

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

**Amendment No. 2  
TO  
FORM S-1**

REGISTRATION STATEMENT  
UNDER  
THE SECURITIES ACT OF 1933

**CORONADO BIOSCIENCES, INC.**

(Exact name of registrant as specified in its charter)

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

**2836**  
(Primary standard industrial  
classification code number)

**20-5157386**  
(I.R.S. employer  
identification number)

**15 New England Executive Park  
Burlington, MA 01803  
(781) 238-6621**

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

**Bobby W. Sandage, Jr., Ph.D.,  
Chief Executive Officer  
15 New England Executive Park  
Burlington, MA 01803  
(781) 238-6621**

(Name, address, including zip code, and telephone number, including area code, of agent for service)

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**Approximate date of commencement of proposed sale to the public:** As soon as practicable after the effective date of this registration statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933 check the following box.

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b2 of the Exchange Act.

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

**CALCULATION OF REGISTRATION FEE**

Title of Each Class of Security Being Registered	Amount Being Registered	Proposed Maximum Offering Price per Security(1)	Proposed Maximum Aggregate Offering Price(1)	Amount of Registration Fee
Common Stock, \$0.001 par value(2)	5,290,000(3)	\$ 5.54	\$ 31,054,600	\$ 3,560(4)

(1) Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(c) based on the high and low price per share of the Common Stock on May 29, 2012 (\$6.30) with respect to 2,300,000 shares and June 15, 2012 (\$5.54) with respect to 2,990,000 shares.  
(2) Pursuant to Rule 416, there are also being registered such additional securities as may be issued to prevent dilution resulting from stock splits, stock dividends or similar transactions.  
(3) Includes 690,000 shares of common stock subject to the underwriters' overallotment option.

(4) \$1,661 of which was previously paid.

**The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.**

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The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and is not soliciting an offer to buy these securities in any state or other jurisdiction where the offer or sale is not permitted.

Subject to Completion, Dated June 21, 2012

**4,600,000 Shares**



**Common Stock**  
**\$ per share**

Coronado Biosciences, Inc. is offering 4,600,000 shares of common stock.

Our common stock is listed on the NASDAQ Capital Market under the symbol "CNDO." On \_\_\_\_\_, 2012, the last reported sale price of our common stock on the NASDAQ Capital Market was \$ \_\_\_\_\_.

**Investing in our common stock involves risks. See "[Risk Factors](#)" beginning on page 5.**

	<u>Per Share</u>	<u>Total</u>
Price to the public	\$	\$
Underwriting discount <sup>(1)</sup>	\$	\$
Proceeds to us	\$	\$

(1) In addition, we have agreed to reimburse the underwriters for certain out-of-pocket expenses. See the section captioned "Underwriting" in this prospectus for additional information.

The underwriters have reserved for sale at the public offering price up to 200,000 shares offered by this prospectus for Lindsay A. Rosenwald, M.D., a principal stockholder and director. In addition, the underwriters have reserved for sale at the public offering price up to 75,000 shares offered by this prospectus for our other officers and directors, including Bobby W. Sandage, Jr., Ph.D., our president, chief executive officer and director. Each of these individuals has entered into lock-up agreements. See "Underwriting."

We have granted an over-allotment option to the underwriters. Under this option, the underwriters may elect to purchase a maximum of 690,000 additional shares from us within 30 days following the date of this prospectus to cover over-allotments.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

**Oppenheimer & Co.**

**Roth Capital Partners**

**National Securities Corporation**

The date of this prospectus is \_\_\_\_\_, 2012

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## Prospectus Summary

*This summary highlights information contained in other parts of this prospectus. Because it is a summary, it does not contain all of the information that you should consider before investing in the shares. You should read the entire prospectus carefully.*

### The Company

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

#### TSO

TSO, or CNDO-201, is a biologic comprising *Trichuris suis* ova, the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's disease, or Crohn's, ulcerative colitis, or UC, and multiple sclerosis, or MS. In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in 36 patients with Crohn's. The trial was a sequential dose-escalation, double-blind, placebo-controlled study to examine safety and tolerability. TSO was safe and well tolerated, with no serious treatment-related adverse events reported. To date, a number of investigator-sponsored clinical trials have been conducted using TSO in patients suffering from Crohn's, UC or MS. These studies also demonstrated that TSO is safe and well tolerated. Two of these studies reported that treatment with TSO could induce clinical remission in Crohn's patients after 24 weeks of treatment (n=29 patients) and in UC patients (n=54 patients). In April 2012, our development partner, Dr. Falk Pharma GmbH, or Falk, reported that an independent data monitoring committee had found no safety concerns and a positive efficacy trend in an interim analysis (blinded to Falk) of clinical data from the initial 120 patients in Falk's ongoing Phase 2 clinical trial in Europe evaluating TSO in Crohn's patients. Based on the committee's recommendations, Falk has advised us that it is increasing the size of its trial and will conduct a subsequent interim analysis at the time the trial reaches approximately 250 patients, which we expect to occur in mid-2013. Pending final discussions with the United States Food and Drug Administration, or FDA, we expect to commence our own 220-patient Phase 2 clinical trial of TSO in Crohn's patients in the third quarter of 2012 and to have initial study results in the second half of 2013. We have the exclusive rights to TSO in North America, South America and Japan under a sublicense agreement with OvaMed GmbH, or OvaMed, as well as a manufacturing and supply agreement with OvaMed to provide us with our clinical and commercial requirements of TSO.

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

#### CNDO-109

CNDO-109 is a biologic that activates the immune system's natural killer, or NK, cells to seek and destroy cancer cells. We intend to study CNDO-109 initially in patients that have been diagnosed with acute myeloid leukemia, or AML. Preclinical studies have demonstrated that CNDO-109 activated NK cells directly kill cells

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that cause hematologic malignancies including myeloid leukemia and multiple myeloma, as well as breast, prostate and ovarian cancers. Eight patients with high-risk AML received CNDO-109 activated NK cells in a recent Phase 1 investigator-sponsored trial. Although the primary endpoint of the Phase 1 clinical trial was safety, based on the data obtained from this Phase 1 study, we believe early efficacy was observed. The clinical investigators observed that the majority of patients experienced a longer complete remission than their previous complete remission. In February 2012, we filed an Investigational New Drug application, or IND, for a multi-center Phase 1/2 clinical trial in patients with relapsed AML that we currently plan to initiate in the second half of 2012. In June 2012, the FDA granted orphan drug designation to CNDO-109 activated NK cells for the treatment of AML. We have exclusive worldwide rights to develop and market CNDO-109 under a license agreement with the University College London Business PLC, or UCLB.

Our principal executive offices are located 15 New England Executive Park, Burlington, MA 01803. Our telephone number is (781) 238-6621.

### The Offering

Common stock offered by us 4,600,000 shares

Common stock to be outstanding after the offering 23,225,749 shares (1)

Use of proceeds We estimate that the net proceeds from this offering, after deducting underwriting discount and estimated offering expenses payable by us, will be approximately \$ . We intend to use the proceeds of this offering to continue clinical development and testing of TSO and CNDO-109 and for working capital and other general corporate purposes.

Risk factors See “Risk Factors” beginning on page 5 for a discussion of risks you should consider before purchasing shares of our common stock.

NASDAQ Capital Market symbol CNDO

- (1) The number of shares of our common stock to be outstanding immediately after this offering is based on 18,625,749 shares of our common stock outstanding as of June 20, 2012. The number of shares outstanding as of June 20, 2012 excludes:
- 2,354,070 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$3.27; and
  - 1,040,814 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of \$6.31.

Unless otherwise stated, all information in this prospectus assumes no exercise of the over-allotment option granted to the underwriters.

#### Conflicts of Interest

National Securities Corporation, or National, one of the underwriters in this offering, is affiliated with Lindsay A. Rosenwald, M.D., a principal stockholder and a member of our board of directors. Under the rules of the Financial Industry Regulatory Authority, Inc., a conflict of interest is deemed to exist with respect to National because Dr. Rosenwald is deemed to control both National (as a beneficial owner of in excess of 10% of the outstanding capital stock of National) and us. As described above under “Certain Transactions – 2011 Series C Financing,” in connection with our Series C Financing, National received commissions of \$2.6 million and five-year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of \$5.59, which were subsequently transferred by National to other individuals and entities and are now exercisable to purchase 458,276 shares of common stock. The underwriters have reserved for sale at the public offering price up to 200,000 shares offered by this prospectus for Dr. Rosenwald.

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**Summary Consolidated Financial Information**

This section presents our summary historical consolidated financial data. You should read carefully the consolidated financial statements included in this prospectus, including the notes to the consolidated financial statements. The summary consolidated data in this section are not intended to replace the consolidated financial statements.

