of the sub- licence other than (i) royalties based on the sale of Licensed Products, and/or (ii) conventional milestones to be paid on the achievement of stages of product development prior to commercial sale (such as those stages set out in Clause 4.2);
- (c) within 30 days of the grant of any sub- licence the Licensee shall provide to UCLB a true copy of it (with confidential information redacted, other than to the extent necessary to determine the financial obligations of Licensee hereunder regarding such sub- licence); and



- (d) the Licensee shall be responsible for any breach of the sub-license by the sub-licensee, as if the breach had been that of Licensee under this Agreement; and
- (e) Upon any termination of this Agreement, UCLB shall grant a direct license to any sub-licensee of Licensee hereunder having the same scope as such sub-license and on terms and conditions no less favorable to such sub-licensee than the terms and conditions of this Agreement, provided that such sub-licensee is not in any uncured default of any applicable obligations under this Agreement and agrees in writing to be bound by the terms and conditions of such direct license.

#### 2.4 *Reservation of rights.*

- (a) UCLB reserves for itself and its Affiliates the non-exclusive, irrevocable, worldwide, royalty-free right to use, and license other academic institutions to use, the Know-how and the Patents in the Field solely for the purposes of non-commercial academic research, publication and teaching.
- (b) Except for the licences expressly granted by this Clause 2, UCLB reserves all its rights. Without prejudice to the generality of the foregoing UCLB grants no rights to any intellectual property other than the Patents and Know-how, and reserves all rights under the Patents and Know-how outside the Field.

2.5 *Quality.* The Licensee shall ensure that all of the Licensed Products marketed by it and its sublicensees shall comply in all material respects with all applicable laws and regulations in each part of the Territory in which they are marketed.

2.6 *Right of First Negotiation.* For a period of four (4) years after the Commencement Date, if UCLB or its Affiliates desires to enter into an agreement with any third party regarding the development or commercialization of the Technology in the Field, UCLB shall give to Licensee express written notice thereof, and the right to negotiate with UCLB to enter into an agreement regarding such development or commercialization. If, within ninety (90) days after receipt of such written notice from UCLB, Licensee gives written notice to UCLB of its exercise of such right of negotiation, then the Parties shall negotiate in good faith, for a period not to exceed ninety (90) days, and attempt to reach mutual agreement regarding terms and conditions of a mutually acceptable agreement regarding such development or commercialization. If Licensee fails to give UCLB timely written notice of its exercise of such right of negotiation, or if the Parties fail to reach mutual agreement regarding such development or commercialization prior to the expiration of such ninety (90) day period, thereafter UCLB and its Affiliates shall have the right to pursue such development or commercialization with any third party with no continuing obligation to Licensee regarding such development or commercialization.

### 3. **Know-how and Confidential Information**

3.1 *Provision of Know-how.* Upon the Licensee's reasonable request, UCLB shall instruct the Principal Investigator to supply the Licensee with all Know-how in his possession that UCLB is at liberty to disclose and has not previously been disclosed to the Licensee and which is reasonably necessary or desirable to enable the Licensee to undertake the further development of the inventions claimed in (or disclosed in the as-filed specification of) any patent or patent

application in the Patents. The method of such supply shall be agreed between the Principal investigator and the Licensee but shall not require the Principal Investigator to undertake more than 2 man-days of work, unless otherwise agreed in writing between the Parties. If it is agreed that the Principal Investigator shall travel to the Licensee's premises in connection with such supply, the Licensee shall reimburse all travel (at business class rates), accommodation and subsistence costs incurred.

- 3.2 *Confidentiality of Know-how.* The Licensee undertakes that for a period of 15 years from the Commencement Date, it shall protect the Know-how as Confidential Information and shall not use the Know-how for any purpose except as expressly licensed hereby and in accordance with the provisions of this Agreement.
- 3.3 *Confidentiality obligations.* Each Party ("Receiving Party") undertakes:
- (a) to maintain as secret and confidential all Confidential Information obtained directly or indirectly from the other Party ("Disclosing Party") in the course of or in anticipation of this Agreement and to respect the Disclosing Party's rights therein;
  - (b) to use such Confidential Information only for the purposes of this Agreement; and
  - (c) to disclose such Confidential Information only to those of its employees, contractors, agents and sub-licensees pursuant to this Agreement (if any) to whom and to the extent that such disclosure is reasonably necessary for the purposes of this Agreement.
- 3.4 *Confidentiality Exceptions.* The confidentiality obligations shall not apply to information which the Receiving Party can demonstrate by reasonable, written evidence:
- (a) was, prior to its receipt by the Receiving Party from the Disclosing Party, in the possession of the Receiving Party and at its free disposal; or
  - (b) is subsequently disclosed to the Receiving Party without any obligations of confidence by a third party who has not derived it directly or indirectly from the Disclosing Party; or
  - (c) is or becomes generally available to the public through no act or default of the Receiving Party or its agents, employees, Affiliates or sub-licensees; or
  - (d) is or was independently developed by the Receiving Party without use of the information disclosed by the other party (each of the foregoing in Clauses 3.4(a) through (d), a "Confidentiality Exception").
- 3.5 *Terms of this Agreement.* Except as otherwise provided in this Section 3, neither Party shall disclose any terms or conditions of this Agreement to any other person or entity without the prior written consent of the other Party, such consent not to be unreasonably withheld or delayed. Notwithstanding the foregoing, within forty-five (45) days of the Commencement Date, the Parties shall agree on the substance of a press release, which will be attached to this Agreement as Schedule 2. The substance of this release included in Schedule 2 can be used by the Parties to describe the terms of this transaction, and either Party may disclose such information, as modified by mutual agreement from time to time, without the other Party's consent.

- 3.6 *Permitted Disclosures.* Notwithstanding anything to the contrary in this Agreement, the provisions of this Section 3 shall not apply to the extent that:
- (a) A Party is required (i) to disclose information by law, regulation or order of a governmental agency or a court of competent jurisdiction, or (ii) to disclose information to any governmental agency for purposes of obtaining approval to test or market a product, provided in either case provided that such Party shall (i) inform the other Party as soon as is reasonably practicable, and (ii) at the other Party's request seek to have the information treated in a confidential manner, where this is possible under the court, agency or authority's procedures; or
  - (b) Licensee may disclose information to any person or entity with whom Licensee has, or is proposing to enter into, a business relationship, as long as such person or entity has entered into written undertakings of confidentiality at least as restrictive as this Section 3.
- 3.7 *Disclosure to employees.* The Receiving Party shall procure that all of its employees, contractors and sub-licensees pursuant to this Agreement (if any) who have access to any of the Disclosing Party's Confidential Information, shall be made aware of and subject to these obligations and shall have entered into written undertakings of confidentiality at least as restrictive as this Section 3 and which apply to the Disclosing Party's Confidential Information.
- 3.8 *Return of information.* Upon any termination of this Agreement, the Receiving Party shall return to the Disclosing Party any documents or other materials that contain the Disclosing Party's Confidential Information including all copies made and, subject to Clause 8.3, make no further use or disclosure thereof; provided, however, that each Party shall have the right to retain one (1) copy for its legal files for the sole purpose of determining its obligations hereunder.

#### 4. Payments

##### 4.1 *Initial payments:*

- (a) Within 90 (ninety) days of the Commencement Date, the Licensee shall pay to UCLB the non-refundable, non-deductible sum of \$50,000 (fifty thousand US Dollars); and
- (b) Within 9 (nine) months after the Commencement Date, the Licensee shall pay to UCLB the non-refundable, non-deductible sum of \$50,000 (fifty thousand US Dollars).

- 4.2 *Milestone payments.* Within thirty (30) days after the first achievement (whether by the Licensee, its Affiliate or sub-licensee) of the each of the milestone events set out in the following table for a Licensed Product, the Licensee shall pay to UCLB the amount(s) set out next to such milestone event in the table:

<u>Milestone event</u>	<u>Amount to be paid (US dollars)</u>
Acceptance of IND or (equivalent) by the FDA for a 1st Indication as demonstrated by appropriate official confirmation.	\$250,000 (two hundred and fifty thousand Dollars)
Completion of the first Phase I study for a 1st Indication.	\$350,000 (three hundred and fifty thousand Dollars)
Completion of the first Phase II study for a 1st Indication.	\$500,000 (five hundred thousand Dollars)

<u>Milestone event</u>	<u>Amount to be paid (US dollars)</u>
Completion of the first Phase III study for a 1st Indication.	\$1,000,000 (one million Dollars)
Completion of the second / pivotal Phase 3 study for a 1st Indication.	\$1,500,000 (one million five hundred thousand Dollars)
Acceptance of NDA (or equivalent) by FDA for a 1st Indication as demonstrated by appropriate official confirmation.	\$2,000,000 (two million Dollars)
Approval of NDA (or equivalent) by FDA for a 1st Indication as demonstrated by appropriate official confirmation.	\$4,000,000 (four million Dollars)
Acceptance of NDA equivalent by EMEA for a 1st Indication as demonstrated by appropriate official confirmation.	\$1,000,000 (one million Dollars)
Approval of NDA equivalent by EMEA for a 1st Indication as demonstrated by appropriate official confirmation.	\$2,000,000 (two million Dollars)
Acceptance of NDA equivalent by MHLW for a 1st Indication as demonstrated by appropriate official confirmation.	\$500,000 (five hundred thousand Dollars)
Approval of NDA equivalent by MHLW for a 1st Indication as demonstrated by appropriate official confirmation.	\$1,000,000 (one million Dollars)
Acceptance of NDA (or equivalent) by FDA for a 2nd Indication as demonstrated by appropriate official confirmation.	\$1,000,000 (one million Dollars)
Approval of NDA (or equivalent) by FDA for a 2nd Indication as demonstrated by appropriate official confirmation.	\$2,000,000 (two million Dollars)
Acceptance of NDA equivalent by EMEA for a 2nd Indication as demonstrated by appropriate official confirmation.	\$500,000 (five hundred thousand Dollars)
Approval of NDA equivalent by EMEA for a 2nd Indication as demonstrated by appropriate official confirmation.	\$1,000,000 (one million Dollars)
Acceptance of NDA equivalent by MHLW for a 2nd Indication as demonstrated by appropriate official confirmation.	\$250,000 (two hundred and fifty thousand Dollars)

<u>Milestone event</u>	<u>Amount to be paid (US dollars)</u>
Approval of NDA equivalent by MHLW for a 2nd Indication	\$500,000 (five hundred thousand Dollars)
Acceptance of NDA (or equivalent) by FDA for a 3rd Indication as demonstrated by appropriate official confirmation.	\$500,000 (five hundred thousand Dollars)
Approval of NDA (or equivalent) by FDA for a 3rd Indication as demonstrated by appropriate official confirmation.	\$1,000,000 (one million Dollars)
Acceptance of NDA equivalent by EMEA for a 3rd Indication as demonstrated by appropriate official confirmation.	\$250,000 (two hundred and fifty thousand Dollars)
Approval of NDA equivalent by EMEA for a 3rd Indication as demonstrated by appropriate official confirmation.	\$500,000 (five hundred thousand Dollars)
Acceptance of NDA equivalent by MHLW for a 3rd Indication	\$125,000 (one hundred and fifty thousand Dollars)
Approval of NDA equivalent by MHLW for a 3rd Indication as demonstrated by appropriate official confirmation.	\$250,000 (two hundred and fifty thousand Dollars)

4.3 *Royalties on Net Sales.* During the applicable Royalty Term, the Licensee shall pay to UCLB a royalty being a percentage of the Net Sales Value of each Licensed Product sold by Licensee or its Affiliates. The percentage shall be applicable percentage(s) set forth below which applies to the Licensed Product in question:

- (a) Three percent (3%) of Net Sales Value, for Net Sales Value of such Licensed Product in the current calendar year up to \$250,000,000 (two hundred and fifty million Dollars);
- (b) Four percent (4%) of Net Sales Value, for Net Sales Value of such Licensed Product in the current calendar year greater than \$250,000,000 (two hundred and fifty million Dollars) and up to \$500,000,000 (five hundred million Dollars); and
- (c) Five percent (5%) of Net Sales Value, for Net Sales Value of such Licensed Product in the current calendar year greater than \$500,000,000 (five hundred million Dollars).

Neither the Licensee nor its Affiliates shall sell any Licensed Product other than in an arm's length transaction.

- 4.4 *Royalties on Net Receipts*. During the applicable Royalty Term, the Licensee shall pay to UCLB a royalty on Net Receipts in respect of each Licensed Product as follows:
- (a) Subject to paragraph (d), a royalty of 30% of Net Receipts where the sub-licence agreement (or related agreement) under which the relevant Net Receipts become due is first executed prior to Completion of the first Phase I study of such Licensed Product; or
  - (b) Subject to paragraph (d), a royalty of 25% of Net Receipts where the sub-licence agreement (or related agreement) under which the relevant Net Receipts become due is first executed after Completion of the first Phase I study of such Licensed Product, but prior to Completion of the first Phase II study of such Licensed Product; or
  - (c) Subject to paragraph (d), a royalty of 20% of Net Receipts where the sub-licence agreement (or related agreement) under which the relevant Net Receipts become due is first executed after Completion of the first Phase II study of such Licensed Product; but
  - (d) Where any royalties to be paid under paragraphs (a) to (c) above are in respect of Net Receipts obtained from the sale of Licensed Product(s) by the sub-licensee, the amount of royalty that the Licensee shall pay UCLB in respect of each such sale shall in no event be less than 2% of the Net Sales Value of such Licensed Product(s) when sold by the sub-licensee.
- 4.5 *Third Party Royalties*. If Licensee, its Affiliates or sublicensees is required to pay royalties to any third party in order to develop, manufacture, have manufactured, import, use, offer for sale and sell Licensed Products, then Licensee shall have the right to credit [\*\*\*\*\*] of such third party royalty payments against the royalties owing to UCLB; provided, however, that Licensee shall not reduce the amount of the royalties paid to UCLB by reason of this Clause 4.5 with respect to sales of a Licensed Product to less than [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of Net Sales Value of such Licensed Product.
- 4.6 *Combination Products*. If any Licensed Product is incorporated as a component in any other product (“Combination Product”), then for purposes of calculating Net Sales of such Licensed Product, such Net Sales, prior to the royalty calculation set forth in above, first shall be multiplied by the fraction  $A/(A+B)$ , where A is the value of the Licensed Product component as reasonably determined by Licensee, and B is the value of the other component(s) as reasonably determined by the Parties for both A and B and such resulting amount shall be the “Net Sales” for purposes of the royalty calculation for such Licensed Product.
- 4.7 *Payment frequency*. Royalties due under this Agreement shall be paid within 60 days of the end of each quarter ending on 31 March, 30 June, 30 September and 31 December, in respect of sales of Licensed Products made and Net Receipts generated during such quarter and within 60 days of the termination of this Agreement.
- 4.8 *Payment terms*. All sums due under this Agreement:
- (a) shall be paid in US Dollars in cash by transferring an amount in aggregate to the following account number [\*\*\*\*\*], and in the case of sales or sub-licence income received by the Licensee in a currency other than US Dollars, the royalty shall be calculated in the other currency and then converted into equivalent US Dollars using the average of the exchange rate (local currency per US\$1) published in The Wall Street Journal, Western Edition, under the heading “Currency Trading” on the last business day of each month during the applicable quarterly period with respect to which the payment is made; and

- (b) shall be made by the due date, failing which UCLB may charge interest on any outstanding amount on a daily basis at a rate equivalent to [\*\*\*\*\*], or the highest rate permitted by applicable law (whichever is lower).
- 4.9 *Withholding Taxes.* Licensee shall be entitled to deduct the amount of any withholding taxes, value-added taxes or other taxes, levies or charges with respect to such amounts, other than United States taxes, payable by Licensee, its Affiliates or sublicensees, or any taxes required to be withheld by Licensee, its Affiliates or sublicensees, to the extent Licensee, its Affiliates or sublicensees pay to the appropriate governmental authority on behalf of UCLB such taxes, levies or charges. Licensee shall use reasonable efforts, in consultation with UCLB, to minimize any such taxes, levies or charges required to be withheld on behalf of UCLB by Licensee, its Affiliates or sublicensees. Licensee promptly shall deliver to UCLB proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto and any other documentation that UCLB may reasonably require in connection with applications for relief from such taxes, levies and charges. Licensee shall cooperate with UCLB in relation to any such applications that UCLB may make.
- 4.10 *Exchange controls.* If at any time during the continuation of this Agreement the Licensee is prohibited from making any of the payments required hereunder by a governmental authority in any country then the Licensee shall within the prescribed period for making the said payments in the appropriate manner use its best endeavours to secure from the proper authority in the relevant country permission to make the said payments and shall make them within [\*\*\*\*\*] days of receiving such permission. If such permission is not received within [\*\*\*\*\*] days of the Licensee making a request for such permission then, at the option of UCLB, the Licensee shall deposit the royalty payments due in the currency of the relevant country either in a bank account designated by UCLB within such country or such royalty payments shall be made to an associated company of UCLB designated by UCLB and having offices in the relevant country designated by UCLB.
- 4.11 *Royalty statements.* The Licensee shall send to UCLB at the same time as each royalty payment is made in accordance with Clause 4.3 or Clause 4.4 a statement setting out, in respect of each territory or region in which Licensed Products are sold, the types of Licensed Product sold, the quantity of each type sold, and the total Net Sales Value, and the total Net Receipts in respect of each type and sublicensee, expressed both in local currency and pounds sterling and showing the conversion rates used, during the period to which the royalty payment relates.
- 4.12 *Records.*
- (a) The Licensee shall keep at its normal place of business detailed and up to date records and accounts showing the quantity, description and value of Licensed Products sold by it, and the amount of sublicensing revenues received by it in respect of Licensed Products, on a country by country basis, and being sufficient to ascertain the payments due under this Agreement.
- (b) Upon the written request of UCLB and not more than once in each calendar year, Licensee shall permit an independent chartered, certified or similarly qualified accountant as selected by UCLB to whom Licensee has no reasonable objection, at UCLB's expense, to have access during normal business hours to such of the financial records of Licensee as may be reasonably necessary to verify the accuracy of the payment reports hereunder for the [\*\*\*\*\*] calendar quarters immediately prior to the date of such request (other than records for which UCLB has already conducted an audit under this Section).

If such accounting firm concludes that additional amounts were owed during the audited period, Licensee shall pay such additional amounts within [\*\*\*\*\*] days after the date UCLB delivers to Licensee such accounting firm's written report so concluding. The fees charged by such accounting firm shall be paid by UCLB; provided, however, if the audit discloses that the royalties payable by Licensee for such period are more than [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of the royalties actually paid for such period, then Licensee shall pay the reasonable fees and expenses charged by such accounting firm. UCLB shall cause its accounting firm to retain all financial information subject to review under this Clause in strict confidence; provided, however, that Licensee shall have the right to require that such accounting firm, prior to conducting such audit, enter into an appropriate non-disclosure agreement with Licensee regarding such financial information. The accounting firm shall disclose to UCLB only whether the reports are correct or not and the amount of any discrepancy. No other information shall be shared. UCLB shall treat all such financial information as Licensee's Confidential Information.