We derived the statement of operations data for the years ended December 31, 2011, 2010 and 2009 and the balance sheet data as of December 31, 2011 and 2010 from the audited consolidated financial statements and related notes included in this prospectus. We derived the statement of operations data and balance sheet data as of and for the three months ended March 31, 2012 and 2011 from the unaudited consolidated financial statements and related notes included in this prospectus. Our management believes that the unaudited historical consolidated financial statements contain all adjustments needed to state fairly the information contained in those statements, and that the adjustments made consist only of normal recurring adjustments.

<u>(In thousands, except share and per share data)</u>	<u>For the year ended December 31,</u>			<u>For the three months ended</u>	
	<u>2011</u>	<u>2010</u>	<u>2009</u>	<u>2012</u>	<u>2011</u>
				<u>unaudited</u>	<u>unaudited</u>
<b>Statement of Operations data:</b>					
Operating expenses:					
Research and development	\$ 8,583	\$ 8,341	\$ 2,270	\$ 4,581	\$ 1,246
General and administrative	5,755	900	343	2,000	593
In-process research and development	20,706	—	—	—	20,706
Loss from operations	(35,044)	(9,241)	(2,613)	(6,581)	(22,545)
Interest income	165	61	—	44	19
Interest expense	(74)	(1,535)	(1,053)	(19)	(17)
Other income	—	733	—	—	—
Warrant expense	(1,407)	—	—	—	—
Net loss	(36,360)	(9,982)	(3,666)	(6,556)	(22,543)
Common Stock dividend to Series A Convertible Preferred Stockholders	(5,861)	—	—	—	—
Net loss attributed to Common Stockholders	\$ (42,221)	\$ (9,982)	\$ (3,666)	\$ (6,556)	\$ (22,543)
Basic and diluted net loss per common share	\$ (5.51)	\$ (2.24)	\$ (1.01)	\$ (0.35)	\$ (4.71)
Weighted average common shares outstanding— basic and diluted	7,662,984	4,453,786	3,612,769	18,604,245	4,791,102
<b>Balance Sheet Data:</b>					
			<u>As of December 31,</u>		<u>As of</u>
			<u>2011</u>	<u>2010</u>	<u>March 31,</u>
					<u>2012</u>
Current assets			\$ 23,375	\$ 14,917	\$18,043
Total assets			\$ 23,375	\$ 14,939	\$18,043
Long-term debt			\$ 750	\$ —	\$ 750
Total liabilities			\$ 4,243	\$ 1,559	\$ 4,593
Total Stockholders' Equity (Deficit)			\$ 19,132	\$ (15,897)	\$13,450
Total Liabilities and Stockholders' Equity (Deficit)			\$ 23,375	\$ 14,939	\$18,043



## Risk Factors

### Risks Related to Our Business and Industry

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

We are a clinical development stage biopharmaceutical company. We have engaged primarily in research and development activities since inception, have not generated any revenues from product sales and have incurred significant net losses since our inception. As of March 31, 2012, we had an accumulated deficit of approximately \$63.1 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

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

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

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

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

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

All of our product candidates, including related intellectual property rights, were in-licensed from third parties. Under the terms of our license agreements, the licensors generally have the right to terminate such agreements in the event of a material breach by us. Our licenses require us to make annual, milestone or other payments prior to commercialization of any product and our ability to make these payments depends on our ability to generate cash in the future. These agreements generally require us to use diligent and reasonable efforts to develop and commercialize the product candidate. In the case of TSO, OvaMed licenses TSO from a third party, University of Iowa Research Foundation, or UIRF, in exchange for annual and milestone payments, patent cost reimbursement, royalties based on sales and diligence obligations. Our rights to TSO are, therefore, also subject to OvaMed's performance of its obligations to UIRF, any breach of which we may be required to remedy in order to preserve our rights.

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

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

Pharmaceutical development has inherent risk. We will be required to demonstrate through well-controlled clinical trials that our product candidates are effective with a favorable benefit-risk profile for use in their target indications before we can seek regulatory approvals for their commercial sale. Success in early clinical trials does not mean that later clinical trials will be successful as product candidates in later-stage clinical trials may fail to demonstrate sufficient safety or efficacy despite having progressed through initial clinical testing. We also may need to conduct additional clinical trials that are not currently anticipated. Companies frequently suffer significant setbacks in advanced clinical trials, even after earlier clinical trials have shown promising results. In addition, only a small percentage of drugs under development result in the submission of a New Drug Application, or NDA, or Biologics License Application, or BLA, to the FDA and even fewer are approved for commercialization.

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

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

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

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- we may be unable to demonstrate to the satisfaction of the FDA that a product candidate is safe and effective for any indication;
- the FDA may not accept clinical data from trials which are conducted by individual investigators or in countries where the standard of care is potentially different from the United States;
- the results of clinical trials may not meet the level of statistical significance required by the FDA for approval;

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- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA may disagree with our interpretation of data from preclinical studies or clinical trials;
- the FDA may fail to approve the manufacturing processes or facilities of third-party manufacturers with which we or our collaborators contract for clinical and commercial supplies; or
- the approval policies or regulations of the FDA may significantly change in a manner rendering our clinical data insufficient for approval.

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

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

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

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

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

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

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and

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- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues.

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

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

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

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

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

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

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

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

We are completely dependent on third party manufacturers for product supply. In particular, we rely and expect to continue to rely exclusively on OvaMed to supply us with our requirements of TSO. OvaMed is the sole

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

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

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

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

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

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

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

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

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

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

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

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- the cost of treatment in relation to alternative treatments;
- the availability of adequate reimbursement and pricing by third parties and government authorities;
- relative convenience and ease of administration;
- the prevalence and severity of adverse events;
- the effectiveness of our sales and marketing efforts; and
- unfavorable publicity relating to the product.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. UIRF, Falk and OvaMed are responsible for prosecuting and maintaining patent protection relating to their respective patents relating to TSO and UCLB is responsible for prosecuting and maintaining patent protection for CNDO-109, in each case at our expense for our territories. If UIRF, Falk, OvaMed and/or UCLB fail to appropriately prosecute and maintain patent protection for these product



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candidates, our ability to develop and commercialize these product candidates may be adversely affected and we may not be able to prevent competitors from making, using and selling competing products. This failure to properly protect the intellectual property rights relating to these product candidates could have a material adverse effect on our financial condition and results of operations.

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

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

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

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

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

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*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 the possibility of treble damages and attorneys' fees, if a court decides that the product or proprietary technology at issue infringes on or violates the third party's rights;
- pay substantial royalties, fees and/or grant cross licenses to our technology; and/or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our financial and management resources.

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

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

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

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

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

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

We are a company in the development stage and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses in all periods since our inception in June 2006, including losses of approximately \$3.7 million, \$10.0 million, and \$36.4 million for the years ended December 31, 2009, 2010 and 2011, respectively, and \$6.6 million in the three months ended March 31, 2012. At March 31, 2012, we had an accumulated deficit of approximately \$63.1 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial activities for our product candidates. Our losses have had, and are expected to continue to have, an adverse impact on our working capital, total assets and stockholders' equity. Because of the risks and uncertainties associated with product development, we are unable to predict the extent of any future losses, whether we will ever generate significant revenues or if we will ever achieve or sustain profitability.

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

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2009, 2010 and 2011, we incurred research and development expenses of approximately \$2.3 million, \$8.3 million and \$8.6 million, respectively, and \$4.6 million in the three months ended March 31, 2012. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates and purchasing clinical trial materials from our suppliers. We believe that our cash on hand and the net proceeds from this offering will sustain our operations through the third quarter of 2013 and that we will require substantial additional funds to support our continued research and development activities, as well as the anticipated costs of preclinical studies and clinical trials, regulatory approvals and potential commercialization. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect. Our current financial condition raises substantial doubt about our ability to continue as a going concern.

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

*We received a report from our independent registered public accounting firm with an explanatory paragraph for the year ended December 31, 2011 with respect to our ability to continue as a going concern. The existence of such a report may adversely affect our stock price and our ability to raise capital. There is no assurance that we will not receive a similar report for our year ending December 31, 2012.*

In their report dated March 29, 2012, our independent registered public accounting firm expressed substantial doubt about our ability to continue as a going concern. We have incurred losses and negative cash flows from operations since inception, have an accumulated deficit as of December 31, 2011 and require additional financing to fund future operations. Our ability to continue as a going concern is subject to our ability to obtain necessary funding from outside sources, including obtaining additional funding from the sale of our securities.

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*Raising additional funds by issuing securities or through licensing or lending arrangements may cause dilution to our existing stockholders, restrict our operations or require us to relinquish proprietary rights.*

To the extent that we raise additional capital by issuing equity securities, the share ownership of existing stockholders will be diluted. Any future debt financing may involve covenants that restrict our operations, including limitations on our ability to incur liens or additional debt, pay dividends, redeem our stock, make certain investments and engage in certain merger, consolidation or asset sale transactions, among other restrictions. In addition, if we raise additional funds through licensing arrangements, it may be necessary to relinquish potentially valuable rights to our product candidates, or grant licenses on terms that are not favorable to us.

*If we fail to maintain proper and effective internal control over financial reporting in the future, our ability to produce accurate and timely financial statements could be impaired, which could harm our operating results, investors' views of us and, as a result, the value of our common stock.*

Pursuant to Section 404 of the Sarbanes-Oxley Act of 2002 and related rules, or SOX, for the year ending December 31, 2012, our management will be required to report on, and our independent registered public accounting firm may be required to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. To comply with the requirements of being a reporting company under the Securities Exchange Act of 1934, or the Exchange Act, we may need to further upgrade our systems, including information technology, implement additional financial and management controls, reporting systems and procedures and hire additional accounting and finance staff.

Historically we did not have sufficient accounting and supervisory personnel with the appropriate level of technical accounting experience and training necessary for, or adequate documented accounting policies and procedures to support effective, internal controls. These material weaknesses contributed to audit adjustments for the years ended December 31, 2010, 2009 and 2008. While we have commenced the process of documenting, reviewing and improving our internal controls over financial reporting for compliance with Section 404 of SOX and have made efforts to improve our internal controls and accounting policies and procedures, including hiring new accounting personnel and engaging external temporary resources, we may in the future identify deficiencies and weaknesses in our internal controls. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our common stock to decline.

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

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

At June 20, 2012, Lindsay A. Rosenwald, M.D., a member of our board of directors, beneficially owned approximately 18.1% of our issued and outstanding capital stock, and certain trusts established for the benefit of Dr. Rosenwald and his family members additionally beneficially owned an aggregate of approximately 7.9% of our issued and outstanding capital stock. By virtue of his holdings and his membership on our board of directors, Dr. Rosenwald may influence the election of the members of our board of directors, our management and our affairs and may make it difficult for us to consummate corporate transactions such as mergers, consolidations or the sale of all or substantially all of our assets that may be favorable from our standpoint or that of our other stockholders. In addition, Dr. Rosenwald is an affiliate of National, which is acting as an underwriter in this offering. Under the rules of the Financial Industry Regulatory Authority, Inc., a conflict of interest is deemed to exist with respect to National because Dr. Rosenwald is deemed to control both National (as a beneficial owner of in excess of 10% of the outstanding capital stock of National) and us. As described

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below under “Certain Transactions—2011 Series C Financing,” in connection with our Series C Financing, National received commissions of \$2.6 million and five-year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of \$5.59, which were subsequently transferred by National to other individuals and entities and are now exercisable to purchase 458,276 shares of common stock. See “Underwriting—Conflicts of Interest.” In addition, the underwriters have reserved for sale at the public offering price up to 200,000 shares offered by this prospectus for Dr. Rosenwald.

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

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

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

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

*Our potential inclusion in the Russell 3000® Index may temporarily result in increased volatility in the price and trading volume of our common stock.*

We have become aware that our common stock may be included in the Russell 3000® Index on or about June 22, 2012. Although no assurance can be given that our common stock will be included in the index or as to the timing thereof, in the event that our common stock is included in the index, asset managers that invest in the index will be required to purchase shares of our common stock at that time. Such purchases, or the perception that such purchases will occur, may temporarily result in increased volatility in the price and trading volume of our common stock.

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

Almost all of our 18.6 million outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act or an effective registration statement. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

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

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt

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agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

*Provisions in our certificate of incorporation, our by-laws and Delaware law might discourage, delay or prevent a change in control of our company or changes in our management and, therefore, depress the trading price of our common stock.*

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

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

In addition, Section 203 of the Delaware General Corporation Law prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder, generally a person which together with its affiliates owns, or within the last three years, has owned 15% of our voting stock, for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is approved in a prescribed manner.

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

### **Risks Associated with the Offering**

*We have broad discretion in the use of the net proceeds of this offering and may not use them effectively.*

We intend to use the net proceeds from this offering for general corporate purposes and to continue clinical trials of our product candidates. However, our management will have broad discretion in the application of the net proceeds from this offering and could spend the proceeds in ways that do not improve our results of operations or enhance the value of our common stock. The failure by management to apply these funds effectively could result in financial losses that could have a material adverse effect on our business, cause the price of our common stock to decline and delay the development of our product candidates. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

*You will experience immediate and substantial dilution in the net tangible book value per share of the common stock you purchase.*

Because the public offering price per share of our common stock is substantially higher than the net tangible book value per share of our common stock, you will suffer substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on an assumed public offering price of \$            per share (the last reported sale price of the common stock on June   , 2012), if you purchase shares of common stock in this offering, you will suffer immediate and substantial dilution of approximately \$            per share in the net tangible book value of the common stock. See the section entitled “Dilution” in this prospectus for a more detailed discussion of the dilution you will incur if you purchase common stock in this offering.

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### Forward-Looking Statements

Some of the information in this prospectus contains forward-looking statements within the meaning of the federal securities laws. These statements include, among others, statements about:

- our plans to develop TSO and CNDO-109;
- ongoing and planned clinical trials of TSO and CNDO-109, particularly the timing for initiation, enrollment and outcome;
- the expected timing of and our ability to obtain and maintain regulatory approvals for our product candidates;
- the potential indications for our product candidates;
- our intellectual property position;
- our manufacturing capabilities and strategy;
- our plans relating to manufacturing, supply and other collaborative agreements; and
- our estimates regarding expenses, capital requirements and needs for additional financing.

These statements may be found under “Prospectus Summary,” “Risk Factors,” Management’s Discussion and Analysis of Financial Condition and Results of Operations” and “Business.” Forward-looking statements typically are identified by the use of terms such as “anticipates,” “believes,” “can,” “continue,” “could,” “estimates,” “expects,” “intends,” “may,” “plans,” “potential,” “predicts,” “should,” or “will” or the negative of these terms, although some forward-looking statements are expressed differently. You should be aware that our actual results could differ materially from those contained in the forward-looking statements due to the factors referenced above.

You should also consider carefully the statements under “Risk Factors” and other sections of this prospectus, which address additional factors that could cause our actual results to differ from those set forth in the forward-looking statements. 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.

### Common Stock Market Data

Our common stock is listed on the NASDAQ Capital Market under the symbol “CNDO.” From November 17, 2011 to December 16, 2011, our common stock was traded in the over-the-counter market and quoted through the Over-The-Counter Bulletin Board under the same symbol.

The following table sets forth the high and low bid prices for our common stock from November 17, 2011, the date trading of our common stock commenced, to December 16, 2011 as reported by the Over-The-Counter Bulletin Board, and the high and low sale prices for our common stock from December 19, 2011 through June 20, 2012, as reported by the NASDAQ Capital Market. Quotations on the Over-The-Counter Bulletin Board reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

<u>Quarter Ending:</u>	<u>High</u>	<u>Low</u>
<b>Fiscal Year 2012</b>		
First Quarter	\$ 9.52	\$5.00
Second Quarter (through June 20, 2012)	\$ 8.50	\$5.41
<b>Fiscal Year 2011</b>		
Fourth Quarter (November 17 to December 16)	\$11.00	\$6.50
Fourth Quarter (December 19 to December 31)	\$ 6.50	\$6.00

At June 20, 2012, there were 18,625,749 shares of our common stock outstanding held by 434 holders of record.

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**Use of Proceeds**

We estimate that the net proceeds from the sale of the shares of common stock we are offering will be approximately \$ . If the underwriters fully exercise the over-allotment option, the net proceeds of the shares we sell will be approximately \$ . “Net proceeds” is what we expect to receive after paying the underwriting discount and other expenses of the offering.

We intend to use the proceeds of this offering to continue clinical development and testing of TSO and CNDO-109 and for working capital and other general corporate purposes.

Until we use the net proceeds of the offering, we will invest the funds in short-term, investment grade, interest-bearing securities, or in savings accounts.

**Dividend Policy**

We have never paid any cash dividends on our capital stock. We anticipate that we will retain earnings, if any, to support operations and to finance the growth and development of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. Therefore, we do not expect to pay cash dividends in the foreseeable future.



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## Capitalization

The following table shows:

- Our capitalization on March 31, 2012; and
- Our capitalization on March 31, 2012, assuming the completion of the offering at an assumed public offering price of \$ \_\_\_\_\_ per share and the use of the net proceeds as described under “Use of Proceeds.”