- (c) The Licensee shall ensure that UCLB has the same rights as those set out in this Clause 4.12 in respect of any person that is sub-licensed under the Patents or Know-how pursuant to this Agreement.

## 5. Commercialisation

- 5.1 *General diligence.* The Licensee shall use Diligent and Reasonable Efforts to develop and commercially exploit Licensed Products worldwide.

*Development Report.* Without prejudice to the generality of the Licensee's obligations under Clause 5.1, the Licensee shall provide at least annually to UCLB an updated, written Development Report that shall report on all activities conducted under this Agreement since the Commencement Date or the date of the previous Development Report provided under this Clause. Licensee shall also set out in the Development Report the past, current and projected activities taken or planned to be taken by the Licensee and its sub-licensees (if any) to bring Licensed Products to market and maximise the sale of Licensed Products in the Territory, provided that Licensee shall not be legally bound to take or achieve any actions set out in any such projections. UCLB's receipt or approval of any Development Report shall not be taken to waive or qualify the Licensee's obligations under Clause 5.1.

- 5.2 *Consequences of expert's decision.* If an arbitrator under Clause 9.10 determines that the Licensee has failed to comply with its obligations under Clause 5.1, and if the Licensee fails to cure such failure within [\*\*\*\*\*] months after such determination, UCLB shall be entitled, by giving, at any time within [\*\*\*\*\*] months after the end of that [\*\*\*\*\*] month period, not less than [\*\*\*\*\*] months notice to terminate this Agreement.

## 6. Intellectual property

- 6.1 *Obtain and maintain the Patents.*

UCLB shall have the right to control, at Licensee's cost and expense, the preparation, filing, prosecution and maintenance of all patents and patent applications within the Patents. Within [\*\*\*\*\*] months of the Commencement Date, UCLB and Licensee shall reasonably agree upon a budget for expenses incurred in connection with such preparation, filing, prosecution and maintenance of the Patents. UCLB and Licensee shall update said budget every [\*\*\*\*\*] year thereafter and shall use reasonable efforts to ensure that the actual costs incurred in connection



with such activities related to the Patents are within [\*\*\*\*\*] percent ([\*\*\*\*\*]%) of such budget for any given one (1) year period, unless the prior written agreement of the Licensee is obtained. UCLB shall provide Licensee with ample opportunity to review and comment on the text of each correspondence for which submission to any patent office is intended (including, without limitation, patent applications and responses to official actions) and shall supply Licensee with a copy of each such correspondence as filed and, in the case of a patent application, its filing date and serial number. UCLB shall consider and incorporate in good faith all of Licensee's reasonable comments and suggestions with respect to any such correspondence for which submission to any patent authority is intended. The Licensee shall, at its own cost and expense, co-operate with UCLB and its licensee(s) outside the Field and endeavour to obtain valid patents in the name of UCLB pursuant to each of the patent applications of the Patents so as to secure the broadest monopoly reasonably available consistent with prudent patent practices. In the event that UCLB wishes to abandon any such application or not to maintain any such Patent (or to cease funding such application or Patent) it shall give [\*\*\*\*\*] months prior written notice to Licensee so that Licensee may have the opportunity to assume control over such Patent at its own expense. In the event that either: (a) such Patent is ultimately abandoned by UCLB; or (b) Licensee assumes control over such Patent before the expiry of such notice period, then such Patent shall be deemed to be removed from the definition of Patents as provided for in this Agreement and Licensee shall have no continuing obligations to UCLB regarding Licensed Products based solely on such Patent

## 6.2 *Infringement of the Patents.*

- (a) Each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement of any of the Patents in the Field, and the Parties shall consult with each other to decide the best way to respond to such infringement.
- (b) If the Parties fail to agree on a joint programme of action, including how the costs of any such action are to be borne and how any damages or other sums received from such action are to be distributed, then the Licensee shall be entitled to take action against the third party at its sole expense, subject to the following provisions of this Clause 6.2.
- (c) Before starting any legal action under Clause 6.2(a), the Licensee shall consult with UCLB as to the advisability of the action or settlement, its effect on the good name of UCLB, the public interest, and how the action should be conducted.
- (d) If the alleged infringement is both within and outside the Field, the Parties shall also cooperate with UCLB's other licensees (if any) in relation to any such action.
- (e) The Licensee shall reimburse UCLB for any reasonable out-of-pocket expenses incurred in assisting the Licensee, at the request of the Licensee, in such action. The Licensee shall pay UCLB a portion of any damages received from such action, after deduction of both Parties reasonable expenses in relation to the action in accordance with the following:
  - (i) where the damages awarded are directly attributable to lost sales of Licensed Products, the amount of such damages will be treated as Net Sales Value and Licensee shall pay UCLB royalties on such damages in accordance with Clause 4.3; or

- (ii) where the damages awarded are not directly attributable to lost sales of Licensed Products, the amount of such damages will be treated as Net Receipts and Licensee shall pay UCLB a portion of such damages in accordance with Clause 4.4.
- (f) UCLB shall agree to be joined in any suit to enforce such rights subject to being indemnified and secured in a reasonable manner as to any costs, damages, expenses or other liability and shall have the right to be separately represented by its own counsel at its own expense.
- (g) If, within [\*\*\*\*\*] months after the Licensee receives written notice from UCLB of any actual, continuing and commercially significant infringement of the Patents, the Licensee is unsuccessful in persuading the alleged infringer to desist or fails to initiate an infringement action, UCLB shall have the right, at its sole discretion, to prosecute such infringement under its sole control and at its sole expense, and UCLB shall pay to Licensee a portion of any damages or other payments recovered from such action, after deduction of both Parties reasonable expenses in relation to the action, in accordance with the following:
  - (i) where the damages awarded are directly attributable to lost sales of Licensed Products, the amount of such damages will be treated as Net Sales Value, and UCLB shall pay the Licensee royalties on such damages in accordance with Clause 4.3; or
  - (ii) where the damages awarded are not directly attributable to lost sales of Licensed Product, the amount of such damages will be treated as Net Receipts and UCLB shall pay the Licensee a portion of such damages in accordance with Clause 4.4 (in such instances, and for purposes of this Section 6.2(g)(ii) only, Licensee shall be deemed to be UCLB in determining the amounts owed to Licensee in accordance with Clause 4.4).

### 6.3 *Infringement of third party rights.*

- (a) If any warning letter or other notice of infringement is received by a Party, or legal suit or other action is brought against a Party, alleging infringement of third party rights in the manufacture, use or sale of any Licensed Product or use of any Patents, that Party shall promptly provide full details to the other Party, and the Parties shall discuss the best way to respond.
- (b) The Licensee shall have the right but not the obligation to defend such suit to the extent it relates to activities in the Field and shall have the right to settle with such third party, provided that if any action or proposed settlement involves the making of any statement, express or implied, adversely affecting the validity of any Patent, the consent of UCLB (which shall not be unreasonably withheld or delayed) must be obtained before taking such action or making such settlement.

## 7. Warranties and liability

### 7.1 *Warranties by UCLB.* UCLB warrants that:

- (a) It is the registered proprietor of, or applicant for, the Patents and has caused all of its employees who are named as inventors on such Patents to execute such assignments of the Patents as may be necessary to pass all of their right, title and interest in and to the Patents to UCLB; and
- (b) UCLB is the sole owner of the Patents, and except as UCLB has expressly informed Licensee in writing prior to the date of this Agreement, has not granted to any third party any license or other interest in the Patents; and UCLB has not received written notice of any third party interest in the Know-how. UCLB has not received written notice of any third party patent, patent application or other intellectual property rights that would be infringed (i) by practicing any process or method or by making, using or selling any composition which is claimed or disclosed in the Patents or which constitutes Know-how, or (ii) by making, using or selling Licensed Products; and does not have actual knowledge of any infringement or misappropriation by a third party of the Patents and Know-how.

### 7.2 *Acknowledgements.* The Licensee acknowledges that:

- (a) The inventions claimed in the Patents, and the Know-how, are at an early stage of development. Accordingly, specific results cannot be guaranteed and any results, materials, information or other items (together “Delivered Items”) provided under this Agreement, except as otherwise set forth in Clause 7.1, are provided ‘as is’ and without any express or implied warranties, representations or undertakings. As examples, but without limiting the foregoing, UCLB does not give any warranty that Delivered Items are of merchantable or satisfactory quality, are fit for any particular purpose, comply with any sample or description, or are viable, uncontaminated, safe or non-toxic.
- (b) UCLB has not performed any searches or investigations into the existence of any third party rights that may affect any of the Patents or Know-how.

### 7.3 *No other warranties.*

- (a) Each of the Licensee and UCLB acknowledges that, in entering into this Agreement, it does not do so in reliance on any representation, warranty or other provision except as expressly provided in this Agreement, and any conditions, warranties or other terms implied by statute or common law are excluded from this Agreement to the fullest extent permitted by law.
- (b) Without limiting the scope of paragraph (a) above, UCLB does not make any representation nor give any warranty or undertaking:
  - (i) as to the efficacy or usefulness of the Patents or Know-how; or
  - (ii) as to the scope of any of the Patents or that any of the Patents is or will be valid or subsisting or (in the case of an application) will proceed to grant; or
  - (iii) except as set forth in Clause 7.1(b), that the use of any of the Patents or Know how, the manufacture, sale or use of the Licensed Products or the exercise of any of the rights granted under this Agreement will not infringe any other intellectual property or other rights of any other person; or

- (iv) that the Know-how or any other information communicated by UCLB to the Licensee under or in connection with this Agreement will produce Licensed Products of satisfactory quality or fit for the purpose for which the Licensee intended or that any product will not have any latent or other defects, whether or not discoverable; or
- (v) as imposing any obligation on UCLB to bring or prosecute actions or proceedings against third parties for infringement or to defend any action or proceedings for revocation of any of the Patents; or
- (vi) as imposing any liability on UCLB in the event that any third party supplies Licensed Products to customers located in the Territory.

7.4 *Responsibility for development of Licensed Products.* The Licensee shall be exclusively responsible for the technical and commercial development and manufacture of Licensed Products and for incorporating any modifications or developments thereto that may be necessary or desirable and for all Licensed Products sold or supplied, notwithstanding any consultancy services or other contributions that UCLB may provide in connection with such activities.

7.5 *Indemnity.* The Licensee shall indemnify UCLB and its Affiliates, and their respective officers, directors, Council members, employees and representatives, including the Principal Investigator (together, the "Indemnitees") against all Losses incurred as a result of any Claims that may be asserted against or suffered by any of the Indemnitees to the extent arising from:

- (a) the use by the Licensee or any of its sub-licensees of any of the Patents or Know-how; or
- (b) the development, manufacture, use, marketing or sale of, or any other dealing in, any of the Licensed Products, by Licensee or any of its sub-licensees, or subsequently by any customer or any other person, including claims based on product liability laws.

except in each case to the extent arising from the gross negligence or willful misconduct of any of the Indemnitees or the material breach of this Agreement by UCLB of any representation, or warranty given in clause 7.1.

7.6 *Limitation of Liability.*

- (a) To the extent that any Indemnitee has any liability in contract, tort, or otherwise under or in connection with this Agreement, including any liability for breach of warranty, their liability shall be limited in accordance with the following provisions of this Clause 7.6.
- (b) In no circumstances shall any of the Indemnitees or Licensee be liable for any loss, damage, costs or expenses of any nature whatsoever incurred or suffered that is (i) of an indirect, special or consequential nature, (ii) any loss of profits, revenue, business opportunity or goodwill, or (iii) for punitive damages.
- (c) Nothing in this Agreement excludes any person's liability to the extent that it may not be so excluded under applicable law, including any such liability for death or personal injury caused by that person's negligence, or liability for fraud.

7.7 *Warranties by Licensee.* Licensee warrants and undertakes that:

- (a) it shall not enter into an agreement with any other person with respect to the marketing or sale of any Competing Product without the prior written consent of UCLB; and
- (b) it shall not market or sell any Competing Product without the prior written consent of UCLB.

Nothing in this Agreement or this Section 7.7 shall be construed as limiting Licensee's ability to research or develop a Competing Product so long as such research or development: (i) does not occur within five (5) years following the Commencement Date; and (ii) does not utilize UCLB's Know-how.

**8. Duration and Termination**

8.1 *Commencement and Termination by Expiry.* This Agreement, and the licences granted hereunder, shall come into effect on the Commencement Date and, unless terminated earlier in accordance with this Clause 8, shall continue in force on a country by country basis until the expiration of Licensee's obligation to pay royalties hereunder. The license grant under Clause 2.1 shall be effective at all times prior to such expiration and following such expiration of this Agreement Licensee shall have a fully paid-up, non-exclusive license (a) under the Patents, with the right to sub-license through multiple tiers, to develop, manufacture, have manufactured, import, use, offer for sale and sell Licensed Products only in the Field in the Territory; and (b) to use the Know-how, with the right to sub-license through multiple tiers, to develop, manufacture, have manufactured, import, use, offer for sale and sell Licensed Products only in the Field in the Territory.

8.2 *Early termination.*

- (a) The Licensee may terminate this Agreement at any time on 30 days' notice in writing to UCLB.
- (b) Either Party may terminate this Agreement at any time by notice in writing to the other Party ("Other Party"), such notice to take effect as specified in the notice:
  - (i) if the Other Party is in material breach of this Agreement and, in the case of a breach capable of remedy within 90 days, the breach is not remedied within 90 days of the Other Party receiving notice specifying the breach and requiring its remedy; or
  - (ii) if: (A) the Other Party is declared by a court of competent jurisdiction to be insolvent or unable to pay its debts as and when they become due, (B) an order is made or a resolution is passed for the winding up of the Other Party (other than voluntarily for the purpose of solvent amalgamation or reconstruction), (C) a liquidator, administrator, administrative receiver, receiver or trustee is appointed in respect of the whole or any part of the Other Party's assets or business, (D) the Other Party makes any composition with its creditors, (E) the Other Party ceases to continue its business or (F) as a result of debt and/or maladministration the other Party takes or suffers any similar or analogous action.
- (c) UCLB may terminate this Agreement by giving written notice to the Licensee, such termination to take effect forthwith or as otherwise stated in the notice, if the Licensee or its Affiliate or sub-licensee commences legal proceedings, or assists any third party to

commence legal proceedings, to challenge the validity or ownership of any of the Patents, or markets or sells a Competing Product, either on its own, or with another person, without the prior written consent of UCLB.

- (d) A Party's right of termination under this Agreement, and the exercise of any such right, shall be without prejudice to any other right or remedy (including any right to claim damages) that such Party may have in the event of a breach of contract or other default by the other Party.

### 8.3 *Consequences of termination*

- (a) Upon termination of this Agreement for any reason otherwise than in accordance with Clause 8.1:
- (i) the Licensee and its sub-licensees shall be entitled to sell, use or otherwise dispose of (subject to payment of royalties under clause 4) any unsold or unused stocks of the Licensed Products for a period of 6 months following the date of termination;
  - (ii) subject to paragraph (i) above, the Licensee shall no longer be licensed to use or otherwise exploit in any way, either directly or indirectly, the Patents, in so far and for as long as any of the Patents remains in force, or the Know-how;
  - (iii) subject to paragraph (i) above, the Licensee shall consent to the cancellation of any formal licence granted to it, or of any registration of it in any register, in relation to any of the Patents;
  - (iv) each Party shall return to the other or, at the other Party's request, destroy any documents or other materials that are in its or its sub-licensees' possession or under its or its sub-licensees' control and that contain the other Party's Confidential Information in accordance with Clause 3.8; and
  - (v) subject as provided in this Clause 8.3, and except in respect of any accrued rights, neither Party shall be under any further obligation to the other.
- (b) Upon termination of this Agreement for any reason otherwise than in accordance with Clause 8.1 and at UCLB' request, the Parties shall negotiate in good faith the terms of an agreement between them on reasonable commercial terms under which the Licensee would:
- (i) transfer to UCLB exclusively all clinical and other data relating to the development of Licensed Products; and
  - (ii) to the extent possible, seek to have any product licences, pricing approvals and other permits and applications transferred into the name of UCLB or its nominee.
  - (iii) grant UCLB an exclusive, worldwide licence, within the Field, with the rights to grant sub-licences, under any improvements and other intellectual property owned or controlled by the Licensee at the time of such termination and relating to the Licensed Products; and

- (iv) grant UCLB or its nominee the right to continue to use any product name that had been applied to the Licensed Products prior to termination of this Agreement.
- (c) If the Parties are unable to agree terms in accordance with paragraph (b) above, either Party may refer the disagreement to arbitration in accordance with Clause 9.10. At the request of UCLB the Parties shall enter into an agreement on the terms specified by the arbitrator(s).
- (d) Upon termination of this Agreement for any reason the provisions of Clauses 2.3(e), 3.2 to 3.8, 4 (in respect of sales made prior to termination or under Clause 8.3(a)(i)), 7.5, 7.6, 8.3 and 9 shall remain in force.

## 9. General

- 9.1 *Force majeure.* Neither Party shall have any liability or be deemed to be in breach of this Agreement for any delays or failures in performance of this Agreement that result from circumstances beyond the reasonable control of that Party, including without limitation labour disputes involving that Party. The Party affected by such circumstances shall promptly notify the other Party in writing when such circumstances cause a delay or failure in performance and when they cease to do so.
- 9.2 *Amendment.* This Agreement may only be amended in writing signed by duly authorised representatives of UCLB and the Licensee.
- 9.3 *Assignment and third party rights.*
- (a) Subject to paragraph (b) below, neither Party shall assign, mortgage, charge or otherwise transfer any rights or obligations under this Agreement, nor any of the Patents or rights under the Patents, without the prior written consent of the other Party.
  - (b) Either Party may assign all its rights and obligations under this Agreement together with its rights in the Patents (i) to any Affiliate, or (ii) in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger, consolidation, change in control or similar transaction; PROVIDED that the assignee undertakes to the other Party to be bound by and perform the obligations of the assignor under this Agreement. However a Party shall not have such a right to assign this Agreement if it is insolvent or any other circumstance described in Clause 8.2(b)(ii) applies to it.
- 9.4 *Waiver.* No failure or delay on the part of either Party to exercise any right or remedy under this Agreement shall be construed or operate as a waiver thereof, nor shall any single or partial exercise of any right or remedy preclude the further exercise of such right or remedy.
- 9.5 *Invalid clauses.* If any provision or part of this Agreement is held to be invalid, amendments to this Agreement may be made by the addition or deletion of wording as appropriate to remove the invalid part or provision but other wise retain the provision and the other provisions of this Agreement to the maximum extent permissible under applicable law
- 9.6 *No Agency.* Neither Party shall act or describe itself as the agent of the other, nor shall it make or represent that it has authority to make any commitments on the other's behalf.