(\$ 000's, except share and per share amounts)	March 31, 2012	
	Actual	As Adjusted
Notes payable to Stockholder—related party	\$ 750	\$ 750
Stockholders' Equity:		
Common Stock, \$.001 par value, 50,000,000 shares authorized, 18,604,245 shares issued and outstanding; 23,204,245 shares issued and outstanding, as adjusted <sup>(1)</sup>	19	
Additional paid-in capital	76,561	
Deficit accumulated during the development stage	(63,130)	
Total stockholders' equity	13,450	
Total capitalization	\$ 14,200	

- (1) The number of shares of our common stock to be outstanding immediately after this offering is based on 18,604,245 shares of our common stock outstanding as of March 31, 2012. The number of shares outstanding as of March 31, 2012 excludes:
- 2,204,070 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$2.96; and
  - 1,068,800 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of \$6.19.

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**Dilution**

Our net tangible book value on March 31, 2012 was approximately \$13.5 million, or \$0.72 per share. “Net tangible book value” is total assets minus the sum of liabilities and intangible assets. “Net tangible book value per share” is net tangible book value divided by the total number of shares outstanding on March 31, 2012.

After giving effect to adjustments relating to the offering, our pro forma net tangible book value on March 31, 2012, would have been \$ \_\_\_\_\_ or \$ \_\_\_\_\_ per share. The adjustments made to determine pro forma net tangible book value per share are the following:

- An increase in total assets to reflect the net proceeds of the offering as described under “Use of Proceeds.” (assuming that the public offering price will be \$ \_\_\_\_\_ per share).
- The addition of the number of shares offered by this prospectus to the number of shares outstanding.

The following table illustrates the pro forma increase in net tangible book value of \$ \_\_\_\_\_ per share and the dilution (the difference between the offering price per share and net tangible book value per share) to new investors:

Assumed public offering price per share	\$ _____
Net tangible book value per share as of March 31, 2012	\$ _____
Increase in net tangible book value per share attributable to the offering	_____
Pro forma net tangible book value per share as of March 31, 2012 after giving effect to the offering	_____
Dilution per share to new investors in the offering	\$ _____

If the underwriters exercise their over-allotment option to purchase up to 690,000 additional shares of common stock from us in full in this offering at the assumed public offering price of \$ \_\_\_\_\_ per share, the adjusted net tangible book value as of March 31, 2012 after giving effect to this offering would increase to \$ \_\_\_\_\_ per share, and dilution per share to new investors in this offering would be \$ \_\_\_\_\_ per share.

The number of shares of our common stock to be outstanding immediately after this offering is based on 18,604,245 shares of our common stock outstanding as of March 31, 2012. The number of shares outstanding as of March 31, 2012 excludes:

- 2,204,070 shares issuable upon exercise of outstanding options with a weighted average exercise price of \$2.96; and
- 1,068,800 shares issuable upon exercise of outstanding warrants with a weighted average exercise price of \$6.19.

The foregoing table does not give effect to the exercise of any outstanding options or warrants. To the extent options and warrants are exercised, there may be further dilution to new investors.

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

*You should read this discussion together with the consolidated financial statements and other consolidated financial information included in this prospectus.*

### **Overview**

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

- TSO, or CNDO-201, the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's, UC and MS; and
- CNDO-109, a biologic that activates NK cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia.

We acquired our exclusive rights to TSO in January 2011 from Asphelia Pharmaceuticals, Inc., or Asphelia, for an aggregate purchase price of \$20.7 million, consisting of 2,525,677 shares of our Series B Convertible Preferred Stock, or Series B Shares, valued at \$6.38 per share, the assumption of promissory notes due to Paramount Credit Partners, LLC, or PCP, in the amount of \$750,000 and the assumption of Asphelia's obligation to reimburse OvaMed for certain development costs. Of this purchase price \$3.8 million was paid in cash, including \$3.4 million to OvaMed and \$0.4 million for repayment of Asphelia's debt, including \$61,000 to a related party. Under the terms of the sublicense agreement with OvaMed acquired from Asphelia, we are required to make annual license payments to OvaMed of \$250,000, reimburse patent expenses, make potential future payments totaling up to \$5.45 million upon the achievement of various milestones related to regulatory events for the first product, and make additional milestone payments upon the achievement of regulatory events relating to subsequent indications. In the event that TSO is commercialized, we will be obligated to pay annual royalties based upon net sales of the product as well as a portion of certain sublicense revenues. We are also required to purchase our clinical and commercial requirements of TSO from OvaMed at pre-determined prices.

In March 2012, we signed a Collaboration Agreement with Falk and OvaMed for the development of TSO for Crohn's. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in Crohn's, including Falk's ongoing Phase 2 clinical trial, for use in North America, South America and Japan. We granted Falk exclusive rights and licenses to data from our clinical trials of TSO in Crohn's for use in Europe. Under the agreement, we agreed to pay Falk (i) a total of €5 million (approximately \$6.5 million) after receipt of certain pre-clinical and clinical data, of which €2.5 million (approximately \$3.3 million) has been paid and the remaining €2.5 million is expected to be paid in the second half of 2013, and (ii) a royalty of 1% of net sales of TSO in North America, South America and Japan. A steering committee comprised of us, Falk and OvaMed representatives is overseeing the clinical development program for Crohn's, under which we and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's in the United States and Europe and will share in certain pre-clinical development costs.

We acquired an exclusive worldwide license to CNDO-109 in November 2007 from UCLB. In consideration for the license, we paid UCLB initial license fees totaling \$0.1 million and are required to make future milestone payments totaling up to \$22 million upon the achievement of various milestones related to regulatory events for the first three indications. In March 2012, we recognized our \$250,000 milestone obligation to UCLB related to our IND filed in February 2012. If CNDO-109 is commercialized, we will be obligated to pay to UCLB annual royalties based upon net sales of the product or a portion of sublicensing revenues.

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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, or GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, revenues and expenses and the disclosure of contingent assets and liabilities in our financial statements. On an ongoing basis, we evaluate our estimates and judgments, including those related to accrued expenses and stock-based compensation. We base our estimates on historical experience, known trends and events and various other factors that are believed to be reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. Actual results may differ from these estimates under different assumptions or conditions.

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

#### *Research and Development Expenses*

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses as of December 31, 2011 include fees to:

- CROs and other service providers in connection with clinical studies;
- Investigative sites in connection with clinical studies;
- Contract manufacturers in connection with the production of clinical trial materials;
- Vendors in connection with the preclinical development activities; and
- Licensors for the achievement of milestone-related events.

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

#### *Stock-Based Compensation*

We expense stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and considering estimated pre-vesting forfeiture rates. For stock-based

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compensation awards to non-employees, we re-measure the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

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

- **Fair Value of our Common Stock.** When our stock was not publicly traded, we estimated the fair value of common stock as discussed in “Common Stock Valuations Prior to Becoming a Publicly Traded Company” below. Since November 17, 2011, we have utilized the public trading price of our common stock.
- **Expected Term.** Due to the limited exercise history of our own stock options, we determined the expected term based on the stratification of employee groups and the expected effect of events that have indications on future exercise activity.
- **Volatility.** As we have a very limited trading history for our common stock, the expected stock price volatility for our common stock was estimated by taking the average historic price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. We did not rely on implied volatilities of traded options in our industry peers’ common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own common stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.
- **Risk-free Rate.** The risk-free interest rate is based on the yields of United States Treasury securities with maturities similar to the expected term of the options for each option group.
- **Dividend Yield.** We have never declared or paid any cash dividends and do not presently plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

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

For the years ended December 31, 2011, 2010, and 2009 and the three months ended March 31, 2012, stock-based compensation expense was \$1.5 million, \$2.3 million, \$39,000 and \$0.9 million, respectively. As of March 31, 2012, we had approximately \$4.3 million of total unrecognized compensation expense, net of related forfeiture estimates which we expect to recognize over a weighted-average period of approximately 2.1 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.

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### *Common Stock Valuations Prior to Becoming a Publicly Traded Company*

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

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

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

As our business and programs evolved, beginning in 2010, we migrated away from the cost approach to a market approach to incorporate the indication of value established through our development efforts and reflected in our Series A share issuances during 2010. Under this approach, the business enterprise value was established based on the contemporaneous equity offerings. Pursuant to the AICPA Guidelines, an option pricing method was used to value the shares using a contingent claims analysis, which applies a series of call options whose inputs reflect the liquidation preferences and conversion behavior of the different classes of equity. The value of our common stock was then derived by analyzing the fair value of these options. After the equity value of the business enterprise was determined, the total equity value of any equity instruments such as preferred stock, stock options, restricted stock and warrants outstanding and the concluded common stock value on a converted basis is allocated. Next, the option pricing method was used to allocate the residual equity value (inclusive of any infusion of cash from in-the-money options and warrants) to our common stock. Since our shares were not publicly traded, a discount for lack of marketability was applied. This lack of marketability

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discount was estimated to be 10% prior to becoming a publicly-traded company, valuations, using a theoretical put option model that captures the cost to ensure stock could be sold at the price prevailing at the valuation date after the time required to finding a market, or the time until an expected liquidity event. The put option model considers the expected time to a liquidity event, estimated volatility based on peer company data, risk free interest rates and management judgment. The ultimate fair values of our common stock were used as an input in determining the fair value of the warrants, restricted stock and stock options at various periods of time.