9.7 *Interpretation.* In this Agreement:

- (a) the headings are used for convenience only and shall not affect its interpretation;
- (b) references to persons shall include incorporated and unincorporated persons; references to the singular include the plural and vice versa; and references to the masculine include the feminine;
- (c) references to Clauses and Schedules mean clauses of, and schedules to, this Agreement;
- (d) references in this Agreement to termination shall include termination by expiry;
- (e) where the word “including” is used it shall be understood as meaning “including without limitation”.

9.8 *Notices.*

- (a) Any notice to be given under this Agreement shall be in writing and shall be sent by first class mail or air mail, or by fax (confirmed by first class mail or air mail) to the address of the relevant Party set out at the head of this Agreement, or to the relevant fax number set out below, or such other address or fax number as that Party may from time to time notify to the other Party in accordance with this Clause 9.8. The fax numbers of the Parties are as follows: [\*\*\*\*\*]
- (b) Notices sent as above shall be deemed to have been received three working days after the day of posting (in the case of inland first class mail), or seven working days after the date of posting (in the case of air mail), or on the next working day after transmission (in the case of fax messages, but only if a transmission report is generated by the sender’s fax machine recording a message from the recipient’s fax machine, confirming that the fax was sent to the number indicated above and confirming that all pages were successfully transmitted).

9.9 *Law and Jurisdiction.* The validity, construction and performance of this Agreement shall be governed by English law and shall be subject to the exclusive jurisdiction of the English courts to which the parties hereby submit, except that a Party may seek an interim injunction in any court of competent jurisdiction.

9.10 *Arbitration.*

- (a) Any dispute, controversy or claim initiated by either Party arising out of, resulting from or relating to this Agreement, or the performance by either Party of its obligations under this Agreement (other than (a) disputes, controversies or claims regarding the validity, enforceability, claim construction or infringement of any patent rights, or defenses to any of the foregoing, and (b) bona fide third party actions or proceedings filed or instituted in an action or proceeding by a third party against a Party), whether before or after termination of this Agreement, shall be finally resolved by binding arbitration. Whenever a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. Any such arbitration shall be conducted under the Rules of London Court of International Arbitration, in the English language, by a panel of three arbitrators appointed in accordance with such rules.



- (b) Subject to paragraph (c) below, any such arbitration shall be held in London, England. The arbitrators shall have the authority to grant specific performance and to allocate between the Parties the costs of arbitration in such equitable manner as they determine. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based upon such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Notwithstanding the foregoing, either Party shall have the right, without waiving any right or remedy available to such Party under this Agreement or otherwise, to seek and obtain from any court of competent jurisdiction any interim or provisional relief that is necessary or desirable to protect the rights or property of such Party, pending the selection of the arbitrators hereunder or pending the arbitrators' determination of any dispute, controversy or claim hereunder.
- (c) Upon the consent of each of the Parties (said consent not to be unreasonably delayed), a dispute under Clause 5.2 or 8.3 (c) shall be referred to arbitration in accordance with the Commercial Arbitration Rules of the American Arbitration Association (the "AAA") by a panel of one arbitrator (unless the Parties agree otherwise) appointed by the AAA and who is knowledgeable as to the subject matter of the dispute. The Parties agree that the MA Expedited Procedures shall apply to all arbitration proceedings under this Clause 9.10 (c). The arbitrator shall have the right to order discovery as he or she deems appropriate, and to order injunctive relief and the payment of legal fees, costs and other damages, excluding punitive damages. Judgment upon the award rendered by the arbitrator may be entered in any court having jurisdiction. Any arbitration conducted under this Agreement shall be conducted in London, England.
- 9.11 *Further action.* Each Party agrees to execute, acknowledge and deliver such further instruments, and do all further similar acts, as may be necessary or appropriate to carry out the purposes and intent of this Agreement.
- 9.12 *Announcements.* Except as otherwise set forth in this Agreement, neither Party shall make any press or other public announcement concerning any aspect of this Agreement, or make any use of the name of the other Party in connection with or in consequence of this Agreement, without the prior written consent of the other Party.
- 9.13 *Entire Agreement.* This Agreement, including its Schedules, sets out the entire agreement between the Parties relating to its subject matter and supersedes all prior oral or written agreements, arrangements or understandings between them relating to such subject matter. Subject to Clause 7.6(c), the Parties acknowledge that they are not relying on any representation, agreement, term or condition which is not set out in this Agreement.
- 9.14 *Third parties.* Except for the rights of the Indemnitees as provided in clause 7.5, who may in their own right enforce the provisions of that Clause, this Agreement does not create any right enforceable by any person who is not a party to it ('Third Party') under the Contracts (Rights of Third Parties) Act 1999, but this clause does not affect any right or remedy of a Third Party which exists or is available apart from that Act. The Parties may amend, renew, terminate or otherwise vary all or any of the provisions of this Agreement, including Clause 7.5, without the consent of the Indemnitees.

9.15 *Export Control Regulations.*

- (a) "Export Control Regulations" mean any United Nations trade sanctions or EU or UK legislation or regulation, from time to time in force, which impose arms embargoes or control the export of goods, technology or software, including weapons of mass destruction and arms, military, paramilitary and security equipment and dual-use items (items designed for civil use but which can be used for military purposes) and certain drugs and chemicals.
- (b) The Licensee shall ensure that, in using the Patents or Know-how and in selling Licensed Products, it shall not and nor shall its or its Affiliates employees or sub-contractors breach or compromise, directly or indirectly, compliance with any Export Control Regulations.

9.16 *Non-use of names and marking of Licensed Products*

- (a) The Licensee shall not use, and shall ensure that its Affiliates and sub-licensees do not use, the name, any adaptation of the name, any logo, trademark or other device of University College London, UCLB, nor of the inventors of the Patents nor the Principal Investigator in any advertising, promotional or sales materials without prior written consent obtained from UCLB in each case, except that Licensee may state that it is licensed by UCLB under the Patents.
- (b) To the extent commercially feasible the Licensee shall mark and cause its Affiliates and Sub-Licensees to mark each Licensed Product with the number of each issued Patent which applies to the Licensed Product.

9.17 *Insurance.* Without limiting its liabilities under clause 7, the Licensee shall take out with a reputable insurance company and maintain at all times during the term of this Agreement public and product liability insurance including against all loss of and damage to property (whether real, personal or intellectual) and injury to persons including death arising out of or in connection with this Agreement and the Licensee's and its Affiliates' and sub-licensees' use of the Patents or Know-how and use, sale of or any other dealing in any of the Licensed Products. Such insurances may be limited in respect of one claim provided that such limit must be at least \$[\*\*\*\*\*]. Product liability insurance shall continue to be maintained for a further [\*\*\*\*\*] years from the end of the term of this Agreement.

**Agreed by the Parties through their authorised signatories:**

For and on behalf of  
**UCL Business PLC**

/s/ Anne Lane  
signed

Anne Lane, M.D.  
print name

Executive Director  
title

2/11/07  
date

For and on behalf of  
**Coronado Biosciences, Inc.**

/s/ Raymond J. Tesi  
signed

Raymond J. Tesi, M.D.  
print name

President and CEO  
title

11/11/07  
date

Schedule 1

*Part A: The Patents*

Patent Application [\*\*\*\*\*] filing date [\*\*\*\*\*] and the refilled patent application [\*\*\*\*\*] filing date [\*\*\*\*\*] both entitled “[\*\*\*\*\*]” and any derivatives thereof. Said patent application entered national phase in at least the following regions: [\*\*\*\*\*].

*Part B: The Know-how*

**Tumour-activated human NK cells — potential for “off-the-shelf” immunotherapy.**  
Mark W. Lowdell, Dept of Haematology, Royal Free & UCL Medical School, London, UK.

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References:

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Testi R, D'Ambrosio, R De Maria, A Santoni. 1994. The CD69 receptor: a multipurpose cell surface trigger for hematopoietic cells. Immunol. Today. 15:479-83.

Schedule 2

The Press Release

**CONFIDENTIAL TREATMENT REQUESTED.  
 INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN  
 REQUESTED IS OMITTED AND MARKED WITH “[\*\*\*\*\*]” OR OTHERWISE  
 CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS  
 ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

<b>SERVICE PROVIDER:</b>	• PROGENITOR CELL THERAPY, LLC
<b>SERVICE PROVIDER CONTACT:</b>	• Robert A. Preti, Ph. D.
<b>CORONADO CONTACT:</b>	• Elizabeth Moore, SVP Regulatory Affairs
<b>EFFECTIVE DATE:</b>	• As of April 1, 2010

**MASTER CONTRACT SERVICES AGREEMENT**

**THIS MASTER CONTRACT SERVICES AGREEMENT** (the “Master Contract Services Agreement”) is made as of the Effective Date set forth above by and between Coronado Biosciences, Inc , a Delaware company with an office at 1700 Seventh Avenue, Seattle, WA 98101 (“CORONADO”) and Progenitor Cell Therapy, LLC, a Delaware limited liability company, with a principal office at 4 Pearl Court, Suite C, Allendale, NJ 07401 (the “Service Provider”) (the Master Contract Services Agreement, together with any Statement(s) of Work (as defined below), all Appendixes attached hereto, is collectively referred to as the “Agreement”). Terms not otherwise defined will have the meaning set forth for such term in Appendix B attached hereto, made a part hereof and incorporated herein by reference.

**1. Agreement Structure.** From time to time, CORONADO may want the Service Provider to provide certain consulting, preclinical, laboratory and/or clinical research-related services, product/process development services, manufacturing services and other services as mutually agreed by the parties, in writing (collectively, the “Services”). This Agreement contains general terms and conditions under which CORONADO would engage the Service Provider and under which the Service Provider would provide Services. CORONADO and the Service Provider must complete and execute a work order, project order or statement of work (“Statement of Work”) before any Services are provided. Each Statement of Work will include, at a minimum, the information relating to the specific Services outlined in the sample Statement of Work attached as **Appendix A**. However, neither CORONADO nor the Service Provider is obligated to execute any Statement of Work. Once executed, a Statement of Work becomes part of this Agreement, although the terms in a Statement of Work will govern only Services described in that Statement of Work.

**2. About the Services.**

**2.1 Provision of Services.** The Service Provider agrees to provide all Services identified in any Statement of Work: (a) in the manner and time provided in such Statement of Work and (b) in accordance with the current state of the FDA’s current GMPs when applicable to do so. Subject to the next succeeding sentences; Service Provider will also comply, in all material respects, with Applicable Laws concerning current GMPs in effect as of the Effective Date appropriate to the Services. Should such Applicable Laws be changed, Service Provider will make all commercially reasonable efforts to satisfy the new requirements. However, in the event that compliance with such new Applicable Laws necessitates a change in the Services, Service Provider will submit a proposed Statement of Work to CORONADO reflecting revised technical and cost proposals for CORONADO’s acceptance prior to making any changes in the Services. In the event of a conflict in Applicable Laws, CORONADO will designate, in writing, which regulations shall be followed by Service Provider in its performance of the Services. For each Statement of Work, Service Provider will designate a “Project Leader” who will be available for frequent communications with CORONADO regarding the Services provided under that Statement of Work. CORONADO will designate a “Representative” who will be the point of contact for the Project Leader. In the event either party fails to designate a Project Leader or Representative in the applicable Statement of Work, the Service Provider Contact shall be the Project Leader and the CORONADO Contact shall be the Representative.

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**2.2 Intentionally Omitted.**

**2.3 Audits.** Upon [\*\*\*\*\*] day written notice by CORONADO to Service Provider, Service Provider will allow CORONADO employees and representatives, and representatives of regulatory agencies, during normal business hours, to conduct a GMP compliance audit at Service Provider's facilities used to render the Services under the applicable Statement of Work [\*\*\*\*\*] during each [\*\*\*\*\*] month period (with the initial [\*\*\*\*\*] month period commencing with the Effective Date), which audit will be at [\*\*\*\*\*] cost and expense. In addition, at [\*\*\*\*\*] cost and expense, as reasonably requested by either party, the Project Leader and Representative and their designees shall participate in meetings at Service Provider's facilities as reasonably determined by Service Provider or elsewhere as the parties mutually agree to review performance of the Services and to coordinate such Services as necessary.

**2.4 Data Verification and Reports.** As provided in the applicable Statement of Work, a copy of all raw data, databases and analytical reports of the data will be provided to CORONADO in Service Provider's standard format. Service Provider will verify the accuracy of the data contained in all databases and/or reports provided by it against the raw data and will attach a signed statement attesting to such verification to each database and/or report provided to CORONADO.

**2.5 Standard Operating Procedures.** As required by any Statement of Work, Service Provider will supply copies to CORONADO of all standard operating procedures of Service Provider relevant to the Services under a Statement of Work, all at CORONADO's sole cost and expense.

**2.6 Regulatory Contacts.** CORONADO will be solely responsible for all contacts and communications with any regulatory authorities with respect to matters relating to any of the Services. Unless required by applicable law, Service Provider will have no contact or communication with any regulatory authority regarding any Services without the prior written consent of CORONADO, which consent will not be unreasonably withheld. Each party will notify the other promptly after such party receives any contact or communication from any regulatory authority relating in to the Services and will provide the notified party with copies of any such communication. Each party will consult with the other party regarding the response to any inquiry or observation from any regulatory authority relating to the Services.

3. **Representations by Service Provider.** The Service Provider makes the following representations, warranties and covenants:

**3.1 Organization of Service Provider.** Service Provider is and will remain a limited liability company duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

**3.2 Enforceability of this Agreement.** The execution and delivery of this Agreement has been authorized by all requisite company action. This Agreement is and will remain a valid and binding obligation of Service Provider, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

**3.3 Absence of Other Contractual Restrictions.** Service Provider is under no contractual or other obligation or restriction that is inconsistent with Service Provider's execution or performance of this Agreement.

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- 3.4 Qualifications of Service Provider Personnel.** Service Provider has, and will engage, employees, subcontractors and/or consultants (“Service Provider Personnel”) with the proper skill, training and experience to provide the Services. Service Provider will be solely responsible for paying Service Provider Personnel and providing any employee or other benefits that they are owed.
- 3.5 Legal Compliance.** Service Provider will comply, in all material respects, with all federal and state laws, regulations and orders applicable to its operations. If specified in a Statement of Work, Services will be rendered in accordance with applicable Good Laboratory Practices (GLP) and/or Good Clinical Practices (GCP).
- 3.6 Conflicts with Rights of Third Parties.** Without conducting any due diligence, to Service Provider’s knowledge, the conduct and provision of the Services will not violate any patent, trade secret or other proprietary or intellectual property right of any third party.
- 3.7 Absence of Debarment.** Neither Service Provider nor any Service Provider Personnel performing Services under this Agreement (i) has been debarred, and (ii) to the best of Service Provider’s knowledge, is under consideration to be debarred, by the FDA from working in or providing services to any pharmaceutical or biotechnology company under the Generic Drug Enforcement Act of 1992.
4. **Compensation.** See Appendix C. Appendix C is attached hereto, made a part hereof and incorporated herein by reference.
5. **Proprietary Rights.**
- 5.1 Materials.** All Confidential Information (as defined in Section 6.1 as set forth in Appendix C) and biological, chemical or other materials controlled by CORONADO and furnished to Service Provider (collectively, the “Materials”) and all associated intellectual property rights will remain the exclusive property of CORONADO. Service Provider will use the Materials as reasonably necessary, as determined by Service Provider, to perform the Services. Service Provider agrees that it shall not use or evaluate such Materials or any portions thereof for any purpose other than in accordance with this Agreement and any Statement of Work or as advised or directed by CORONADO.
- 5.2 Intellectual Property.** 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 Service Provider (the “Intellectual Property”) will be owned solely and exclusively by and assigned to CORONADO. Service Provider will, at CORONADO’s cost and expense, make reasonable commercial business efforts to cooperate with and assist CORONADO or its nominees in all reasonable ways and at all reasonable times, including, but not limited to, testifying in all legal proceedings, signing all lawful papers and in general performing all lawful acts reasonably necessary or proper, to aid CORONADO in obtaining, maintaining, defending and enforcing all lawful patent, copyright, trade secret, know-how and the like in the United States and elsewhere for Intellectual Property. Notwithstanding the preceding, any process or process improvement, inventions or discoveries, including related patent rights, made by Service Provider which Service Provider utilizes in connection with services provided to its clients, in general, including in connection with the Services provided to CORONADO (“Service Provider Intellectual Property”) will be owned solely and exclusively by Service Provider and not be assigned to CORONADO. However, Service Provider hereby grants to



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CORONADO a fully paid-up, irrevocable, worldwide license to use any Service Provider Intellectual Property for purposes of developing and commercializing products relating to the Services being provided hereunder. Any such process or process improvement, inventions or discoveries and related patent rights which are made jointly by the parties shall be owned jointly by the parties. Service Provider shall maintain such information and communications in confidence as Confidential Information. Nothing contained herein shall be construed to grant to Service Provider any rights to technology or any license to product resulting from the Services performed by Service Provider under the Agreement and each Statement of Work under any patent, copyright or trademark now or hereinafter in existence except for the limited purposes set forth herein. CORONADO will be free to use all Intellectual Property for any and all purposes. Service Provider will retain ownership of any pre-existing products, materials, tools, methodologies, technologies and Service Provider Intellectual Property (collectively, "Service Provider Technology"). Service Provider agrees not to incorporate any Service Provider Technology into Intellectual Property that would prevent CORONADO from using its Intellectual Property for any and all purposes.

**5.3 Intentionally Omitted.**

**5.4 Records; Records Storage.** Service Provider will maintain all written materials and all other data and documentation obtained or generated by Service Provider in the course of preparing for and providing Services hereunder, including all computerized records and files (the "Records").

**5.5 Record Retention.** Upon written instruction of CORONADO and at CORONADO's cost and expense (which will include reimbursing Service Provider for Service Provider's time using an hourly fee for its employees or representatives equal to the then internal fully burdened costs to Service Provider for such employee or representative) all Records will, at CORONADO's option either be (a) delivered to CORONADO or to its designee in such form as is then currently in the possession of Service Provider, (b) retained by Service Provider for a period of [\*\*\*\*\*] years, or as otherwise required under Applicable Law or regulation, or (c) disposed of, at the direction and written request of CORONADO, unless such Records are otherwise required to be stored or maintained by Service Provider as a matter of Applicable Law. In no event will Service Provider dispose of any such Records without first giving CORONADO [\*\*\*\*\*] days prior written notice of its intent to do so. Service Provider may, however, retain copies of any Records as Service Provider reasonably determines is necessary for regulatory or insurance purposes, subject to Service Provider's obligation of confidentiality.

6. **Confidential Information.** See Appendix C.

7. **Indemnification and Insurance.** See Appendix C.

8. **Expiration and Termination.**

**8.1 Expiration.** This Agreement will expire on the completion of all Services provided in the Statement(s) of Work executed by the parties. The Agreement may be extended by mutual agreement of the parties pursuant to a Statement of Work or earlier terminated in accordance with Section 8.2 or 8.3 below.

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## 8.2 Termination by CORONADO.

- (a) If Service Provider is in default of its material obligations under the Master Contract Services Agreement or any Statement of Work (the Master Contract Services Agreement as it incorporates any one Statement of Work, is referred to herein as the "Applicable Services Agreement"), CORONADO shall promptly notify Service Provider, in writing, either by certified mail, return receipt requested or by a national overnight courier service ("Written Notice") of such material default under the Applicable Services Agreement. Service Provider shall have a period of forty-five (45) days from the date of its receipt of the Written Notice relating to a particular Applicable Services Agreement within which to cure such default. If Service Provider shall fail to cure the default of such Applicable Services Agreement within the specified cure period, then the Applicable Services Agreement shall, at CORONADO's option, terminate upon delivery to Service Provider of a Written Notice of termination. Upon Service Provider's receipt of the termination notice of the Applicable Services Agreement, Service Provider shall comply with such notice to terminate all Services under the Applicable Services Agreement and use commercially reasonable efforts to reduce costs to the CORONADO.
- (b) CORONADO, at its option, may terminate any one or more Applicable Services Agreement without cause upon providing no less than sixty (60) days Written Notice to Service Provider of Service Provider's intent to terminate one or more Applicable Services Agreement(s) with the termination date of the Applicable Services Agreement to occur on the last day of the month following the expiration of the sixty (60) day notice period set forth in the Written Notice terminating such Applicable Services Agreement.

**8.3 Termination by Service Provider.** If CORONADO is in default of any of its material obligations under any Applicable Services Agreement, Service Provider shall promptly notify CORONADO, in writing, by Written Notice of such default under the Applicable Services Agreement. CORONADO shall have a period of thirty (30) days from the date of receipt of such Written Notice of the default under the Applicable Services Agreement within which to cure such default. If CORONADO shall fail to cure the default of such Applicable Services Agreement within the specified cure period, then, at Service Provider's option, Service Provider may terminate the Agreement or any or all of the Applicable Service Agreements upon delivery to CORONADO of a Written Notice of termination of the Agreement or, if applicable, the Applicable Services Agreement Service Provider is terminating.

## 8.4 Effect of Termination or Expiration.

- (a) In the event of termination of the Agreement or, if applicable, any Applicable Services Agreement, CORONADO shall pay for the Services performed and any costs and expenses incurred by Service Provider prior to the date of termination of the Agreement or, if applicable, the Applicable Services Agreement.
- (b) CORONADO shall pay for any costs, expenses and pass through costs and expenses which Service Provider is irrevocably obligated to pay after the termination of the Agreement or, if applicable, the Applicable Services Agreement, (provided such irrevocable obligations were incurred prior to its receipt of Written Notice of termination of the Agreement or, if applicable, the Applicable Services Agreement).
- (c) It is understood that the parties intend to discuss, pursuant to the provisions of this Section, any alleged default and its remediation as soon as it is known, and that such discussion shall not be a waiver of the right to terminate pursuant to this Agreement. For purposes of this Section 8: (i) a "default of its material obligations" shall be defined as a breach by a party

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that directly caused a significant delay or obstacle that prevented the non-breaching party from achieving a material goal or objective as contemplated under the Agreement or, if applicable, the Applicable Services Agreement, and shall also include a failure by CORONADO to pay Service Provider any amounts set forth in Section 4 and the related Statements of Work when due and (ii) no default that is caused or contributed to by the non-breaching party or Force Majeure shall constitute a “default of its material obligations”.

- (d) The Agreement may be automatically and immediately terminated by either party, upon providing Written Notice to the other party of the termination of the Agreement, if the other party has a liquidator, receiver, manager, receiver or administrator appointed, or ceases to continue trading or is unable to pay debts.
- (e) The termination of the Agreement or, if applicable, any Applicable Services Agreement, for any reason shall not relieve either party of its obligation to the other that expressly survive the termination of the Agreement or, if applicable, the Applicable Services Agreement.
- (f) Notwithstanding anything herein to the contrary, UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE ENTITLED TO INCIDENTAL, INDIRECT, CONSEQUENTIAL OR SPECIAL DAMAGES ARISING IN CONNECTION WITH THE DEFAULT OR BREACH OF ANY OBLIGATION OF THE OTHER PARTY UNDER THE AGREEMENT OR ANY APPLICABLE SERVICES AGREEMENT, THE SCOPE OR ANY DOCUMENTS OR APPENDIXES RELATED THERETO.

9. **Miscellaneous.**

- 9.1 Independent Contractor.** All Services will be rendered by Service Provider as an independent contractor and this Agreement does not create an employer-employee relationship between CORONADO and Service Provider. Service Provider shall not in any way represent itself to be a partner or joint venturer of or with CORONADO.
- 9.2 Publicity.** Neither party may use the other party’s name in any form of advertising, promotion or publicity, including press releases, without the prior written consent of the other party. This term does not restrict a party’s ability to use the other party’s name in filings with the Securities and Exchange Commission, FDA, any patent office, or other governmental or regulatory agencies, when required to do so.
- 9.3 Notices.** Except where Written Notice is expressly required in the Agreement and Appendix C, all notices required or permitted under this Agreement must be written and sent to the address or facsimile number identified in this Agreement or a subsequent notice. All notices must be given (a) by personal delivery, with receipt acknowledged, (b) by facsimile followed by hard copy delivered by the methods under (c) or (d), (c) by prepaid certified or registered mail, return receipt requested, or (d) by prepaid recognized next business day delivery service. Notices will be effective upon receipt or as stated in the notice. Notices to CORONADO must be marked “Attention: Elizabeth Moore, SVP, Regulatory Affairs”. Notices to Service Provider must be marked “Attention: George S Goldberger, Chief Business Officer”.
- 9.4 Assignment.** Neither this Agreement nor any Applicable Services Agreement may be assigned in whole or in part by either party without the prior written consent of the other party, which consent shall not be unreasonably withheld or delayed, except CORONADO may assign this Agreement without Service Provider’s consent in the event of a merger, acquisition, or transfer of all of its assets related to this Agreement to a third party that is not an Affiliate of

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CORONADO, provided further that such assignee, in the reasonable opinion of Service Provider has financial resources and financial strength comparable to CORONADO's as of the Effective Date. Any attempt to assign this Agreement or any Applicable Services Agreement without such consent, where required, shall be void and of no effect subject to the limitations on assignment herein. This Agreement shall be binding upon and inure to the benefit of the successors and assigns of the parties hereto. No assignment will relieve either party of the performance of any accrued obligation that such party may then have under this Agreement.

- 9.5 Entire Agreement.** This Agreement constitutes the entire agreement of the parties with regard to its subject matter, and supersedes all previous written or oral representations, agreements and understandings between CORONADO and Service Provider. In the event of any conflict, discrepancy, or inconsistency between this Agreement and any Statement of Work, the terms of the Statement of Work will control. The execution of a Statement of Work by one party which is not executed by the other party shall not be deemed an agreement or evidence against the party executing the Statement of Work as to the intent of the parties at the time of the first party's execution of the Statement of Work.
- 9.6 No Modification.** This Agreement and/or any Statement of Work may be changed only by a Statement of Work signed by authorized representatives of both parties.
- 9.7 Severability; Reformation.** Each and every provision set forth in this Agreement is independent and severable from the others, and no restriction will be rendered unenforceable by virtue of the fact that, for any reason, any other or others of them may be invalid or unenforceable in whole or in part. If any provision of this Agreement or any Statement of Work is invalid or unenforceable for any reason whatsoever, that provision will be appropriately limited and reformed to the maximum extent provided by applicable law. If the scope of any restriction contained herein is too broad to permit enforcement to its full extent, then such restriction will be enforced to the maximum extent permitted by law so as to be judged reasonable and enforceable.
- 9.8 Governing Law; Jurisdiction; Service of Process.** The Agreement, the Quality Agreement and all Statement(s) of Work shall be governed by the laws of the State of New York, without reference to choice or conflict of law principles, otherwise applicable. The parties consent and agree that any legal action or proceeding against either party or any of their property with respect to any matter arising under or relating to this Agreement, the Quality Agreement and all Statements of Work may be brought in any court of the City and State of New York or any Federal Court of the United States of America located in the City and State of New York as Service Provider may elect. By execution and delivery of the Agreement, both CORONADO and Service Provider each hereby submits to and accepts with regard to any such action or proceeding, for itself and in respect of its property, generally and unconditionally, the jurisdiction of the aforesaid courts. By execution and delivery of the Agreement, both CORONADO and Service Provider further irrevocably consents to the service of process in any such action or proceeding by the mailing of copies thereof by registered or certified mail, postage prepaid, in the case of the Service Provider, to the attention of the Service Provider Contact at its address set forth at the beginning of the Agreement and, in the case of CORONADO, to the attention of the CORONADO Contact at its address set forth at the beginning of the Agreement. CORONADO and Service Provider each hereby irrevocably waives any objection which it may now or hereafter have to the laying of the venue of any suit, action or proceeding arising out of or relating to this Agreement, the Quality Agreement and each Statement of Work, and each hereby further irrevocably waives any claim that the State of New York is not a convenient forum for any such suit, action or proceeding.

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- 9.9 Waiver.** No waiver of any term, provision or condition of this Agreement (whether by conduct or otherwise) in any one or more instances will be deemed to be or construed as a further or continuing waiver of any such term, provision or condition of this Agreement.
- 9.10 Counterparts.** This Agreement and each Statement of Work may be executed in any number of counterparts, each of which will be deemed to be an original and all of which together will constitute one and the same instrument.
- 9.11 Headings.** This Agreement contains headings only for convenience and the headings do not constitute or form a part of this Agreement, and should not be used in the construction of this Agreement.
- 9.12 WAIVER OF JURY TRIAL. SERVICE PROVIDER AND CORONADO WAIVE ANY RIGHTS THEY MAY HAVE TO A TRIAL BY JURY OF ANY DISPUTE ARISING UNDER OR RELATING TO THIS AGREEMENT, THE QUALITY AGREEMENT AND EACH STATEMENT OF WORK. SERVICE PROVIDER AND CORONADO AGREE THAT ANY SUCH DISPUTE SHALL BE TRIED BEFORE A JUDGE SITTING WITHOUT A JURY.**

**IN WITNESS WHEREOF**, the parties have caused this Agreement to be executed by their duly authorized representatives as of the Effective Date.

**CORONADO BIOSCIENCES, INC**

**PROGENITOR CELL THERAPY, LLC**

By /s/ Raymond J. Tesi

By /s/ Robert A. Preti

Name Raymond J. Tesi, M.D.

Name Robert A. Preti, Ph.D.

Title: President and CEO

Title President and CSO

APPENDIX A

STATEMENT OF WORK NO.: \_\_\_\_\_-PAO-\_\_\_\_\_

Project Title and Number: (CORONADO BIOSCIENCES) \_\_\_\_\_

THIS STATEMENT OF WORK (the "Statement of Work") dated \_\_\_\_\_, 20\_\_ (the "Statement of Work Effective Date") is by and between Coronado BioSciences, INC ("CORONADO") and Progenitor Cell Therapy, LLC (the "Service Provider"). Upon execution of this Statement of Work, the Statement of Work will incorporate by reference the Master Contract Services Agreement (the "Master Contract Services Agreement") between CORONADO and Service Provider having an Effective Date of March \_\_, 2010 (this Statement of Work as it incorporates by reference the Master Contract Services Agreement, the "Agreement"). Capitalized terms in this Statement of Work and not otherwise defined herein will have the same meaning as set forth in the Master Contract Services Agreement.

CORONADO hereby engages Service Provider to provide Services, as follows:

1. **Services.** Service Provider will render to CORONADO the following Services:  
*Describe specific Service to be provided including all Deliverables.*
2. **Materials.** CORONADO will provide to Service Provider the following Materials for the Services:  
*Describe specific materials being provided by CORONADO.*
3. **Completion.** The Services will be completed as provided in this Statement of Work.
4. **Service Provider Project Leader.** *Name and Title*
5. **CORONADO Contact.** *Name and Title*
6. **Compensation.** The Price due Service Provider for Services under for the Services described in this Statement of Work is set forth below.
7. **Other:**

Except as modified by this Statement of Work, all other terms and conditions of the Agreement will apply to this Statement of Work.

This Statement of Work shall become effective when each of the parties have duly executed the same copy or counterpart copies of this Statement of Work and be deemed effective as of the Statement of Work Effective Date set forth above. Except as specifically amended and modified by this Statement of Work, the Agreement is and shall continue to be in full force and effect and is hereby in all respects ratified and confirmed.

CORONADO BIOSCIENCES, INC

PROGENITOR CELL THERAPY, LLC

By \_\_\_\_\_

By \_\_\_\_\_

Name \_\_\_\_\_

Name \_\_\_\_\_

Title: \_\_\_\_\_

Title: \_\_\_\_\_

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**APPENDIX B**

**DEFINITIONS**

The following terms shall have the following meanings:

<b>Affiliate</b>	With respect to any person or entity, another person or entity that directly, or indirectly through one or more intermediaries, Controls or is Controlled by or is under common Control with the person or entity specified.
<b>Agreement</b>	Has the meaning set forth in the opening paragraph of the Master Contract Services Agreement.
<b>Applicable Laws</b>	All laws, ordinances, rules, orders and regulations of any state, federal or local governmental or regulatory authority of the United States that governs the Services.
<b>Applicable Services Agreement</b>	Has the meaning set forth in Section 8.2(a) of the Master Contract Services Agreement.
<b>Control</b>	The possession, directly or indirectly, of the power to direct or cause the direction of the management or policies of a person or entity, whether through the ability to exercise voting power, by contract or otherwise. "Controlled" has the meaning correlative thereto.
<b>Coronado</b>	Has the meaning set forth in the opening paragraph of the Master Contract Services Agreement.
<b>FDA</b>	The United States Food and Drug Administration, or any successor agency thereto.
<b>Force Majeure</b>	Any cause beyond the reasonable control of the party in question which for the avoidance of doubt and without prejudice to the generality of the foregoing includes governmental actions, war, riots, terrorism, civil commotion, fire, flood, epidemic, labor disputes (excluding labor disputes involving the work force or any part thereof of the party in question), restraints or delays affecting shipping or carriers, and act of God.
<b>GMP</b>	Current Good Manufacturing Practice regulations, as set forth in the United States Code of Federal Regulations Title 21 (21 C.F.R. §§ 210 and 211), in effect as of the Effective Date.
<b>Intellectual Property</b>	Has the meaning set forth in Section 5.2 of the Master Contract Services Agreement.
<b>Materials</b>	Has the meaning set forth in Section 5.1 of the Master Contract Services Agreement.
<b>Records</b>	Has the meaning set forth in Section 5.4 of the Master Contract Services Agreement.

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<b>Service Provider</b>	Has the meaning set forth in the opening paragraph of the Master Contract Services Agreement.
<b>Service Provider</b>	Has the meaning set forth in Section 5.2 of the Master Contract Services Agreement.
<b>Intellectual Property</b>	
<b>Service Provider</b>	Has the meaning set forth in Section 3.4 of the Master Contract Services Agreement.
<b>Personnel</b>	
<b>Service Provider</b>	Has the meaning set forth in Section 5.2 of the Master Contract Services Agreement.
<b>Technology</b>	
<b>Services</b>	Has the meaning set forth in the opening paragraph of the Master Contract Services Agreement.
<b>Statement of Work</b>	Has the meaning set forth in the opening paragraph of the Master Contract Services Agreement.
<b>Written Notice</b>	Has the meaning set forth in Section 8.2(a) of the Master Contract Services Agreement.



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## APPENDIX C

### ADDITIONAL TERMS AND PROVISIONS

Reference is made to the Master Contract Services Agreement having an Effective Date as of April 1, 2010 (the "Master Contract Services Agreement") between Progenitor Cell Therapy, LLC ("Service Provider") and Coronado Biosciences, Inc. ("CORONADO").

The parties agree that the terms and provisions set forth in this Appendix C supersede any contrary provisions contained in the Master Contract Services Agreement and in the event of a conflict between the terms and provisions of the Master Contract Services Agreement and the terms and provisions of this Appendix C (and except as may be set forth in any Statement of Work between the parties), the terms and provisions contained in this Appendix C shall control.

The parties agree that the terms and provisions of this Appendix C are incorporated by reference into the Master Contract Services Agreement as if such terms and provisions were set forth therein and that such terms and provisions of this Appendix C are an integral part of the Agreement (as defined in the Master Contract Services Agreement). Terms not defined in this Appendix C shall have the meaning provided for such term in Appendix B attached to the Master Contract Services Agreement which Appendix B is incorporated by reference into the Master Contract Services Agreement and is an integral part thereof.

#### 1. Quality Agreement.

(a) The parties agree that based upon the Services to be provided (as set forth in each particular Statement of Work), within [\*\*\*\*\*] days after Service Provider's request for a Quality Agreement, the parties, using their best respective efforts, agree to negotiate and execute a Quality Agreement which shall be in form and substance reasonably satisfactory to each party. The Quality Agreement will define the responsibilities of the respective party for compliance with applicable GMP for the manufacture, storage and shipping services for the production of product resulting from the Services set forth in the applicable Statement of Work for clinical and/or commercial purposes. Service Provider is to be responsible for compliance with all applicable requirements while the product resulting from the Services described in the particular Statement of Work is under the direct control of the Service Provider and CORONADO is to be responsible for compliance with all applicable requirements while the product resulting from the Services described in such Statement of Work is under the direct control of CORONADO. The parties agree that the failure of the parties to execute a Quality Agreement will not be deemed a default under the Applicable Services Agreement nor will the failure to execute a Quality Agreement be the basis of a termination of this Agreement or any Applicable Services Agreement.

(b) Either Service Provider or CORONADO, as provided in the Quality Agreement, will bear the upfront costs of any investigation into the cause(s) for any Product Failure (as defined in the Quality Agreement) as required by the provisions of the Quality Agreement. If a Quality Agreement is not entered into between the parties, CORONADO shall be responsible for such costs. Following the investigation's completion, the parties agree to retrospectively share the costs of such investigation in a manner equal to the share of responsibility the parties agree should be assigned to each party based on the investigation's conclusions and to the extent either party, as applicable, can and does provide evidence of the costs of such investigation. If the parties cannot agree as to apportionment of the costs of the investigation, the parties, within [\*\*\*\*\*] days of the determination by either party that a resolution cannot be reached, shall

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appoint a third party that is not an Affiliate of either party, to whom they both agree, to review the results of the investigation and apportion liability for the costs of the investigation between the parties based on a root cause analysis. If the parties cannot agree upon a single third party, then each party shall appoint a third party that is not an Affiliate of either party and such third party shall appoint a third party that is not an Affiliate of either party. The three third parties shall review the results of the investigation and apportion liability for the costs of the investigation between the parties based on a root cause analysis. The parties agree to be bound by the third party(ies)'s ruling and to apportion the cost of the third party(ies) between the parties based on the same root cause analysis outlined above.