### **Results of Operations**

#### *General*

To date, we have not generated any revenues from operations and, at March 31, 2012, we had an accumulated deficit of \$63.1 million primarily as a result of research and development expenses, purchase of in-process research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant revenues.

#### *Research and Development Expenses*

Conducting research and development is central to our business. For the years ended December 31, 2009, 2010 and 2011 and the three months ended March 31, 2012, research and development expenses were \$2.3 million, \$8.3 million, \$8.6 million and \$4.6 million, respectively, and such expenses were \$29.1 million for the period from inception (June 28, 2006) to March 31, 2012. Research and development 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 intellectual property;
- expenses incurred under agreements with CROs, investigative sites and consultants that conduct or provide other services relating to our clinical trials and a substantial portion of our preclinical activities;
- the cost of acquiring clinical trial materials from third party manufacturers; and
- costs associated with non-clinical activities, patent filings and regulatory filings.

We expect to continue to incur substantial expenses related to our research and development activities for the foreseeable future as we continue product development. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product. From inception through March 31, 2012, direct, external development costs incurred for our CNDO-109 product development program were \$5.0 million, including \$0.4 million, \$2.1 million, \$1.9 million and \$0.6 million, respectively, for the years ended December 31, 2009, 2010 and 2011 and the three months ended March 31, 2012. From inception through March 31, 2012, direct, external development costs incurred for our TSO product development program were \$5.6 million, excluding \$20.7 million of in-process research and development costs related to our acquisition of the asset in 2011. Our results of operations for the years ended December 31, 2009, 2010 and 2011 include direct, external development costs incurred in connection with two product development programs that have been discontinued. From inception through March 31, 2012, such expenses totaled \$5.2 million.

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### *General and Administrative Expenses*

General and administrative expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in research and development expenses. For the years ended December 31, 2009, 2010 and 2011 and the three months ended March 31, 2012, general and administrative expenses were \$0.3 million, \$0.9 million, \$5.8 million and \$2.0 million, respectively, and such expenses were \$9.6 million from inception through March 31, 2012. We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

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

### *Comparison of Three Months Ended March 31, 2012 and 2011*

(\$ in thousands)	For the three months ended March 31,		Variance	
	2012	2011	\$	%
Operating expenses:				
Research and development	\$ 4,581	\$ 1,246	\$ 3,335	268%
General and administrative	2,000	593	1,407	237%
In-process research and development	—	20,706	(20,706)	NM
Loss from operations	(6,581)	(22,545)	(15,964)	(71)%
Interest income	44	19	25	132%
Interest expense	(19)	(17)	(2)	(12)%
Net loss	<u>\$ (6,556)</u>	<u>\$ (22,543)</u>	<u>\$ (15,987)</u>	(71)%

NM—Not meaningful

Research and development expenses increased \$3.3 million, or 268%, from the three months ended March 31, 2011 to the three months ended March 31, 2012. This increase was primarily due to \$2.6 million of increased external development costs related to TSO, including the initial \$1.4 million payment to Falk pursuant the Collaboration Agreement, and a \$200,000 accrued contractual milestone payment payable to OvaMed. Additionally, external development costs related to CNDO-109 increased \$0.4 million, including a \$250,000 milestone payment due to UCLB relating to the filing of the IND for CNDO-109. Personnel costs increased \$0.4 million due to increased staffing. We expect our research and development expenses to increase in future quarters as we continue clinical development, including providing clinical supplies or grants for investigator-initiated studies evaluating TSO in various autoimmune disorders. In April 2012, we paid and expensed \$2.0 million for the second milestone payment due to Falk pursuant to the Collaboration Agreement.

General and administrative expenses increased \$1.4 million from the three months ended March 31, 2011 to the three months ended March 31, 2012, reflecting the substantial increase in the level of our business activity that commenced during 2011 and our transition to being a public company. The increase in general and administrative expenses to support these activities consisted primarily of a \$0.6 million increase in personnel costs, \$0.3 million in increased stock compensation expense, and a \$0.2 million increase in professional fees.

In January 2011, we acquired from Asphelia a sublicense and related agreements for TSO and assumed certain liabilities of Asphelia. As consideration for such acquisition, we issued 2,525,677 Series B Shares valued at \$6.38 per share, assumed the \$750,000 PCP Note and made cash payments totaling \$3.8 million, including \$3.4 million to OvaMed and \$0.4 million for repayment of Asphelia's debt, including \$61,000 to a related party. The



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total consideration paid in connection with the acquisition of Asphelia's assets, including the assumption of certain liabilities of Asphelia, was \$20.7 million, which was recorded as in-process research and development expense in 2011.

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

### *Comparison of Years Ended December 31, 2011 and 2010*

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

NM–Not meaningful

Research and development expenses increased \$242,000, or 3%, from the year ended December 31, 2010 to the year ended December 31, 2011. This increase was primarily due to \$2.5 million of external development costs related to TSO, including a milestone-related charge of \$1.5 million relating to the filing of an IND for TSO and \$0.6 million of increased consulting expenses, severance-related costs, and other general expenses, primarily offset by a \$1.4 million decrease in stock-based compensation expense related to the 2010 vesting of restricted common stock issued to non-employees in 2007, a \$1.2 million decrease in development costs related to discontinued product candidates and a \$0.3 million decrease in CNDO-109 development costs. Payment of the milestone to OvaMed is due in the fourth quarter of 2012. We expect our research and development expenses to increase in future quarters as we commence our clinical programs for TSO and CNDO-109 and for the contractual payments to Falk of approximately \$6.5 million, all of which is currently expected to be paid by the second half of 2013.

General and administrative expenses increased \$4.9 million from the year ended December 31, 2010 to the year ended December 31, 2011, reflecting the substantial increase in the level of our business activity during 2011 and transition to a public company. The increase in general and administrative expenses to support these activities consisted primarily of a \$1.9 million increase in professional fees, consisting of legal and accounting fees, a \$1.3 million increase in personnel costs, \$0.5 million in increased stock compensation expense, and \$0.4 million increase in consulting and outside services.

In January 2011, we acquired from Asphelia a sublicense and related agreements for TSO and assumed certain liabilities of Asphelia. As consideration for such acquisition, we issued 2,525,677 Series B shares valued at \$6.38 per share, assumed the PCP Note of \$750,000 and made cash payments totaling \$3.8 million, including \$3.4 million to OvaMed and \$0.4 million for repayment of Asphelia's debt, including \$61,000 to a related party. The total consideration paid in connection with the acquisition of Asphelia's assets, including the assumption of certain liabilities of Asphelia, was \$20.7 million, which was recorded as in-process research and development expense in 2011.

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

The increase in interest income in 2011 compared to the same period last year was primarily due to higher cash balances.

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

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

(\$ 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%
Interest income	61	–	61	NM
Interest expense	(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%

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

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

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

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

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

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### Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities aggregating \$52.1 million of net proceeds. At March 31, 2012, we had cash and cash equivalents of \$17.7 million.

We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates. We will require additional financing to develop, prepare regulatory filings and obtain regulatory approvals, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt. We believe that our current cash and cash equivalents, together with the net proceeds of this offering, are sufficient to fund operations through the third quarter of 2013 based on our current business plan. Our current financial condition raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We will seek funds through additional equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us, we will be required to delay, curtail or eliminate one or more of our research and development programs.

At March 31, 2012, we had outstanding \$750,000 of promissory notes due to PCP which we assumed from Asphelia. These notes are due in December 2013 or earlier in the event of a merger transaction.

#### *Cash Flows for the Three Months Ended March 31, 2012 and 2011*

(\$ in thousands)	For the Three Months Ended March 31,	
	2012	2011
<b>Statement of Cash Flows Data:</b>		
Total cash provided by (used in):		
Operating activities	\$ (5,425)	\$ (1,784)
Investing activities	—	(3,809)
Increase in cash and cash equivalents	<u>\$ (5,425)</u>	<u>\$ (5,593)</u>

*Operating Activities.* Net cash used in operating activities increased \$3.6 million from the three months ended March 31, 2011 to the three months ended March 31, 2012 and primarily reflects increased costs related to research and development and management of the company. Cash used in operating activities of \$1.8 million in the three months ended March 31, 2011 primarily reflects the net loss of \$22.5 million offset by \$20.7 million of noncash expense for in-process research and development expense related to the purchase of assets from Asphelia, or the Asphelia Asset Purchase. Cash used in operating activities of \$5.4 million in the three months ended March 31, 2012 primarily reflects the net loss of \$6.7 million offset by \$0.8 million of noncash expense stock-based compensation and an increase in accounts payable and accrued expenses of \$0.5 million.

*Investing Activities.* Net cash used in investing activities was \$3.8 million in 2011 and consisted solely of cash payments related to the Asphelia Asset Purchase.

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

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

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*Operating Activities.* Net cash used in operating activities increased \$5.3 million from the year ended December 31, 2010 to the year ended December 31, 2011. The increase in net loss of \$26.3 million, included \$1.4 million related to the increase to the fair value of the Series C warrant liability and \$1.6 million related to the increase in accounts payable and accrued expenses, offset by \$20.7 million of noncash expense for in-process research and development expense related to the Asphelia Asset Purchase, a \$0.9 million decrease in stock-based compensation and a \$0.9 million decrease in the change in fair value of a warrant-embedded conversion feature.

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

*Investing Activities.* Net cash used in investing activities was \$3.8 million in 2011 and consisted solely of cash payments related to the Asphelia Asset Purchase.

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

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

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

*Contingent Contractual Payments.* The following table summarizes our contractual obligations as of March 31, 2012, 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	\$ 901	\$ 75	\$ 826	\$ –	\$ –
Annual license fees(1)	10,950	4,200	4,250	500	2,000
Purchase and other obligations	4,281	1,799	2,482	–	–
Total	<u>\$16,132</u>	<u>\$ 6,074</u>	<u>\$7,558</u>	<u>\$500</u>	<u>\$2,000</u>

(1) Annual sublicense fees are projected through 2025 and include payments to OvaMed, Falk and UCLB. We have a right to terminate the related OvaMed sublicense with a 30-day notice period.

In April 2012, we paid the second milestone payment of €1.5 million (approximately \$2.0 million) to Falk upon receipt of the recommendation of the independent data monitoring committee that conducted an analysis of the Falk Phase 2 trial evaluating TSO in Crohn's. We anticipate the final payment of €2.5 million (approximately \$3.3 million) to be paid to Falk in the second half of 2013.

As of March 31, 2012, \$2.1 million of the contingent contracted payments are recorded in accrued expenses.

Our purchase and other obligations are primarily associated with our planned Phase 2 TSO trial and our Phase 1/2 CNDO-109 trial. In April 2012, we entered into an agreement with the CRO for our Phase 2 TSO trial providing for aggregate payments of approximately \$3.4 million, which is expected to be paid over the course of the Phase 2 trial.

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

*Quantitative and Qualitative Disclosures about Market Risks.* We held no marketable securities at December 31, 2010 and 2011 and at March 31, 2012. Our existing debt is at a fixed rate and we currently do not have exposure to foreign currency fluctuations.

*Net Operating Loss Tax Carry-Forwards.* As of December 31, 2011, we had net federal operating loss carryforwards of approximately \$27.9 million to offset future federal income taxes which expire beginning in 2026. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change. Even if the carryforwards are available, they may be subject to substantial annual limitations, due to ownership change limitations provided by the Internal Revenue Code of 1986 as amended, or IRC and similar state provisions. At December 31, 2010 and 2011, we recorded a 100% valuation allowance against our deferred tax assets, as our management believes it is more likely than not that they will not be fully realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

*Recently Issued Accounting Pronouncements.* Refer to Note 2 of Notes to Financial Statements for a discussion of recent accounting standards and pronouncements.

## Business

### Overview

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

- TSO (*Trichuris suis ova* or CNDO-201) a biologic comprising of the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's disease, ulcerative colitis and multiple sclerosis; and
- CNDO-109, a biologic that activates natural killer cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia.

#### *TSO*

TSO, or CNDO-201, is a biologic comprising *Trichuris suis ova*, the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's, UC and MS. In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in 36 patients with Crohn's. The trial was a sequential dose-escalation, double-blind, placebo-controlled study to examine safety and tolerability. TSO was safe and well tolerated, with no serious treatment-related adverse events reported. To date, a number of investigator-sponsored clinical trials have been conducted using TSO in patients suffering from Crohn's, UC or MS. These studies also demonstrated that TSO is safe and well tolerated. Two of these studies reported that treatment with TSO could induce clinical remission in Crohn's patients (n=29 patients) and in UC patients (n=54 patients). In April 2012, our development partner, Falk, reported that an independent data monitoring committee had found no safety concerns and a positive efficacy trend in an interim analysis (blinded to Falk) of clinical data from the initial 120 patients in Falk's ongoing Phase 2 clinical trial in Europe evaluating TSO in Crohn's patients. Based on the committee's recommendations, Falk has advised us that it is increasing the size of its trial and will conduct a subsequent interim analysis at the time the trial reaches approximately 250 patients, which we expect to occur in mid-2013. Pending final discussions with the FDA, we expect to commence our own 220-patient Phase 2 clinical trial of TSO in Crohn's patients in the third quarter of 2012 and to have initial study results in the second half of 2013. We have the exclusive rights to TSO in North America, South America and Japan under a sublicense agreement with OvaMed, as well as a manufacturing and supply agreement with OvaMed to provide us with our clinical and commercial requirements of TSO.

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

#### *CNDO-109*

CNDO-109 is a biologic that activates the immune system's NK cells to seek and destroy cancer cells. We intend to study CNDO-109 initially in patients that have been diagnosed with AML. Preclinical studies have demonstrated that CNDO-109 activated NK cells directly kill cells that cause hematologic malignancies including myeloid leukemia and multiple myeloma, as well as breast, prostate and ovarian cancers. Eight patients with high-risk AML received CNDO-109 activated NK cells in a recent Phase 1 investigator-sponsored

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trial. Although the primary endpoint of the Phase 1 clinical trial was safety, based on the data obtained from this Phase 1 study, we believe early efficacy was observed. The investigators observed that the majority of patients experienced a longer complete remission than their previous complete remission. In February 2012, we filed an IND for a multi-center Phase 1/2 clinical trial in patients with relapsed AML that we currently plan to initiate in the second half of 2012. In June 2012, the FDA granted orphan drug designation to CNDO-109 activated NK cells for the treatment of AML. We have exclusive worldwide rights to develop and market CNDO-109 under a license agreement with UCLB.

### **Industry**

#### *Immunology Therapeutics Markets*

Autoimmune diseases represent a diverse collection of diseases in terms of their demographic profile and primary clinical manifestations. The phenotypic commonality between them, however, is the damage to tissues and organs that arise from the loss of tolerance or recognition of “self.” Autoimmune disorders include inflammatory bowel disease, or IBD, such as Crohn’s and UC, MS, rheumatoid arthritis, lupus, and type-1 diabetes. According to 2012 *Decision Resources* reports in 2011, in the United States and Japan, the estimated prevalence of Crohn’s was 534,000 patients, UC was 669,000 patients and MS was 485,000 patients. Prevalence rates for all autoimmune disorders are expected to continue to rise in the next several years. Each of these diseases is believed to be associated with an excessive inflammatory response by the T helper (Th) cells and suppressed activity of T regulatory (Treg) cells.

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

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

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

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

#### *Oncology Therapeutics Markets*

The American Cancer Society estimates that over 1.6 million people in the United States are expected to be diagnosed with cancer in 2012, excluding basal and squamous cell skin cancers and in situ carcinomas (other

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than urinary bladder carcinomas). This is an increase of approximately 33% from the estimated number of new cancer diagnoses in 2000. We believe this rate is unlikely to decrease in the foreseeable future as the causes of cancer are multiple and poorly understood.

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

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

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

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

### **Our Product Candidates**

#### *TSO*

TSO is a biologic product candidate for the treatment of autoimmune diseases. We initially plan to investigate TSO for the treatment of Crohn's, UC and MS. TSO originates from the work of Dr. Joel V. Weinstock, currently the Chief of the Division of Gastroenterology/Hepatology at Tufts New England Medical Center in Boston. Dr. Weinstock's research has centered on the evolutionary role of parasitic helminth (worm) infections in the prevention of inflammatory diseases such as IBD, specifically Crohn's and UC. Dr. Weinstock has discovered that when the microscopic eggs of a certain helminth, preferably *T. suis*, the porcine whipworm, are administered to patients with IBD a beneficial immune response is induced, which provides clinical benefit to the underlying disease with minimal side-effects. Dr. Weinstock is a consultant to us and a member of our scientific advisory board and certain of his colleagues are also consultants to us.