2. The parties agree that Section 4 (Compensation) contained in the Master Contract Services Agreement is deleted in its entirety and the below sections relating to Pricing and Payments are inserted in lieu thereof:

#### **“4. Pricing and Payments**

**4.1 Pricing.** The amount to be charged by Service Provider for the Services described in a particular Statement of Work shall be set forth in such applicable Statement of Work (the “Price”). The Price shall become due after CORONADO’s receipt of the applicable invoice, all as specified in Section 4.2 below.

**4.2 Invoices and Payment.** Service Provider shall provide monthly invoices to CORONADO, in paper form, sent to the address set forth at the beginning of the Master Contract Services Agreement or to such other address as instructed by CORONADO in writing to the Service Provider. CORONADO agrees that all payments owed to Service Provider pursuant to the Agreement and in any Statement of Work are due no later than [\*\*\*\*\*] days after the due date (as the Price may be expressly set forth in any Statement of Work) or no later than [\*\*\*\*\*] days after the date of invoice (for all other costs and expenses). All payments due under the Agreement and any Statement of Work shall be made in United States Dollars. CORONADO acknowledges and agrees that CORONADO shall pay the Price expressly set forth in any Statement of Work at the times set forth in such Statement of Work.

**4.3 Late Payments.** In the event any payment due to Service Provider is not received by Service Provider when due under Section 4.2 above, the overdue amount shall incur a charge at the rate of [\*\*\*\*\*] percent ([\*\*\*\*\*]%) per month, or the maximum allowed by law, whichever is less; commencing from the date such payment was originally due until such payment is paid in full.

**4.4 Reimbursable Expenses.** Unless expressly set forth to the contrary in any Statement of Work, CORONADO will also reimburse Service Provider, and Service Provider will separately invoice CORONADO, for Service Provider’s reasonable out of pocket and pass through costs and expenses including, but not limited to, those relating to the following:

- (i) Costs of reagents and materials.
- (ii) Service related travel, accommodation and meal costs incurred by Service Provider and other person(s) or entity(ies) retained by Service Provider to perform Service Provider’s obligations pursuant the Agreement and each Statement of Work as reasonably determined by Service Provider, with such costs and expenses to be at the business class level.
- (iii) All applicable and actual foreign, federal, state and local taxes, including, without limitation, sales taxes, assessed on any aspect of the Services; excluding income taxes, franchise taxes or any other tax imposed on Service Provider’s net income by the United States or any political subdivision thereof.

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- (iv) Costs associated with outside services, including, but not limited to [\*\*\*\*\*].
  - (v) Costs associated with installing the technology and other software and items relating to the Services.
  - (vi) Packaging & shipping costs for test samples to CORONADO or to a third party as instructed by the CORONADO.
  - (vii) Costs associated with packing and shipping of product resulting from the Services to CORONADO designated clinical and/or storage sites.
  - (viii) Costs associated with development and/or validation/qualification of assay methods and/or shipping methods.
  - (ix) Costs associated with the development of the production record.
  - (x) Costs associated with any stability trials for raw materials, starting material, intermediate products, final products and/or the costs of reagents used in the manufacture of product resulting from the Services.
  - (xi) Costs associated with environmental monitoring or Service Provider facility cleaning beyond that currently executed by Service Provider.
  - (xii) Except as expressly provided in any Statement of Work, costs associated with the preparation and submission of any Investigation New Drug application (“*IND*”) or sections of an IND to the FDA relating in any manner to the Services.
  - (xiii) Costs of regulatory services beyond supplying information (if expressly provided in a Statement of Work) for the compilation of Phase II/Phase III IND CMC submissions.
  - (xiv) Costs related to regulatory and quality services and interactions, including, but not limited to, costs of any additional qualification and or validation activities to address specific requests received from any regulatory authority, including the FDA following submission of regulatory documentation.
  - (xv) Except as expressly provided in any Statement of Work, costs associated with assisting CORONADO with a regulatory submissions (including, but not limited to assisting with the completion of any BLA with the FDA) or providing validation reports (including any shipping validation which may be required in connection with any BLA submission.
  - (xvi) Extension of the manufacturing campaign for the clinical trial beyond the estimated durations set forth in any Statement of Work, additional patients or dose cohorts. Should an extension of any duration of any Stage set forth in a Statement of Work occur, then the costs, if any, associated such extension, including, without limitation, any additional manufacturing facility suite operations and other costs shall be addressed in an appropriate Statement of Work.
  - (xvii) Costs that may be associated with the technology transfer of the developed processes and procedures resulting from the Services to any GMP manufacturing facility/organization as requested by CORONADO.
  - (xviii) Costs of process and assay test method validation to the level required for further submission of the product and/or processes results to the FDA.

The parties agree that in connection with the costs set forth in Sections 4.4(i), (v) and (vi) above, a [\*\*\*\*\*] percent ([\*\*\*\*\*]%) handling fee will be added by the Service Provider to any invoice relating to such costs. Further, in connection with the costs and expenses covered by Section 4.4(ii) above, prior to such trips and related costs and expenses being incurred, Service Provider will contact CORONADO (either verbally or in writing) and obtain CORONADO’s consent, in writing, to the proposed trip(s) to be made.

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**4.5 Costs of Disposal.** Either Service Provider or CORONADO will be responsible for the costs of disposal of any product resulting from the Services as may be required by the provisions of the applicable Quality Agreement. If a Quality Agreement is not entered into between the parties, CORONADO shall be responsible for such costs.

**4.6 COLA.** CORONADO expressly understands and agrees that all payments and fees (whether pursuant to the Agreement, any Statement of Work, the Quality Agreement or in any other document executed between the parties) payable by CORONADO to Service Provider after January 1, 2011 are subject to a cost of living adjustment (“COLA”) effective [\*\*\*\*\*] and each successive [\*\*\*\*\*] (each, a “Determination Date”). The COLA calculation will be equal to the [\*\*\*\*\*] for a base [\*\*\*\*\*] which shall be deemed the [\*\*\*\*\*] period immediately preceding the Determination Date and each anniversary thereafter. Upon the occurrence of a price adjustment as a result of COLA as of a Determination Date, Service Provider will notify CORONADO, in writing of the COLA adjustments (including the calculation thereof) and the resultant changes, if any, in the various payments and fees payable by CORONADO to Service Provider. Such written notification by Service Provider to CORONADO will be binding and enforceable against CORONADO absent manifest error and such written notice of the COLA adjustments will be deemed a Statement of Work without any additional action on the part of either party.”

3. The parties agree that Section 6 (Confidential Information) contained in the Master Contract Services Agreement is deleted in its entirety and the below sections relating to Confidential Information (as defined below) are inserted in lieu thereof:

**“6. Confidential Information.**

**6.1 Definition.** The term “Confidential Information” shall mean any information received by one party (the “Receiving Party”) from the other party (the “Disclosing Party”) that is identified as being proprietary or confidential to the Disclosing Party or which might permit the Disclosing Party or its customers to obtain a competitive advantage over those who do not have access to the information, including without limitation each party’s technology and documentation, technical information and customer lists. Confidential Information shall not include information which (a) is or becomes a part of the public domain through no act or omission of the Receiving Party, (b) is or was in the Receiving Party’s lawful possession prior to the disclosure by the Disclosing Party, (c) is disclosed to the Receiving Party by a Third Party entitled to disclose such Confidential Information, or (d) was independently developed by the Receiving Party without use of or access or reference to the Confidential Information of the Disclosing Party.

**6.2 Confidentiality Obligations.** It is anticipated that each of the parties will disclose to the other party Confidential Information in the course of performing such parties’ obligations under the Agreement, including each Statement of Work. Notwithstanding anything to the contrary herein, Receiving Party may disclose the Confidential Information of the Disclosing Party to an Affiliate who is under similar obligations to keep such Confidential Information confidential and to the extent required by law. If such disclosure is requested by legal process, the Receiving Party will make commercially reasonable efforts to notify the Disclosing Party of this request to disclose Confidential Information prior to any disclosure in order to permit the Disclosing Party to oppose such disclosure, at the sole cost and expense of the Disclosing Party, by appropriate

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legal action. If as a result of the application of the preceding sentence, Service Provider becomes obligated to provide testimony or records regarding any aspects of the Services in any legal or administrative proceeding, then CORONADO shall reimburse Service Provider all of Service Provider's costs and expenses related thereto plus an hourly fee for Service Provider's employees or representatives equal to the then internal fully burdened costs to Service Provider of such employee or representative.

**6.3 Non-Disclosure and Limitation of Use.** Except as provided in Section 6.1, Receiving Party shall not disclose the Disclosing Party's Confidential Information, except to its employees or agents in accordance with Section 6 and shall take at least the same precautions to protect the confidentiality of the Disclosing Party's Confidential Information as it takes to protect its own Confidential Information, but in no event less than commercially reasonable precautions. Receiving Party shall not remove any trademark, copyright, restricted rights, limited rights, proprietary rights or confidentiality notices included in or affixed to the Disclosing Party's Confidential Information and shall reproduce all such notices on any copies of the Disclosing Party's Confidential Information made in accordance with this Agreement. Receiving Party may use the Disclosing Party's Confidential Information only to the extent reasonably necessary to carry out its obligations under this Agreement.

**6.4 No Rights Granted.** The disclosure of Confidential Information by the Disclosing Party hereunder shall not be construed as a grant to the Receiving Party of any ownership or other proprietary right or interest in such Confidential Information, except as set forth in the Agreement. The Receiving Party shall not acquire any title, ownership, or other intellectual property rights or license from the Disclosing Party to any Confidential Information of the Disclosing Party by virtue of such disclosure.

**6.5 Return of Confidential Information.** Upon expiration or termination of the Agreement for any reason, the Receiving Party shall (a) immediately cease using any of the Confidential Information of the Disclosing Party, and (b) at the written request of Disclosing Party, which notice shall specify the subject Confidential Information, promptly, at Receiving Party's cost and expense, return to the Disclosing Party all tangible embodiments of Disclosing Party's Confidential Information. Notwithstanding anything to the contrary herein, Receiving Party may retain secure copy(ies) of Confidential Information of the Disclosing Party solely for the purpose of determining its obligations hereunder. The confidentiality and non-use obligations of each Receiving Party under this Agreement shall continue in effect for a period of [\*\*\*\*\*] year after the expiration or termination of this Agreement. Notwithstanding the preceding, nothing shall prohibit the Receiving Party from summarizing the terms of this Agreement, or from filing this Agreement as an exhibit, in documents the Receiving Party is required to file with any Governmental Agency, including, but not limited to, the Securities and Exchange Commission; provided that such disclosure shall be only to the extent required to comply with applicable Laws, and provided further: (i) that the Receiving Party shall provide a copy of the proposed disclosure to the Disclosing Party at least [\*\*\*\*\*] days in advance of such disclosure; and (ii) the parties shall mutually agree to the content of such disclosure.

**6.6 Irreparable Injury.** The Receiving Party agrees that money damages would not be a sufficient remedy for any breach of the confidentiality obligations set forth in Section 6 and that, in addition to all other remedies, Disclosing Party will be entitled to seek injunctive or other equitable relief as a remedy for any such breach by the Receiving Party without having to post a bond.”

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**4. Representations by CORONADO.** CORONADO makes the following representations, warranties and covenants to Service Provider:

(a) CORONADO is and will remain a corporation duly organized, validly existing and in good standing under the laws of its jurisdiction of organization.

(b) The execution and delivery of the Agreement (and all appendixes thereto) and each Statement of Work has been and will be authorized by all requisite corporate action. The Agreement (and all appendixes thereto) and each Statement of Work is and will remain a valid and binding obligation of CORONADO, enforceable in accordance with its terms, subject to laws of general application relating to bankruptcy, insolvency and the relief of debtors.

(c) CORONADO is and will be under no contractual or other obligation or restriction that is inconsistent with CORONADO's execution or performance of the Agreement (together with all appendixes attached thereto) and any Statement of Work.

(d) CORONADO shall perform its obligations under the Agreement and each Statement of Work and each Quality Agreement in a professional and workmanlike manner with due care and will fully cooperate with reasonable requests of Service Provider, at Service Provider's cost and expense, in connection with Service Provider's performance of the Services.

(e) CORONADO shall obtain and maintain all necessary permits, licenses and authorizations as required under the Agreement, any Statement of Work and all Applicable Laws with respect to the manufacture of product pursuant to the Services described in a particular Statement of Work and human clinical use of such product.

(f) Neither CORONADO nor any employees of CORONADO shall be, at the time of performance of any activity hereunder: (a) disqualified or debarred by the FDA or any other regulatory agency for any purpose; or (b) charged with or convicted under United States Federal law or foreign counterpart thereof, for conduct relating to the development or approval, or otherwise relating to the regulation, manufacture, research or development of biological products.

(g) In performing any of its work or carrying out its obligations under the Agreement and any Statement of Work, CORONADO: (a) shall not knowingly infringe upon any United States or foreign copyright, patent, trademark, trade secret or other proprietary right, or misappropriate any trade secret of any third party in any manner that would cause any liability, loss or damage to Service Provider; and (b) has neither assigned nor otherwise entered into any agreement by which it purports to assign or transfer any right, title or interest to any technology or intellectual property right that would conflict with its obligations under this Agreement and any Statement of Work.

(h) To the best of Coronado's knowledge, all materials, reagents and other product required for the processes relating to the Services can be sourced and are of a grade/nature/origin acceptable for GMP use and for human administration according to all Applicable Laws (including current FDA regulations) and Service Provider's standards that are disclosed, in writing, to CORONADO.

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5. The parties agree that Section 7 (Indemnification and Insurance ) contained in the Master Contract Services Agreement is deleted in its entirety and the below sections relating to Pricing and Payments are inserted in lieu thereof:

**“7. Indemnification and Insurance.**

**7.1 Indemnification by Service Provider.** Service Provider shall indemnify, defend and hold harmless CORONADO and CORONADO’s agents, servants, directors, officers and employees (collectively, “**CORONADO’s Agents**”) from and against any and all claims, damages, losses, expenses, and liabilities of any nature whatsoever, including reasonable attorney’s fees and disbursements (collectively, “**Claims**”), incurred, caused, based upon, arising out of or resulting from or failure to perform, or misrepresentation with respect to, any of the terms, covenants or conditions of the Agreement and each Statement of Work, except to the extent incurred, caused or occasioned by, in connection with or arising out of the acts or omissions of CORONADO and/or CORONADO’s Agents including, but not limited to, CORONADO’s violation or failure to perform, or misrepresentation with respect to, any of the terms, covenants or conditions of the Agreement and each Statement of Work. In the event that a Claim arises in whole or in part from CORONADO’s and/or CORONADO’s Agents negligence, gross negligence or intentional misconduct or inaction, then the amount of the Claim that Service Provider shall indemnify CORONADO or, if applicable, CORONADO’s Agents pursuant to this Section 7.1 shall be reduced by an amount in proportion to the percentage of CORONADO’s and/or CORONADO’s Agents’ responsibilities for such Claim as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the parties. Nothing in this Agreement or in any Statement of Work shall be deemed to require Service Provider to indemnify CORONADO or CORONADO’s Agents for or with respect to any bodily injury caused by any product resulting from the Services. CORONADO hereby acknowledges that it has exclusive control and decision making authority with respect to: (i) the specifications that govern the manufacture and use of the any product resulting from the Services; and (ii) specifications that govern the manufacture, packaging and distribution of product resulting from the Services. CORONADO further acknowledges that Service Provider has no control over the “use” of any product resulting from the Services after being shipped by Service Provider in accordance with the Agreement and any Statement of Work.

**7.2 Indemnification by CORONADO.** CORONADO shall indemnify, defend, and hold harmless Service Provider and Service Provider’s agents, servants, directors, officers, managers, members and employees (collectively, “Service Provider’s Agents”) from and against any and all Claims incurred, caused, based upon, arising out of or resulting from: (i) the use of any products resulting from the Services, including the product’s use in the treatment of human subjects; (ii) personal injury to a participant in any clinical trial using any product resulting from the Services or personal injury to any Service Provider Agent directly or indirectly caused by materials, reagents and/or blood related product required for the Services (collectively, “Raw Materials”); (iii) Service Provider’s performance of or involvement with Raw Materials or Service Provider’s obligations under the Agreement and each Statement of Work; (iv) Service Provider’s performance of the Services violating or infringing on the patents, trademarks, trade names, service marks or copyrights of any third party with respect to the Services and/or the process to manufacture product resulting from the Services, product intermediates or the Raw Materials; (v) the harmful or otherwise unsafe effect of the Raw Materials or the product resulting from the Services, including without limitation, a Claim based upon CORONADO or any other person’s use, consumption, sale, distribution or marketing of any substance, including the Raw Materials or the product resulting from the Services; (vi) any acts or omissions of CORONADO and/or CORONADO’s Agents, including, but not limited to, CORONADO’s or CORONADO’s Agents’ violation or failure to perform, or misrepresentation with respect to, any of the terms, covenants or conditions of the Agreement and any Statement of Work, except to the extent incurred, caused or occasioned by, in connection with or arising out of the acts or omissions of Service Provider and/or Service Provider’s Agents including, but not limited to, Service

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Provider's violation or failure to perform, or misrepresentation with respect to, any of the terms, covenants or conditions of the Agreement and any Statement of Work. In the event that a Claim arises in whole or in part from Service Provider's and/or Service Provider's Agents' negligence, gross negligence or intentional misconduct or inaction, then the amount of the Claim that CORONADO shall indemnify Service Provider or, if applicable, Service Provider's Agents pursuant to this Section 7.2 shall be reduced by an amount in proportion to the percentage of Service Provider's and/or Service Provider's Agents' responsibilities for such Claim as determined by a court of competent jurisdiction in a final and non-appealable decision or in a binding settlement between the parties.