#### *Background*

The use of helminths in the treatment of autoimmune disease is based on the belief that the immune systems of populations living in the relatively sterile environments found in developed countries with little or no exposure to parasites may develop in abnormal ways. This "hygiene hypothesis" is based on epidemiologic findings of an inverse relationship between autoimmune diseases and helminthic colonization. According to articles published in the *New England Journal of Medicine* in 2002 and *Inflammatory Bowel Disease* in 2009, the incidence of IBD is highest in the developed world and in temperate climates, with positive correlations noted among persons of higher socioeconomic status and high levels of domestic hygiene experienced in childhood. Conversely, the incidence of IBD is rare in less developed countries and in persons with blue-collar jobs involving exposure to dirt and physical exercise.



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In contrast to the epidemiologic findings of IBD, according to articles by Dr. Weinstock and others published in the *New England Journal of Medicine* in 2002 and the *International Journal for Parasitology* in 2007, the prevalence of helminths is highest in warm climates and in populations characterized by crowding, poor sanitation, and impure food supply. Furthermore, the incidence of IBD has increased over the past several decades, while the prevalence of helminths in the United States and Europe has steadily declined during the same time period. These findings have led to the hypothesis that eliminating intestinal helminths in the industrialized world has eliminated a natural T regulatory cell mechanism that prevents excessive T-cell activation such as occurs in IBD as well as in other immune-mediated diseases such as MS and allergies.

The immunologic basis for helminth therapy for IBD is derived from experimental animal and human data demonstrating that these organisms alter immune responses beyond those directed against the worms. In animal models, helminths blunt Th1 responses and promote Th2 responses associated with increased production of IL-4 and IL-3. Helminthic colonization in humans can result in diminished Th1 immune responses to challenges with unrelated antigens, as well as increased production of immunomodulatory molecules such as IL-10, transforming growth factor (TGF)- $\beta$ , 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.

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, we believe ova are not infective until incubating in the soil for several weeks, thereby preventing direct host-to-host transmission. We believe that no human diseases have been associated with exposure to *T. suis* or TSO.

*Third Party Clinical Trials.* The initial safety and efficacy of TSO in Crohn's has been evaluated in two open-label investigator-sponsored clinical trials. The first, a 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 CDAI and the Inflammatory Bowel Disease Quality of Life questionnaire, or IBDQ. Using an IBDQ score  $> 170$  to indicate remission, three of four (75%) patients achieved remission by week 8. Similarly, three of four (75%) patients achieved remission during the observation period as assessed by a CDAI  $< 150$ . However, two of the three patients who achieved remission relapsed at the end of the 12-week observation period. No significant clinical complications or adverse events occurred in any of the patients in this study.

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

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

Two investigator-sponsored studies of TSO have been conducted in patients with UC. The first study was a pilot study conducted by Dr. Weinstock and his colleagues (*American Journal of Gastroenterology*, 2003) in

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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 > 170 to define remission, all three patients had achieved remission by week eight. Using an SCCAI < 4 to indicate remission, each of the UC patients achieved remission during the treatment and observation period, and one patient experienced a relapse. No significant clinical complications or adverse events occurred in any of the patients in this study.

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

In a study reported in the *Multiple Sclerosis Journal* in 2011, Dr. John Fleming and his colleagues at the University of Wisconsin studied five subjects with newly diagnosed, treatment-naïve, relapsing–remitting multiple sclerosis, or RRMS. The patients were given 2500 TSO orally every two weeks for three months in a baseline versus treatment controlled trial. The study showed that the mean number of new gadolinium-enhancing magnetic resonance imaging, or MRI, lesions (n-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 ten months. Results from this second cohort are expected in the first half of 2013.

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

We are also aware of additional ongoing or proposed investigator-initiated clinical trials evaluating TSO in various indications, including MS, UC, psoriasis, psoriatic arthritis, Type 1 Diabetes, autism and rheumatoid arthritis. We intend to support, by providing product supply and in some cases grants, certain of these investigator-initiated trials.

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

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

In March 2012, we signed a Collaboration Agreement with Falk and OvaMed for the development of TSO for Crohn's. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in Crohn's, including Falk's ongoing Phase 2 clinical trial, for use in North America, South America and Japan. We granted Falk exclusive rights and licenses to data from our clinical trials of TSO in Crohn's for use in Europe. Under the agreement, we agreed to pay Falk (i) a total of €5 million (approximately \$6.5 million) after receipt of certain pre-clinical and clinical data, €2.5 million (approximately \$3.3 million) of which has been paid and the remaining €2.5 million of which is expected to be paid in the second half of 2013, and (ii) a royalty of 1% of net sales of TSO in North America, South America and Japan. A steering committee comprised of our representatives and representatives of Falk and OvaMed is overseeing the clinical development program for Crohn's, under which we and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's in the United States and Europe and will share in certain pre-clinical development costs.

In April 2012, we received from Falk a recommendation from the independent data monitoring committee that conducted an interim analysis (blinded to Falk) of clinical data from the initial 120 patients in Falk's Phase 2 clinical trial in Europe evaluating TSO in Crohn's. The committee noted no safety concerns and a positive efficacy trend in its recommendation that the study continue. Falk advised us that they are adopting the committee's recommendations to increase the sample size and to conduct a subsequent interim analysis at the time the trial reaches approximately 250 patients. The Falk Phase 2 clinical trial was initially expected to enroll approximately 212 patients and to evaluate three different dosages of TSO versus placebo. The interim analysis aimed to verify the assumptions of the sample size calculation or to recalculate sample size based on the effect size estimations of the interim analysis, as well as evaluating whether to discontinue one or two of the active treatment arms. Based on currently projected enrollment rates, we expect the additional analysis to occur in mid-2013.

We are using the information and recommendations derived from the interim analysis to finalize the design of our planned Phase 2 clinical trial of TSO in Crohn's. Because the committee noted a positive efficacy trend and no safety concerns in addition to its sample size recommendations, we are planning dosage and sample size adjustments to maximize the probability of observing a TSO treatment effect. Pending discussions with the FDA, we currently plan to commence the trial in the third quarter of 2012 and to have initial study results in the second half of 2013.

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As part of our strategy to evaluate additional potential therapeutic applications of TSO, we plan to support certain investigator-initiated clinical trials and conduct pilot proof-of-concept clinical studies investigating TSO in various indications, including MS, UC, psoriasis, autism, psoriatic arthritis, Type 1 Diabetes, and rheumatoid arthritis, subject to discussions with the FDA.

*Manufacturing.* We have contracted with OvaMed to produce and supply us with all of our requirements of TSO. OvaMed's contractor inoculates young pathogen-free pigs with *T. suis* from a master ova bank and harvests the ova which are incubated to maturity and are processed to remove any viruses and other pathogens. Ova then are processed and extensively tested to assure uniformity. They are then used to repopulate the master ova bank and are processed further by OvaMed into a final formulation of the drug product that is a clear, tasteless and odorless liquid. OvaMed manufacturing is conducted at one facility in Germany, which has received Good Manufacturing Practice, or GMP, certification by the European Medicines Agency, or EMA. OvaMed's manufacturing operations will be subject to an FDA inspection to assess compliance with FDA standards. 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, or ALL. We acquired exclusive worldwide rights to develop and commercialize CNDO-109 activated NK cells for the treatment of cancer from UCLB.

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

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

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

The importance of NK cells in the host system's defense against cancer was recognized by Dr. Mark Lowdell at the Royal Free Hospital in London and others when they noted that patients who could mount an immune response to their AML became long-term survivors after chemotherapy. Researchers identified that a key to the successful immune response of the patient's immune systems was the NK cell. Dr. Lowdell determined that activated NK cells were the key to eliminating AML cells and that NK cells require two signals to kill a tumor cell—a priming signal followed by a trigger signal. NK cells that can be activated by certain cancer cells provide both signals resulting in killing the cancer cell. Cancer cells that cannot be killed only trigger one signal and therefore are considered resistant to NK cells. NK cells which have not been primed cannot respond to the trigger. The "priming signal" can be provided by either cytokines, such as high dose IL-2 or IL-15 or by

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CNDO-109. In contrast to IL-2 or IL-15, NK cells activated by CNDO-109 retain their activated state after freezing and thawing. This allows commercialization of the process since the NK cells can be activated with CNDO-109 and prepared at a manufacturing facility under GMP conditions and shipped to the clinical center as a frozen patient-specific dose, ready for infusion. The results of the research conducted by Dr. Lowdell and his colleagues were published in the British Journal of Haematology in 2002 and The Journal of Immunology in 2007 and all inventions and related intellectual property that arose from such research are covered by our license agreement with UCLB. Dr. Lowdell is a consultant to us.