**7.3 Notification of Claim.** Upon receipt of notice of any Claim which may give rise to a right of indemnity from the other party hereto, the party seeking indemnification (the "Indemnified Party") shall give written notice thereof to the other party, (the "Indemnifying Party") with a Claim for indemnity. Such Claim for indemnity shall indicate the nature of the Claim and the basis therefore. Promptly after a claim is made for which the Indemnified Party seeks indemnity, the Indemnified Party shall permit the Indemnifying Party, at its option and expense, to assume the complete defense of such Claim, provided that; (i) the Indemnified Party will have the right to participate in the defense of any such Claim at its own cost and expense; (ii) the Indemnifying Party will conduct the defense of any such Claim with due regard for the business interests and potential related liabilities of the Indemnified Party; and (iii) the Indemnifying Party will, prior to making any settlement, notify the Indemnified Party, in writing, of such settlement offer and subsequently consult with the Indemnified Party as to the terms of such settlement. The Indemnified Party shall have the right, at its election, to release and hold harmless the Indemnifying Party from its obligations hereunder with respect to such Claim and assume the complete defense of the same in return for payment by the Indemnifying Party to the Indemnified Party of the amount of the Indemnifying Party's settlement offer. The Indemnifying Party will not, in defense of any such Claim, except with the consent of the Indemnified Party, consent to the entry of any judgment or enter into any settlement which does not include, as an unconditional term thereof, the giving by the claimant or plaintiff to the Indemnified Party of a release from all liability in respect thereof. After notice to the Indemnified Party of the Indemnifying Party's election to assume the defense of such Claim, the Indemnifying Party shall be liable to the Indemnified Party for such legal or other reasonable expenses subsequently incurred by the Indemnified Party in connection with the defense thereof at the request of the Indemnifying Party. As to those Claims with respect to which the Indemnifying Party does not elect to assume control of the defense, the Indemnified Party will have the sole and exclusive right to settle or otherwise dispose of any of the same without the consent of the Indemnifying Party.

**7.3 Survival; Limitation of Liability.** Each party's indemnification obligations to the other party shall survive the expiration or earlier termination of the Applicable Services Agreement. Notwithstanding anything in this Section 7.3 or the Applicable Services Agreement to the contrary, Service Provider's liability to CORONADO pursuant to Section 7 shall not, under any circumstance, exceed an amount equal to the total of all payments actually paid by CORONADO to Service Provider for Services provided by Service Provider pursuant to any Statement of Work (the maximum amount shall exclude all reimbursable amounts described in Section 4.4 as set forth in Appendix C to the Agreement). Further, in no event shall either party be liable to the other for any special damages of any nature whatsoever, including, but not limited to, liability for special, indirect, punitive, exemplary or consequential damages (including damages relating to lost profits, lost business or lost savings), even if a party has been advised of the possibility of and/or incurred such damages.



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#### 7.4 **Insurance.**

A. Each party shall, at all times during the period of the Agreement, obtain and maintain fully paid insurance coverage with limits no less than:

- i) Comprehensive General Liability (including coverage for bodily injury and property damage) with limits no less than [\*\*\*\*\*] Dollars (\$[\*\*\*\*\*]) aggregate, per occurrence; and
- ii) In the case of the Service Provider, Workers Compensation with limits no less than the minimum statutory amounts under Applicable Laws.

B. Service Provider shall, at all times during the period of the Agreement, obtain and maintain Professional Liability insurance coverage with limits no less than [\*\*\*\*\*] Dollars (\$[\*\*\*\*\*]) per occurrence.

C. CORONADO shall, immediately prior to the initiation of any human clinical trials using product resulting from the Services, and at all times afterward for the duration of the Agreement, and for a period of [\*\*\*\*\*] years following the termination or earlier expiration of the Agreement, obtain and maintain Product Liability insurance coverage (“clinical trial insurance”) with limits no less than the greater of (i) [\*\*\*\*\*] (\$[\*\*\*\*\*]) dollars per occurrence and (ii) or an amount, as reasonably determined by CORONADO which is appropriate for the size and scope of the human clinical trials CORONADO intends to engage in, taking into account the number of patients and nature of the human trial.

D. Each party shall furnish to the other a certificate of such insurance evidencing the required policies of insurance set forth above, which certificate shall provide that no such policy shall be materially altered, amended or cancelled without providing the other party with at least [\*\*\*\*\*] days prior written notice of such change and be in form and substance (including deductible amounts) reasonably satisfactory to such other party.

6. The parties agree that Service Provider shall provide the required personnel and support necessary to perform the Services at one or more of Service Provider’s facilities located in the United States, as determined solely by Service Provider. Service Provider shall perform the Services as provided in the Agreement and each Statement of Work and each Quality Agreement. Notwithstanding the previous sentence, CORONADO recognizes and agrees that the completion of Services, the timelines and cost figures set forth in the Agreement and each Statement of Work are estimates made by Service Provider in its commercially reasonable determination and that the same may be affected by third parties not directly controlled by Service Provider.

7. Service Provider and CORONADO each acknowledges and agrees to the other that because the Services to be performed is by its nature developmental, Service Provider can only assure compliance with CORONADO’s specifications as outlined in the Agreement, each Statement of Work and the applicable Quality Agreement and Service Provider EXPRESSLY MAKES NO WARRANTY OR GUARANTY WHATSOEVER REGARDING THE ACHIEVEMENT OF A SUCCESSFUL OUTCOME FOR THE PROGRAM RESULTING FROM THE SERVICES.

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8. **DISCLAIMERS:**

- (a) **DISCLAIMER BY SERVICE PROVIDER. SERVICE PROVIDER DOES NOT WARRANT THAT ANY PRODUCT RESULTING FROM THE SERVICES PERFORMED WILL BE SAFE OR EFFICACIOUS OR THAT ANY FDA SUBMISSION PREPARED AS A RESULT OF PERFORMING THE SERVICES WILL SATISFY ALL THE REQUIREMENTS OF ANY REGULATORY AGENCY AT THE TIME OF SUBMISSION.**
- (b) **DISCLAIMER OF WARRANTIES. EXCEPT AS EXPRESSLY PROVIDED IN THE AGREEMENT, NEITHER PARTY MAKES ANY WARRANTY WITH RESPECT TO THE SERVICES OR OBLIGATIONS TO BE SUPPLIED BY SUCH PARTY HEREUNDER AND BOTH PARTIES SPECIFICALLY DISCLAIM ALL EXPRESS OR IMPLIED REPRESENTATIONS OR WARRANTIES WITH RESPECT TO THE SERVICES, INCLUDING ANY WARRANTY OF MERCHANTABILITY, FITNESS FOR ANY PARTICULAR PURPOSE OR NONINFRINGEMENT, OR ANY IMPLIED WARRANTY ARISING FROM COURSE OF PERFORMANCE, COURSE OF DEALING OR USAGE OF TRADE.**

9. **Prospective Events.** For purposes of this Section, the following terms shall have the meanings given to them as set forth below:

- (a) **“Prospective Illegality”** means any foreign, state or federal statute or common law, or foreign, state or federal administrative agency rule, guidance or directive now existing or enacted or promulgated or re-interpreted after the Effective Date of this Agreement that is interpreted by judicial decision, a regulatory agency or legal counsel (in the case of legal counsel pursuant to a legal opinion reasonably acceptable to the receiving party from legal counsel reasonably acceptable to the receiving party and addressed to such receiving party) in such manner as to result in the conclusion that any act or service required of Service Provider or CORONADO under the Agreement or any Statement of Work is in violation of such law, rule, guidance or directive.
- (b) **“Prospective Cost Increase”** means either the (a) occurrence of an event outside the control of Service Provider, including, without limitation, any Force Majeure event or (b) the enactment of a foreign, state or federal statute, common law, foreign, state or federal administrative agency rule, guidance or directive or amendment thereof, in any case, after the Effective Date of the Agreement as to which compliance by Service Provider with the terms and provisions of the Agreement or any Statement of Work imposes an extraordinary and unanticipated financial burden that is generally applicable to all providers of cell processing services.
- (c) **Effect of a Prospective Illegality.** In the event of a Prospective Illegality, CORONADO and Service Provider shall promptly negotiate in good faith a Statement of Work to the Agreement and any applicable, Statement of Work as necessary to address such Prospective Illegality. Pending agreement on the appropriate amendment, either CORONADO or Service Provider, on [\*\*\*\*\*] days Written Notice to the other, may cease to perform a questioned act; provided, however, that the Agreement will nevertheless be performed by both CORONADO and Service Provider to the extent possible.
- (d) **Effect of a Prospective Cost Increase.** In the event of a Prospective Cost Increase, CORONADO and Service Provider shall negotiate in good faith a Statement of Work to the payment terms of the applicable Statement of Work to address such cost increase. To the maximum extent possible, any such Statement of Work agreed to pursuant to this Section 9 of Appendix C shall preserve the primary benefits sought to be achieved by this Agreement and the underlying economic and financial arrangements between the parties. If Client and PCT agree that the primary benefits sought to be achieved by this Agreement cannot be achieved

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through an appropriate Statement of Work, then this Agreement, unless an earlier date is agreed to by both parties, will be automatically terminated on the last day of the month which first occurs on or after [\*\*\*\*\*] days after Written Notice by either party to the Point of Contract of the other party referring to this Section 9 of Appendix C as the basis of the Termination of this Agreement. A termination of this Agreement pursuant to this Section 9(d) of Appendix C shall be deemed a termination by the CORONADO without cause pursuant to Section 8.2(b) of the Agreement and the balance of the terms and provisions of Section 8 of the Agreement shall be applicable.

10. Force Majeure. Either party shall be excused from performing its respective obligations under the Agreement and any Statement of Work if its performance is delayed or prevented by Force Majeure, provided that such performance shall be excused only to the extent of and during such disability. Any time specified for completion of performance in the Services falling due during or subsequent to the occurrence of any Force Majeure event shall be automatically extended for a period of time to recover from such disability. Service Provider will promptly notify CORONADO if, by reason of any Force Majeure event Service Provider is unable to meet any such time for performance specified in the Services. If any portion of the Services is invalid as a result of such disability, Service Provider will, upon written request from CORONADO, but at CORONADO's sole cost and expense, repeat that portion of the Services affected by the disability. If Service Provider is likely to be unable to perform for a period in excess of [\*\*\*\*\*] days, then the parties agree to negotiate in good faith a mutually satisfactory approach to resolve the delay resulting from this Force Majeure. If the parties cannot reach a mutually satisfactory approach within such [\*\*\*\*\*] day period, then CORONADO shall be entitled to terminate the Agreement without payment of any damages pursuant to Section 8 of this Agreement.

**CONFIDENTIAL TREATMENT REQUESTED.  
INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN  
REQUESTED IS OMITTED AND MARKED WITH “[\*\*\*\*\*]” OR OTHERWISE  
CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS  
ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

**Term Sheet in causa Ovamed / Asphelia**

**Partys:**

- Ovamed GmbH, Kiebitzhörn 33-35, 22885 Barsbüttel, Germany  
— Hereafter Ovamed -
- Asphelia Inc., 787 7th Ave 48th floor, NY 10019, USA  
— Hereafter Asphelia -

The parties herewith agree the following:

1. Asphelia (respectively formerly Collingwood Pharmaceuticals, Inc.) and Ovamed have entered an exclusive sublicense agreement relating to parasitic biological agents for the prevention, treatment and control of autoimmune diseases (the “Technology”) on December 12, 2005, wherein Asphelia is given the exclusive rights by Ovamed (regarding the territories of North- and South America and Japan; referring of the past amendments the parties declare for the avoidance of doubt that the territory of Europe or other territories with exception of the mentioned above are not enfolded) to inter alia use and sell respective products and practice respective processes relating to the Technology (“SL Agreement”). An amendment of the SL Agreement was agreed on November 8, 2007. Furthermore a Manufacturing and Supply Agreement was entered into between the parties on March 29, 2006. (“M&S Agreement”). The M&S Agreement has also been amended on November 8, 2007. After resumption of the above mentioned privity of contracts subsequent to a termination notice by Ovamed on January 8, 2009, the parties refer also to those modified conditions.
2. Due to Asphelia’s recent payments relating to the amended SL Agreement, Ovamed herewith confirms good standing of the aforementioned sublicense and resolution of all past disputes between Asphelia and Ovamed, thus, Ovamed confirms Asphelia’s compliance with the terms of the amended SL Agreement and accordingly undertakes to immediately withdraw the complaint against Asphelia before the court of Lübeck (LG Lübeck 10 O 210/09). In addition the parties agree to the following terms of the term sheet below.
3. The parties acknowledge that Asphelia did not file its own data since the beginning of the privity of contract because and therefore is unable to file an Investigational New Drug (IND) application with the US Food and Drug Administration (FDA) for early clinical studies (i.e. Phase I and II clinical trials) in the United States for products relating to the Technology, unless all data and information required to pursue and obtain an approval for an IND for such studies in the US including but not limited to Chemistry, Manufacturing and

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Controls (CM&C) data and other relevant IND information (e.g., updated nonclinical data) and other aspects of the Technology and the products comprising it (“Required Data”) is made available to Asphelia. Ovamed has produced and still is producing such Required Data in a joint cooperation with [\*\*\*\*\*] (“[\*\*\*\*\*]”) and therefore — under the joint cooperation agreement with [\*\*\*\*\*] - Ovamed is unable to provide Asphelia with the right to use and reference such Required Data until certain financial obligations, of Ovamed to [\*\*\*\*\*] are met and the unrefusable consent of [\*\*\*\*\*] is given. Ovamed confirms that under its agreement with [\*\*\*\*\*] (sec. 5.5 of such agreement) it is required to reimburse [\*\*\*\*\*] for fifty percent (50%) of the costs incurred above [\*\*\*\*\*] EUR in the generation of such Required Data and other data in the joint cooperation.

4. As of the date of this Term Sheet, such financial obligations of Ovamed to [\*\*\*\*\*] exclusively incurred by the generation of the Required Data are estimated to be approximately [\*\*\*\*\*] USD.
5. Asphelia agrees to make a milestone payment, in USD, according to the following formula:  $0.5X(a-b)$ , where:
  - “a” equals the total costs (exclusive of VAT) spent by [\*\*\*\*\*] on the Required Data in particular on preclinical data, manufacturing development, and IMPD documentation preparation (but not to include any costs associated with the development, set up or execution of any clinical study by [\*\*\*\*\*]) up to the date of the closing of the intended financing by Asphelia as described in section 6
  - “b” equals the [\*\*\*\*\*] EUR of the costs as described in section (5) a that [\*\*\*\*\*] must absorb under [\*\*\*\*\*].Ovamed shall provide to Asphelia a detailed, accounting of the costs related to the generation of the required data, on Asphelia’s request.
6. This milestone payment described in section (5) will be made within thirty (30) days of closing of Asphelia’s intended IPO or alternate financing (scheduled and planned in the second half of 2010). If Asphelia fails to close such IPO or alternate financing within seven months after the execution of this agreement, and the milestone payment is not made within 30 days of such closing then this agreement (including the terms below) will expire. Ovamed herewith confirms and undertakes to make all Required Data available to Asphelia according to section (7) or at least according to section (8) and Asphelia confirms to make the mentioned payments to Ovamed subject to the closing of Asphelia’s intended IPO or alternative financing within seven months after execution of this Term Sheet.
7. On receipt of this milestone payment described in section (5) by Ovamed, Ovamed shall immediately pay to [\*\*\*\*\*] the balance of its financial obligations to [\*\*\*\*\*] specifically related to and limited to the activities above, and Ovamed shall submit with the unrefusable consent by [\*\*\*\*\*] all [\*\*\*\*\*] to Asphelia for the use in regulatory submissions and other

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filings, including use in the IND application for submission to FDA and permit its release to regulatory authorities and other third parties as required for the conduct of clinical trials and other corporate purposes of Asphelia in the Territory.

8. In case, that there will be no consent by [\*\*\*\*\*] (7) or there are any other impediments to the transfer of the [\*\*\*\*\*] Ovamed and Asphelia agree that Ovamed will on its own behalf - under the terms of its agreement with [\*\*\*\*\*] – initiate preparation of the IND application for FDA review by transmitting the [\*\*\*\*\*] to Asphelia for the sole purpose of its use in the preparation and submission of the US IND by [\*\*\*\*\*], and such activities (ethics review, Investigator Brochure etc) as may be required by regulation to conduct clinical trials in the United States, provided that Ovamed and Asphelia agree to prepare and submit the IND and the data therein in the name of Ovamed whereby the existing IND, if any is effective, is transferred to Ovamed and Ovamed executes a transfer of obligations to Asphelia whereby Asphelia shall act as the agent of Ovamed in the USA for the IND and its execution. The [\*\*\*\*\*] will only be used for the purposes of the agreements - in particular for the IND application [\*\*\*\*\*] and any other activities as may be required by regulation for the conduct of clinical trials in the United States - between the parties. Notwithstanding anything in the foregoing to the contrary, once the IND is approved by the FDA Ovamed shall agree at Asphelia's request, to transfer [\*\*\*\*\*], but not before [\*\*\*\*\*]. To the extent such request is not made by Asphelia at that time, then upon the completion of [\*\*\*\*\*] Ovamed shall [\*\*\*\*\*] on Asphelia's request.
9. Within 10 days of execution of this agreement Asphelia shall pay to Ovamed 200,000 USD being 50% of the remaining IND milestone prepayment. When the milestone payment described in section (5) is made by Asphelia to Ovamed and the [\*\*\*\*\*] are received by Asphelia as provided for in section (7), or when the [\*\*\*\*\*] are received by Asphelia for [\*\*\*\*\*] in advance of the payments being made, according to the conditions described in section (8), Asphelia shall within 1 month make the remaining portion (50%) of the final "IND prepayment" milestone payment (described in the Amendment dd Nov 8 2007) to Ovamed of 200.00 USD and Asphelia shall submit [\*\*\*\*\*] within [\*\*\*\*\*] months after receiving the [\*\*\*\*\*].
10. The parties preferred to enter into a three-party agreement with [\*\*\*\*\*]. The contract negotiations were unsuccessful so far. In the event, that [\*\*\*\*\*], Asphelia and Ovamed will find into a three-party agreement, any payment made or to be made by Asphelia because of this Term Sheet will be set off with the financial obligations between Asphelia and Ovamed of the three-party agreement. By signing the above mentioned three-party agreement this Term Sheet will expire in it's entirety.

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11. All other future payment obligations according to the SL Agreement, amendment dd. Nov. 8. 2007, the modified conditions of the termination notice dd. Jan. 8, 2009 remain unaffected. If Asphelia fails to close the IPO or alternate financing and cannot fulfill their further payments commitments in accordance to section (5) and (9) of this agreement and the milestone payments specified in this agreement are not made in time then this agreement shall expire in its entirety without any obligations from Ovamed to Asphelia. Furthermore Asphelia will accept a termination of all existing contracts between Ovamed and Asphelia without any obligations from Ovamed to Asphelia if the payments required under those agreements are not made within 30 days of receipt of written notice from Ovamed.

June 8, 2010 /s/ Detlev Goj  
Date, Signature (Ovamed)

June 8, 2010 /s/ J. Jay Lobell  
Date, Signature (Asphelia)

Company: Ovamed GmbH

Company: Asphelia

By (Name): Detlev Goj

By (Name): J. Jay Lobell

As Its: Chief Executive Officer

As Its: Acting CEO and Director

**CONFIDENTIAL TREATMENT REQUESTED.  
INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN  
REQUESTED IS OMITTED AND MARKED WITH “[\*\*\*\*\*]” OR OTHERWISE  
CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS  
ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.**

**Execution Copy**

**AMENDMENT AND AGREEMENT**

**THIS AMENDMENT AND AGREEMENT (“Amendment”)** is made as of January 7, 2011 (“**Amendment Effective Date**”) by and among Asphelia Pharmaceuticals, Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 787 Seventh Avenue, 48th floor, New York, NY 10019, United States (“**Asphelia**”), Coronado Biosciences Inc., a corporation organized and existing under the laws of the State of Delaware and having its principal office at 45 Rockefeller Plaza, Suite 2000, New York, NY 10111, United States (“**Coronado**”), and OvaMed GmbH, a company with limited liability organized and existing under the laws of Germany and having its principal office at Kiebitzhörn 33-35, 22885 Barsbüttel, Germany (“**OvaMed**”). Asphelia, Coronado and OvaMed are sometimes collectively referred to herein as the “**Parties**”.

**WITNESSETH:**

WHEREAS, on December 12, 2005, Asphelia and OvaMed entered into an Exclusive Sublicense Agreement (the “**Sublicense Agreement**”) pursuant to which OvaMed granted Asphelia an exclusive sublicense under Patent Rights and Know-How in the Field in the Territory (each as defined in the Sublicense Agreement), on the terms and conditions set forth therein;

WHEREAS, effective March 29, 2006 Asphelia and OvaMed entered into a Manufacturing and Supply Agreement (the “**Supply Agreement**”) pursuant to which OvaMed agreed to manufacture and supply Product (as defined in the Supply Agreement) to Asphelia on the terms and conditions set forth therein;

WHEREAS, Asphelia and OvaMed amended or agreed to amend certain provisions of the Sublicense Agreement and the Supply Agreement and entered into certain additional agreements by letter agreement dated November 8, 2007 (the “**2007 Letter Agreement**”);

WHEREAS, Asphelia and OvaMed further amended certain provisions of the Sublicense Agreement and the Supply Agreement, resolved certain disputes, and entered into certain additional agreements by term sheet dated June 8, 2010 (the “**2010 Term Sheet**”);

WHEREAS, the Parties agree that certain provisions of the Sublicense Agreement, the Supply Agreement, the 2007 Letter Agreement and the 2010 Term Sheet (collectively, the “**Agreements**”) should be further clarified, amended or restated to reflect the current intentions of the Parties with respect to such Agreements, and that it is in their mutual best interests to resolve and compromise amicably any actual or potential disputes and to avoid future disputes arising under the Agreements, and to provide for certain additional agreements between and among the Parties;

WHEREAS, simultaneously with the execution of this Amendment, Asphelia and Coronado have entered into the Asset Purchase Agreement (as defined below); and

WHEREAS, on the Amendment Payment Date (as defined below), and subject to the terms and conditions contained herein, Coronado is making the Amendment Payment (as defined below).



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**NOW, THEREFORE**, in consideration of the foregoing statements and the mutual agreements and covenants herein contained, and for other good and valuable consideration, the adequacy and receipt of which are hereby acknowledged, the Parties hereto intending to be legally bound agree as follows:

1. **Definitions.** Except as set forth herein, capitalized terms not otherwise defined or amended in this Amendment shall have the meaning ascribed to them in the Agreements. The following terms, where used in this Amendment (including in amendments to any of the Agreements) in the singular or plural, shall have the respective meanings set forth below:

“**Amendment Payment**” means 2,390,679.92 EUR, to be paid by Coronado to OvaMed on January 11, 2011 (the “**Amendment Payment Date**”), calculated pursuant to section 5 of the 2010 Term Sheet and representing that portion of the Term Sheet Milestone Payment set forth on the Development Costs Schedule provided to Coronado prior to the Amendment Effective Date and attached hereto as **Appendix 1**.

“**Asset Purchase Agreement**” means the asset purchase agreement entered into simultaneously with the execution of this Amendment by and between Asphelia and Coronado pursuant to which Coronado will acquire the assets and rights of Asphelia related to or used in connection with Asphelia’s product candidate referred to as ASP-1002, including Asphelia’s rights and interests in and under the Agreements, and Coronado will assume certain liabilities of Asphelia thereunder (the “**Agreements Assignment**”).

“**Closing**” means the closing of the sale and purchase of the assets provided for in the Asset Purchase Agreement.

“**Development Costs Reimbursement**” means OvaMed’s [\*\*\*\*\*]% share of [\*\*\*\*\*]’s Development Costs (as defined in the [\*\*\*\*\*] Agreement) in excess of [\*\*\*\*\*] EUR, incurred on or before the Amendment Effective Date.

“**Development Costs Schedule**” means the accounting of the Development Costs Reimbursement, as evidenced by invoices provided by [\*\*\*\*\*] to OvaMed and from OvaMed to Coronado, in sufficient detail to permit accurate determination and verification of the Amendment Payment, and, if applicable, the Post-Amendment Payment, in accordance with section 5 of the 2010 Term Sheet.

“[\*\*\*\*\*]” means [\*\*\*\*\*], a [\*\*\*\*\*] corporation with its principal business office at [\*\*\*\*\*].

“[\*\*\*\*\*] **Payment**” means the payment(s) to be made by OvaMed to [\*\*\*\*\*] immediately following receipt by OvaMed of the Amendment Payment and, if applicable, the Post-Amendment Payment, in an amount equal to the then outstanding amount of OvaMed’s financial obligations to [\*\*\*\*\*] under Section 5.5 of the [\*\*\*\*\*] Agreement.

“**IND**” means an Investigational New Drug Application, including all reports and amendments thereto, submitted to the FDA for purposes of conducting clinical trials with respect to Licensed Product in the Territory, in accordance with FDA rules and regulations.

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“**IND Data**” means all data, including pharmaceutical, toxicological, pharmacology, preclinical, clinical, safety, chemistry, manufacturing and control (CMC) data and/or all other data, information, and documentation, including regulatory authorizations or communications, that are required to be included in an IND (including the “Required Data” as defined in the 2010 Term Sheet).

“**IND Transfer Date**” means, if the IND is initially submitted by OvaMed, the effective date of transfer of the IND to Coronado, in accordance with the terms of this Amendment.

“**License Agreement**” means the exclusive License Agreement dated December 8, 2005 by and between the University of Iowa Research Foundation (“**UIRF**”) and OvaMed.

“**[\*\*\*\*\*] Agreement**” means the Development, Manufacturing and Commercialization Agreement dated January 9, 2004 by and between OvaMed (f/k/a Biocure GmbH) and [\*\*\*\*\*].

“**Post-Amendment Payment**” means an amount equal to the difference between the Term Sheet Milestone Payment and the Amendment Payment, payable thirty (30) days after Coronado’s receipt of a Development Costs Schedule evidencing invoices received from [\*\*\*\*\*] for Development Costs Reimbursement relating to (i) [\*\*\*\*\*]’s Development Costs incurred from January 1, 2011 through January 8, 2011 and (ii) OvaMed’s portion of [\*\*\*\*\*]’s Development Costs representing third party invoices to [\*\*\*\*\*] for the period from December 1, 2010 through December 31, 2010 but not provided as of the Amendment Effective Date (estimated not to exceed EUR[\*\*\*\*\*]) (the “**Post-Amendment Payment**”).

“**Term Sheet Milestone Payment**” means the amount payable to OvaMed under sections 5 and 6 of the 2010 Term Sheet, as amended, representing the Development Costs Reimbursement relating to [\*\*\*\*\*]’s Development Costs incurred before the Amendment Effective Date, as evidenced by a Development Costs Schedule as contemplated by such section 5.

## 2. Amendments to the Agreements.

(a) Asphelia was formerly known as Sunset Cliffs Therapeutics, Inc., which was the successor by assignment to the rights and interests of Collingwood Pharmaceuticals, Inc. in the Sublicense Agreement and the Supply Agreement. Pursuant to the Agreements Assignment, Coronado will be assigned and assume rights and obligations of Asphelia under the Agreements. Each of the Agreements is hereby amended effective as of and after the Amendment Effective Date as follows: all references therein to “Collingwood Pharmaceuticals, Inc.” “Collingwood”, “Asphelia Pharmaceuticals, Inc.” and/or “Asphelia” shall be changed to and construed as “Coronado Biosciences Inc.” or “Coronado”, respectively, *mutatis mutandis*.

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(b) The Sublicense Agreement, as amended or otherwise referred to in the 2007 Letter Agreement or the 2010 Term Sheet, is hereby amended as of the Amendment Effective Date as follows:

(i) As the name and legal form of the contracting party was stated incorrectly as “Ovamed GbmH & Co KG”, such name is hereby corrected to read “Ovamed GmbH”;

(ii) The following is hereby added as a new Section 2.4 to the Sublicense Agreement:

“2.4 As provided by Section 9.5 of the License Agreement, the License Agreement shall be assigned to the Company upon termination of the License Agreement, provided, however, that in the event the License Agreement is terminated due to OvaMed’s breach, the Company shall have the rights set forth in Section 9.5 of the License Agreement to bring the License Agreement back into good standing. In the event OvaMed receives notice of a breach of the License Agreement, OvaMed shall notify the Company of such situation as soon as practicable. However, if OvaMed is unable to or does not cure such breach on a timely basis, and such breach gives rise to a right by UIRF to terminate the License Agreement in a way that would terminate or adversely affect the Company’s ability to perform its obligations or exercise its rights under this Agreement, OvaMed shall, at the Company’s option, permit the Company to cure such breach. If the Company elects to cure such breach, OvaMed shall reimburse the Company for any costs associated with curing such breach, or the Company shall be permitted to set off such costs against amounts owed by the Company to OvaMed under this Agreement”;

(iii) The numbering of sub-sections 4.1.1 and 4.1.2 under Section 4.2 of the Sublicense Agreement is hereby corrected, changed to and construed as sub-sections 4.2.1 and 4.2.2, respectively, and any references in the Sublicense Agreement to such sub-sections are hereby changed to and construed as sub-sections 4.2.1 and 4.2.2, respectively; and

(iv) Consistent with the revised definition of the term “Territory” in the 2010 Term Sheet, Coronado shall have no obligation to OvaMed or UIRF under the Sublicense Agreement with respect to, that arises in connection with, or that relates to any country, jurisdiction or territory outside the Territory. Without limiting the generality of the foregoing, Section 4.3 and Article 6 of the Sublicense Agreement are hereby amended to delete therefrom any financial obligation of the Company to OvaMed or UIRF with respect to, arising out of or relating to any country, jurisdiction or territory outside the Territory.

(c) Section 8.1 of the Supply Agreement, as amended or otherwise referred to in the 2007 Letter Agreement or the 2010 Term Sheet, is hereby amended and restated as of the Amendment Effective Date to read as follows:

“8.1. Term

Unless earlier terminated in accordance with Section 8.2, the term (the “Term”) of this Agreement shall commence on the Effective Date and shall continue until March 31, 2012, provided, however, that this Agreement shall renew for additional one-year periods unless Coronado provides written notice of termination of this Agreement not later than twelve (12) months prior to the then expiration date of the Term.”

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(d) Subject to the terms and conditions of this Amendment, the 2010 Term Sheet is hereby amended, effective as of the Amendment Effective Date, as follows:

Section 6 of the 2010 Term Sheet is hereby amended and restated in its entirety to read as follows:

“6. The milestone payment described in Section (5) (the “Term Sheet Milestone Payment”) shall be made not later than January 11, 2011 (the “Term Sheet Milestone Payment Date”), except that the portion of the Term Sheet Milestone Payment calculated under Section (5) representing the Development Costs Reimbursement relating to [\*\*\*\*\*]’s Development Costs incurred from January 1, 2011 through January 8, 2011 and OvaMed’s portion of [\*\*\*\*\*]’s Development Costs representing third party invoices to [\*\*\*\*\*] for the period from December 1, 2010 through December 31, 2010 but not provided as of the Amendment Effective Date (estimated not to exceed EUR [\*\*\*\*\*]) shall be payable on the Post Amendment Payment Date. OvaMed herewith confirms and undertakes to make all Required Data available to Coronado according to section (7) or at least according to section (8) and Coronado herewith undertakes to make the Term Sheet Milestone Payment in accordance with the preceding sentence.”

Section 11 of the 2010 Term Sheet is hereby amended and restated to read in its entirety as follows:

“11. All other future payment obligations according to the SL Agreement, as amended by the amendment dated November 8, 2007 and this agreement shall remain unaffected. If Coronado cannot fulfill its further payment commitments in accordance with Section (5) and (9) of this agreement, as amended by the Amendment, and the milestone payments specified in this agreement are not made on the dates set forth in Section (6) of this Agreement, as amended by the Amendment, then this agreement, the SL Agreement, and the amendment dated November 8, 2007 shall expire in its entirety without any obligations from OvaMed to Coronado; provided, however, that with the exception of the Term Sheet Milestone Payment, which shall be payable on the dates set forth in Section (6) of this Agreement, as amended by the Amendment, the provisions of Section 9.2 of the SL Agreement shall remain applicable to amounts payable by Coronado to OvaMed”.

**3. Additional Agreements of the Parties.** Notwithstanding any other provision of the Agreements or any other prior agreements or arrangements between any of the Parties, and subject to the terms and conditions of this Amendment, the Parties agree that as of and on the Amendment Effective Date:

(a) in compliance with Section 6 of the 2010 Term Sheet, as amended, Coronado shall make the Amendment Payment (and, if applicable, the Post-Amendment Payment) to OvaMed on the Amendment Payment Date (and, if applicable, the Post-Amendment Date, respectively) to an account designated by OvaMed in writing, provided that OvaMed shall provide such written wire instructions to Coronado not later than two (2) business days prior to the Amendment Effective Date (and, if applicable, the Post-Amendment Date);

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(b) in compliance with Section 7 of the 2010 Term Sheet, OvaMed shall immediately upon receipt of the Amendment Payment and, if applicable, the Post-Amendment Payment, make the [\*\*\*\*\*] Payment to [\*\*\*\*\*] and shall (i) provide Coronado with a complete and accurate copy of the confirmation(s) of the wire transfer of the [\*\*\*\*\*] Payment; and (ii) use its best efforts to obtain from [\*\*\*\*\*] (and provide a true and accurate copy to Coronado of) a confirmation acknowledging [\*\*\*\*\*]'s receipt of the [\*\*\*\*\*] Payment and confirming that such payments are in full satisfaction of OvaMed's obligations to [\*\*\*\*\*] under Section 5.5 of the [\*\*\*\*\*] Agreement;

(c) in compliance with Section 2.3 of the Sublicense Agreement and Sections 6-8 of the 2010 Term Sheet, OvaMed shall no later than the [\*\*\*\*\*] day after receipt of the Amendment Payment make available to representatives of Coronado (in English, to the extent available; otherwise in German) in hard copy, pdf and, to the extent available, CTD (Common Technical Document) format, true, accurate and complete copies of all IND Data, including (i) those components of the IND Data previously made available for review by representatives of Asphelia and Coronado prior to the Amendment Effective Date, and (ii) those components of the IND Data listed on **Appendix A**;

(d) with respect to the Term Sheet Milestone Payment and the [\*\*\*\*\*] Payment:

(i) OvaMed hereby represents and warrants to Coronado (by way of an independent warranty under German law, "Represents and Warrants") that:

(A) the Development Costs Schedule provided by OvaMed to Asphelia and Coronado prior to the Amendment Effective Date and attached hereto as **Appendix 1** represents a complete and accurate accounting of invoices received by OvaMed from [\*\*\*\*\*] of the Development Costs Reimbursement relating to [\*\*\*\*\*]'s Development Costs incurred as of the Amendment Effective Date, and represents all amounts payable by OvaMed to [\*\*\*\*\*] under Section 5.5 of the [\*\*\*\*\*] Agreement as of the Amendment Effective Date; the schedule of Development Costs incurred by [\*\*\*\*\*] up to [\*\*\*\*\*] EUR provided by OvaMed to Coronado, as set forth under Section 5.6 of the [\*\*\*\*\*] Agreement, represents a complete and accurate schedule of such Development Costs received by OvaMed from [\*\*\*\*\*];

(B) the Amendment Payment (together with, if applicable, the Post-Amendment Payment) constitutes payment in full of the Term Sheet Milestone Payment contemplated by Section 5 of the 2010 Term Sheet and payable in accordance with Section 6 of the 2010 Term Sheet, as amended; and

(C) upon payment to OvaMed of the Amendment Payment and immediate payment by OvaMed to [\*\*\*\*\*] of the [\*\*\*\*\*] Payment, (1) OvaMed shall have satisfied in full the outstanding balance of OvaMed's financial obligations to [\*\*\*\*\*] under Section 5.5 of the [\*\*\*\*\*] Agreement as of the

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Amendment Effective Date and no further amounts shall be payable by OvaMed to [\*\*\*\*\*] in order for OvaMed to receive from [\*\*\*\*\*] the [\*\*\*\*\*]; and (2) OvaMed will have all right and authority under the [\*\*\*\*\*] Agreement to [\*\*\*\*\*], if the [\*\*\*\*\*] consent referred to in Paragraph 3(e)(ii) of this Amendment is obtained or, if such [\*\*\*\*\*] consent is not obtained prior to the [\*\*\*\*\*], on the terms and conditions set forth in Paragraph 3(e) of this Amendment.

(ii) in accordance with the foregoing, OvaMed further agrees and confirms with Coronado that:

(A) upon payment to OvaMed of the Amendment Payment and the amounts set forth on **Appendix B**, all payment obligations to OvaMed as of the Amendment Effective Date (including under any of the Agreements, including patent reimbursement fees under Section 4.1.2 of the Sublicense Agreement; the milestone payment under Section 4.3.1 of the Sublicense Agreement and referred to in Section 4 of the 2007 Letter Agreement, in paragraph 9 of the 2010 Term Sheet and elsewhere as the IND milestone prepayment; license maintenance fees under Section 4.8 of the Sublicense Agreement; and the Term Sheet Milestone Payment) have been satisfied in full, except for the Post-Amendment Payment which shall be payable in accordance with this Amendment (the Parties confirming that neither the payments set forth on **Appendix 1** nor the payments set forth on **Appendix B** shall be offset against the license maintenance fee under Section 4.8 of the Sublicense Agreement);

(B) upon payment to OvaMed of the Amendment Payment, Coronado shall have no further financial obligation to OvaMed in order for OvaMed to make available to Coronado (1) all IND Data; or (2) any other data and Documentation related to development or commercialization of Licensed Products or Licensed Processes that is developed, owned or controlled by OvaMed, that OvaMed has the right to license to Coronado, or that is required to be provided by OvaMed to Coronado under the Agreements, including under Section 2.3 of the Sublicense Agreement, Section 2.7 of the Supply Agreement, Sections 6-8 of the 2010 Term Sheet, and including in connection with the preparation and submission of the IND; and

(C) OvaMed shall provide Coronado with a complete and accurate accounting of invoices received by OvaMed from [\*\*\*\*\*] of the Development Costs Reimbursement relating to (i) [\*\*\*\*\*]'s Development Costs incurred from January 1, 2011 through January 8, 2011 and (ii) OvaMed's portion of [\*\*\*\*\*]'s Development Costs representing third party invoices to [\*\*\*\*\*] for the period from December 1, 2010 through December 31, 2010 but not provided as of the Amendment Effective Date (estimated not to exceed EUR [\*\*\*\*\*]), as soon as invoices relating thereto are obtained by OvaMed.

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(e) with respect to the IND Data and the IND:

(i) OvaMed hereby Represents and Warrants that prior to the Amendment Effective Date, OvaMed provided representatives of Asphelia and Coronado with access to true, accurate and complete copies of all IND Data, except for the documents listed and described on **Appendix A**; in addition to the IND Data to be made available to Coronado under Paragraph 3(c) of this Amendment, OvaMed shall also make available to Coronado after the Amendment Effective Date without any additional consideration any additional or updated IND Data requested by the FDA in connection with the IND; and

(ii) OvaMed hereby covenants and agrees with Coronado as follows:

(A) as soon as practicable after payment of the Amendment Payment, OvaMed shall provide Coronado with the consent by [\*\*\*\*\*] for [\*\*\*\*\*]; in such event, assuming [\*\*\*\*\*]; provided, however, that if [\*\*\*\*\*], the following subsections (B) through (F) shall apply during the period ending on the IND Transfer Date;

(B) as soon as practicable after receipt of the IND Data, OvaMed and Coronado, as consultant to OvaMed, shall cooperate in preparing the IND and OvaMed shall initially submit the IND; as IND sponsor, OvaMed shall be the primary contact with the FDA and shall be responsible for all communications with the FDA, *provided, however*, that Coronado shall have the right to assist and consult with OvaMed with respect to all regulatory submissions or communications relating to the IND prior to making any such submission or communication;

(C) at least thirty (30) days prior to the filing of any document or correspondence with the FDA relating to the IND, OvaMed shall provide Coronado with draft copies thereof and OvaMed shall incorporate any comments of Coronado with respect to the foregoing;

(D) OvaMed shall provide advance notice to Coronado of any planned meetings, discussions, or other communications with the FDA relating to the IND and Coronado shall have the right to participate in such meetings, discussions, or other communications;

(E) OvaMed shall promptly provide Coronado with copies of all filings and submissions made by OvaMed with the FDA relating to the IND shall request that FDA copy Coronado on all correspondence and other communications from the FDA relating to the IND, and shall in any event copy Coronado as on all correspondence and other communications obtained or received by OvaMed from the FDA relating to the IND immediately upon receipt thereof by OvaMed; and

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(F) upon the written request of Coronado, provided not less than [\*\*\*\*\*] months after submission of the IND with the FDA, OvaMed shall transfer the IND to Coronado without any additional consideration, including by executing and delivering to Coronado a fully executed assignment document and submitting to the FDA a letter of authorization to transfer to Coronado the IND, in form and substance satisfactory to Coronado. As soon as practicable after the submission of such letter and the receipt by Coronado of the FDA's acknowledgment letter, Coronado shall execute and submit to the FDA a letter, accompanied by the IND transfer letter referred to in the preceding sentence, acknowledging Coronado's commitment to assume ownership of the IND; from and after the IND Transfer Date, Coronado shall be the IND sponsor, the primary contact with the FDA and shall be responsible for all communications and submissions with the FDA relating to the IND.

(f) with respect to the [\*\*\*\*\*] Agreement and the License Agreement, as applicable, OvaMed hereby Represents and Warrants to Coronado as follows:

(i) The [\*\*\*\*\*] Agreement is valid and in full force and effect in accordance with its terms. OvaMed is not in default or breach of the [\*\*\*\*\*] Agreement, nor has it received any notice of any defaults, breaches or violation thereunder. To OvaMed's knowledge, [\*\*\*\*\*] is not in default or breach of such agreement and OvaMed has no knowledge of any pending or threatened bankruptcy, insolvency or similar proceeding with respect to any party to the [\*\*\*\*\*] Agreement;

(ii) [\*\*\*\*\*]'s [\*\*\*\*\*] provided for in Article 19 of the [\*\*\*\*\*] Agreement in connection with the Sublicense Agreement or the rights granted thereby was not exercised, was waived, or terminated, in any case in accordance with the terms of such Article 19;

(iii) the License Agreement is valid and in full force and effect in accordance with its terms. OvaMed is not in default or breach of the License Agreement nor has it received any notice of any defaults, breaches or violation thereunder and, to OvaMed's knowledge, UIRF is not in default or breach of such agreement; and

(iv) OvaMed has provided Coronado with a complete and accurate copy of UIRF's confirmation that OvaMed is in good standing under the License Agreement.



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**(g)** Each of OvaMed and Asphelia hereby:

(i) Represents and Warrants to Coronado that:

(G) the Sublicense Agreement and the Supply Agreement have been duly and validly assigned to Asphelia from Collingwood Pharmaceuticals, Inc.; the Agreements are valid and in full force and effect in accordance with their respective terms, and there are no breaches, defaults or events by either party thereto which would (with the giving of notice, the passage of time, or both) give rise to a breach, default or other right to terminate or render non-exclusive the Agreements; and

(H) there are no outstanding, pending or threatened claims, lawsuits or other proceedings initiated or threatened to be initiated directly or indirectly by or on behalf of either OvaMed or Asphelia or any affiliate of OvaMed or Asphelia (or, to OvaMed's knowledge, by or on behalf of [\*\*\*\*\*] or any affiliate of [\*\*\*\*\*]) against the other party to the Agreements, any affiliate of such other party or Coronado.

(ii) waives any breach by the other party thereto of any of the Agreements and any failure to comply or delay in compliance with the notice provisions set forth therein, including in Section 8.1 of the Supply Agreement to extend the Term of the Supply Agreement.

**(h)** OvaMed hereby consents to the Agreements Assignment, effective as of the Amendment Effective Date.

**(i)** As soon as practicable after the Amendment Effective Date, Coronado and OvaMed shall negotiate in good faith to enter

into:

(A) a mutually acceptable amendment to the Supply Agreement, including incorporating the provisions set forth in paragraph 2 of the 2007 Letter Agreement, and

(B) a mutually acceptable three-party agreement with [\*\*\*\*\*] providing for the ongoing exchange among the parties thereto of safety information and pre-clinical, clinical and other data sharing and reporting in accordance with appropriate laws and regulations of relevant countries and authorities; *provided, however*, that Coronado shall not enter into any agreement with [\*\*\*\*\*] to which OvaMed is not also a party that relates to the subject matter of the Sublicense Agreement without the prior written agreement of OvaMed, unless OvaMed fails to negotiate in good faith to enter into such three-party agreement; similarly, OvaMed shall not enter into any agreement with [\*\*\*\*\*] to which Coronado is not also a party that relates to the subject matter of the Sublicense Agreement without the prior written agreement of Coronado, unless Coronado fails to negotiate in good faith to enter into such three-party agreement.

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(j) Coronado hereby agrees with OvaMed to commence an FDA-approved clinical study with respect to Licensed Product within [\*\*\*\*\*] months after the date the IND is approved by the FDA, subject to the provisions of this paragraph 3(j):

(i) The foregoing obligation shall not apply if the inability or failure to satisfy such obligation arises from any of the following: (A) an inability to obtain from OvaMed sufficient quantities of clinical supplies in compliance with specifications and FDA regulations; (B) an inability to conduct such clinical study due to action, instruction, delay or guidance by the FDA; (C) a good faith determination on the part of Coronado that the product that is intended to be studied in the clinical study is not safe or efficacious in its then current formulation or dosage form or dose level; (D) any action by or inaction of OvaMed resulting in a breach or termination of any of the Agreements or the License Agreement; or (E) the occurrence of an unexpected or unforeseen “force majeure” event preventing such commencement.

(ii) In the event that Coronado fails to fulfill such obligation and none of the provisions of subsection (i) above are applicable, Coronado shall make a US \$[\*\*\*\*\*] payment to OvaMed. In such event, the obligation to commence a clinical study as set forth in this Paragraph 3(j) shall be extended for an additional [\*\*\*\*\*] months, provided that in the event that Coronado fails to fulfill such obligation by such extended date ([\*\*\*\*\*]) and none of the provisions of subsection (i) above are applicable, Coronado shall make an additional US \$[\*\*\*\*\*] payment to OvaMed. Such US \$[\*\*\*\*\*] payment obligation for failure to fulfill the obligation to commence a clinical study by the then applicable date shall continue to apply for each additional [\*\*\*\*\*] month extension of such date. As a result of any such payments, the failure to fulfill the obligation to commence such clinical study by the then applicable date shall not constitute a breach of this Paragraph 3(j).

(iii) No payments made under this Paragraph 3(j) shall be offset against the license maintenance fee under Section 4.8 of the Sublicense Agreement.

#### 4. Mutual Releases.

(a) **Release by Asphelia.** Asphelia, on its own behalf and on behalf of its Affiliates, predecessors, successors, and assigns and all others claiming by or through any of the foregoing (collectively, the “**Asphelia Parties**”), hereby releases and forever discharges OvaMed, its Affiliates and their respective assigns, attorneys, agents, legal representatives, officers, directors, employees, predecessors, successors, distributors, manufacturers and Affiliates (collectively, the “**OvaMed Releasees**”) from any and all claims, causes of action, actions, duties, damages, liabilities, losses, and obligations of every kind and manner whatsoever, in law or in equity, judicial or administrative, civil or criminal, whether or not now known, claimed or asserted, which any Asphelia Party now has, had at any time or may in the future claim to have, against any of the OvaMed Releasees based on, arising out of or related to the Agreements and arising from or relating to any actions, omissions, or events prior to the Amendment Effective Date, provided, however, that the foregoing release shall not include, and Coronado shall retain, all claims, causes of action, actions, duties, rights, damages, liabilities, losses, or obligations arising out of or under this Amendment or under the Agreements to the extent arising from any actions, omissions, or events after the Amendment Effective Date.

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**(b) Release by OvaMed.** OvaMed, on its own behalf and on behalf of its Affiliates, predecessors, successors, and assigns and all others claiming by or through any of the foregoing (collectively, the “**OvaMed Parties**”) hereby releases and forever discharges the Asphelia Parties, Coronado, and their respective assigns, attorneys, agents, legal representatives, officers, directors, employees, predecessors, successors, distributors, manufacturers and Affiliates (collectively, the “**Asphelia Releasees**”) from any and all claims, causes of action, actions, duties, damages, liabilities, losses, and obligations of every kind and manner whatsoever, in law or in equity, judicial or administrative, civil or criminal, whether or not now known, claimed or asserted, which any OvaMed Party now has, had at any time or may in the future claim to have, against any of the Asphelia Releasees based on, arising out of or related to the Agreements and arising from any actions, omissions, or events prior to the Amendment Effective Date, provided, however, that the foregoing release shall not include, and OvaMed shall retain, all claims, causes of action, actions, duties, rights, damages, liabilities, losses, or obligations arising out of or under this Amendment or under the Agreements to the extent arising from any actions, omissions, or events after the Amendment Effective Date.

**5. Representations and Warranties.** Each Party hereby represents and warrants to the other Parties hereto that:

**(a)** Such Party has the requisite corporate power and authority to execute and deliver this Amendment, to grant the releases and perform its other obligations hereunder and to consummate the transactions contemplated hereby; the execution, delivery and performance of this Amendment have been duly and validly authorized and no other corporate proceedings are necessary to authorize this Amendment or the performance hereof or thereof by such Party; and

**(b)** This Amendment has been duly and validly executed and delivered by such Party and, assuming due authorization, execution and delivery by the other Parties, constitutes the valid and binding obligations of such Party, enforceable against such Party in accordance with its terms.

**6. Other.**

**(a)** From and after the Amendment Effective Date, all references to the Agreements shall mean the Agreements as amended by this Amendment. Except as expressly amended or satisfied by the transactions contemplated by this Amendment, all of the provisions of the Agreements shall remain in full force and effect. Notwithstanding any other provision of this Amendment, including this Paragraph 6, the Parties hereby expressly agree with respect to the letter dated January 8, 2009 from OvaMed to Asphelia stating a termination of the Sublicense Agreement, including the terms and conditions contained therein (the “**2009 Letter**”), that (i) the 2009 Letter shall terminate and shall be deemed terminated in its entirety and shall be void and of no force and effect and (ii) no Party shall have any rights, obligation or liability to any other Party under or as a result of the 2009 Letter or in connection with the termination thereof except as specifically set forth in this Amendment. From and after the Amendment Effective Date, in the event of any ambiguity interpreting any provision of any of the Agreements whether or not as a result of this Amendment, the Parties shall in good faith interpret such provisions to be consistent with the specified terms and provisions and the overall intent and purposes of this Amendment.

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**(b)** This Amendment contains the entire understanding of the Parties with respect to the subject matter of this Amendment. All express or implied agreements and understandings, either oral or written, made on or before the Amendment Effective Date, including any correspondence, emails or term sheets, are expressly superseded by this Amendment. This Amendment may be amended, or any term hereof modified, including this Paragraph 6(b), only by a written instrument duly executed by all Parties. In the event the Closing does not occur on or before January 10, 2011, this Amendment shall be void and of no force and effect.

**(c)** This Amendment may be executed in two or more counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Signatures to this Amendment transmitted by fax, by email in “portable document format” (“**.pdf**”) or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Amendment shall have the same effect as physical delivery of the paper document bearing original signature.

**(d)** This Amendment, the Agreements, the rights of the Parties, and all claims arising under or in connection herewith shall be governed by and interpreted in accordance with the substantive laws of Germany, Hamburg, without regard to conflict of laws principles thereof that would cause the application of the laws of any other jurisdiction. The parties irrevocably submit to the jurisdiction of the courts of Germany, Hamburg for the purpose of any claim, controversy, action, cause in action, suit or litigation between the parties arising in whole or in part under or in connection with this Amendment.

**(e)** All notices, requests and other communications hereunder shall be in writing and shall be personally delivered or sent by fax transmission (and promptly confirmed by personal delivery, registered or certified mail or overnight courier) or by registered or certified mail, return receipt requested, postage prepaid, or sent by internationally-recognized overnight courier, in each case to the respective address specified below, or such other address as may be specified in writing to the other party hereto:

if to Asphelia to:

Asphelia Pharmaceuticals, Inc.  
787 Seventh Avenue, 48th Floor  
New York, NY 10019, United States  
Attention: Chief Executive Officer  
Fax No.: 212-554-4488

if to Coronado to:

Coronado Biosciences, Inc.  
45 Rockefeller Plaza, 20<sup>th</sup> Floor  
New York, NY 10111, United States  
Attention: Chief Operating Officer  
Fax No.: 212-332-1667

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if to OvaMed and relating to the IND or IND Data to:

OvaMed GmbH  
Kiebitzhörn 33-35  
22885 Barsbützel, Germany  
Attention: General Manager, (COO), Detlev Goj  
Fax No.: +49 40 675 095 59

if to OvaMed and relating to any other matters to:

OvaMed GmbH  
Kiebitzhörn 33-35  
22885 Barsbützel, Germany  
Attention: General Manager, (CEO), Mr. Alexander Beese  
Fax No.: +49 40 675 095 59

[Remainder of page intentionally left blank]

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IN WITNESS WHEREOF, the Parties have executed this Amendment as of the date first set forth above.

**Asphelia Pharmaceuticals, Inc.**

By: /s/ J. Jay Lobell

Name: J. Jay Lobell

Title: Interim Chief Executive Officer

**OvaMed GmbH**

By: /s/ Alexander Beese

Name: Alexander Beese

Title: General Manager (CEO)

**OvaMed GmbH**

By: /s/ Detlev Goj

Name: Detlev Goj

Title: General Manager (COO)

**Coronado Biosciences, Inc.**

By: /s/ Glenn L. Cooper

Name: Glenn L. Cooper, M.D.

Title: Chairman

**OvaMed Amendment final**

Appendix 1

Development Costs Schedule

Invoices from [\*\*\*\*\*] to Ovamed: [\*\*\*\*\*]% of costs exceeding €[\*\*\*\*\*]

<u>Invoice No.</u>	<u>Invoice Date</u>	<u>Amount in €*</u>
16805	13.05.2009/13.07.2009	[*****]
16806	30.06.2009/13.07.2009	[*****]
16807	7/15/09	[*****]
16808	7/15/09	[*****]
16825	8/20/09	[*****]
16828	9/15/09	[*****]
16839	9/15/09	[*****]
16860	30.09.2009/16.10.2009	[*****]
16879	31.10.2009/24.11.2009	[*****]
16888	12/10/09	[*****]
16898	20.12.2009/13.01.2010	[*****]
16903	30.11.2009/31.12.2009	[*****]
16904	30.12.2009/20.01.2010	[*****]
16911	1/29/10	[*****]
16920	30.12.2009/20.01.2010	[*****]
16933	4/7/10	[*****]
16936	2/28/10	[*****]
16941	4/22/10	[*****]
16949	4/30/10	[*****]
16962	6/16/10	[*****]
16978	31.05.2010/30.06.2010	[*****]
16979	30.06.2010/20.07.2010	[*****]
16980	7/20/10	[*****]
17008	9/7/10	[*****]
17009	9/8/10	[*****]
17044	Sept. 2010 - Dec. 2010	[*****]
<b>Total</b>		<b><u>2,390,679.92</u></b>

\* Payable in EUR (€)

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**Appendix A**

**IND Data Not Provided Prior to Amendment Effective Date**

[\*\*\*\*\*]:

1. [\*\*\*\*\*]
2. [\*\*\*\*\*]
3. [\*\*\*\*\*]



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**Appendix B**

**Amount Payable to OvaMed as of Amendment Effective Date<sup>1</sup>**

December 2010 Annual License Fee	US \$250,000
Net UIRF patent reimbursement	\$ 30,883 <sup>2</sup>
<b>Net payable on or before January 11, 2011</b>	<b><u>US \$280,883</u></b>

<sup>1</sup> Payable in US\$. Excludes (i) Term Sheet Milestone Payment, and (ii) remaining balance (US\$[\*\*\*\*\*]) of IND pre-payment milestone payable per 2010 Term Sheet one month after IND Data received by Coronado.

<sup>2</sup> For invoices ORE02884, ORE03070, ORE03074, ORE03078 and ORE03165