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

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

### *Completed Clinical Trial*

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

### *Our Clinical Program*

We submitted an IND for the CNDO-109 activated NK cell product in the United States in February 2012 using data from UCL's Phase 1 clinical trial in the United Kingdom. We plan to initiate a Phase 1/2 clinical trial in the United States in the second half of 2012 using CNDO-109 to activate NK cells to treat MRD in AML patients with relapsed/refractory disease. In Phase 1/2 oncology clinical trials, dose limiting toxicity stopping rules are commonly applied. The CNDO-109 Phase 1/2 trial is subject to a set of DLTs that could suspend or stop dose escalation by predetermined criteria, including allergic reactions, prolonged aplasia or other organ toxicities of a serious nature. We are also evaluating selected pilot Phase 1 clinical trials in other tumor types, including multiple myeloma breast, prostate and ovarian cancer, with both allogeneic and autologous cells.

### *Manufacturing*

The manufacturing process for CNDO-109 activated NK cells is currently under development. We have produced a master cell bank and a working cell bank of CTV-1 cells in collaboration with BioReliance. Manufacture and testing of CNDO-109 activated NK cells for our planned Phase 1/2 clinical trial is expected to be conducted by PCT. We have entered into master service agreements with both companies as well as a supply agreement with PCT. The master service agreements provide the general framework for the relationships, with specific terms to be established in connection with particular projects. Indirectly, we also rely on Miltenyi Biotec to provide the equipment and reagents necessary for the identification and selection of NK cells.

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### **Strategic Alliances and Commercial Agreements**

#### *TSO*

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

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

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

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

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

In addition, we agreed to pay Falk a total of €5 million after receipt of certain preclinical and clinical data, half of which has been paid and half of which is expected to be paid by the second half of 2013, and a royalty equal to 1% of net sales of TSO in North America, South America and Japan.

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Under the Collaboration Agreement, a Steering Committee comprised of our representatives and representatives of Falk and OvaMed will oversee the TSO development program for Crohn's, under which we and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's in the United States and Europe and will share in certain pre-clinical development costs.

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

*License Agreement with UCLB.* In November 2007, we entered into a license agreement with UCLB under which we received an exclusive, worldwide license to develop and commercialize CNDO-109 to activate NK cells for the treatment of cancer and related conditions. 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. Under a May 2012 amendment, additional patent rights and rights to certain additional inventions were added to the license agreement.

In consideration for the license, we will be required to make future milestone payments totaling up to approximately \$22 million contingent upon the achievement of various milestones related to regulatory events for the first three indications for which CNDO-109 is developed. In March 2012, we recognized our obligation to pay UCLB a \$250,000 milestone related to the IND for CNDO-109. In the event that CNDO-109 is commercialized, we will be obligated to pay to UCLB royalties ranging from 3% to 5% of net sales of the product or, if commercialized by a sublicensee, a percentage of certain consideration we receive from such sublicensee (ranging from 20% to 30% of such consideration depending on the stage of clinical development at the time of the sublicense). Under the terms of the agreement, we must use diligent and reasonable efforts to develop and commercialize CNDO-109 activated NK cells worldwide and may grant sublicenses to third parties without the prior approval of UCLB.

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

We have entered into consulting agreements with Dr. Mark Lowdell and UCL Consultants Limited (a wholly-owned subsidiary of UCLB) that provide for Dr. Lowdell to provide various services to us relating to our CNDO-109 program.

*Services Agreement with PCT.* In April 2010, we entered into a master contract services agreement, or the PCT agreement, with PCT pursuant to which PCT may, from time to time, provide consulting, preclinical, laboratory and/or clinical research-related services, product/process development services, manufacturing services and other services to us in connection with the CNDO-109 development program. PCT is currently performing services related to the development of manufacturing processes for CNDO-109 under the PCT agreement. We pay for services under the PCT agreement pursuant to statements of work entered into from time to time. Any product resulting from the services performed or product improvement, inventions or discoveries, including new uses for product resulting from the services performed and related patent rights which arise as a result of the services performed by PCT under the PCT agreement are owned solely and exclusively by and assigned to us. Through December 31, 2011, we have entered into statements of work with PCT aggregating \$1.1 million.

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### **Intellectual Property**

#### *General*

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

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

#### *TSO*

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

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

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



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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 United States and foreign counterpart applications including pending United States Patent Application Serial No. 11/856,466 and the corresponding national phase applications filed in Australia, Canada, Europe, India and Japan, directed to the method of stimulating natural killer cells using CNDO-109 for the treatment of cancer and other conditions. In May 2012, we received a Notice of Allowance from the United States Patent and Trademark Office for this patent application. This patent family has been in-licensed on an exclusive basis from UCLB. The CNDO-109 patents that are issuable from this patent family would expire in March 2026 in the absence of any patent term extension.

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

### **Competition**

We operate in highly competitive segments of the biotechnology and biopharmaceutical markets. We face competition from many different sources, including commercial pharmaceutical and biotechnology enterprises, academic institutions, government agencies, and private and public research institutions. Many of our competitors have significantly greater financial, product development, manufacturing and marketing resources than us. Large pharmaceutical companies have extensive experience in clinical testing and obtaining regulatory approval for drugs. In addition, many universities and private and public research institutes are active in cancer research, some in direct competition with us. We also may compete with these organizations to recruit scientists and clinical development personnel. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies.

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

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

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### **Manufacturing**

We do not own or operate manufacturing facilities for the production of TSO or CNDO-109 nor do we plan to develop our own manufacturing operations in the foreseeable future. We currently depend on third-party contract manufacturers for all of our required raw materials, active pharmaceutical ingredient and finished products for our preclinical and clinical trials. Pursuant to the OvaMed Supply Agreement, we are required to purchase from OvaMed and OvaMed has agreed to manufacture and supply us with clinical and commercial requirements of TSO at pre-determined prices. PCT provides us with clinical services and supplies for CNDO-109. We do not have a contractual arrangement for the manufacture of commercial supplies of CNDO-109.

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

### **Government Regulation and Product Approval**

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

#### *United States Pharmaceutical Product Development Process*

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

- Completion of preclinical laboratory tests, animal studies and formulation studies according to Good Laboratory Practices or other applicable regulations;
- Submission to the FDA of an IND, which must become effective before human clinical trials may begin in the United States;
- Performance of adequate and well-controlled human clinical trials according to the FDA's current good clinical practices, or GCPs, to establish the safety and efficacy of the proposed pharmaceutical product for its intended use;

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- 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 IRB or ethics committee if conducted outside of the US, at or servicing each institution at which the clinical trial will be conducted. An IRB or ethics committee is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB or ethics committee also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. We intend to use third party clinical research organizations to administer and conduct our planned clinical trials and will rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols and to play a significant role in the subsequent collection and analysis of

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data from these trials. The failure by any of such third parties to meet expected timelines, adhere to our protocols or meet regulatory standards could adversely impact the subject product development program.

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

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

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

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

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

### *United States Review and Approval Processes*

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

The NDA/BLA review and approval process is lengthy and difficult and the FDA may refuse to approve an NDA/BLA if the applicable regulatory criteria are not satisfied or may require additional clinical data or other

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

### *Post-Approval Requirements*

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

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

### *Orphan Drugs*

Under the Orphan Drug Act, special incentives exist for sponsors to develop products for rare diseases or conditions, which are defined to include those diseases or conditions that affect fewer than 200,000 people in the U.S. Requests for orphan drug designation must be submitted before the submission of an NDA or BLA. We have received orphan drug designation for CNDO-109 activated NK cells for the treatment of AML.

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

### *Pediatric Information*

Under the Pediatric Research Equity Act, or PREA, NDAs and BLAs or supplements to NDAs and BLAs must contain data to assess the safety and effectiveness of the treatment for the claimed indications in all relevant

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pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the treatment is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any product for an indication for which orphan designation has been granted.

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

### *Other Healthcare Laws and Compliance Requirements*

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

### **Pharmaceutical Coverage, Pricing and Reimbursement**

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

### **International Regulation**

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

### **Employees**

As of June 20, 2012, we had 14 full-time employees.

### **Properties**

Our principal executive offices at 15 New England Executive Park, Burlington, Massachusetts 01803 are occupied under a one-year lease expiring in August 2012 (with an option for September 2012) for approximately 700 square feet of space providing for rental payments of approximately \$5,900 per month through July 2012 and payments of approximately \$9,300 per month for August and September 2012. We believe alternative office space is available on substantially similar terms as our current lease.

### **Legal Proceedings**

There is no litigation currently pending or threatened against us, our initial stockholders or any of our officers or directors in their capacity as such.

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## Management

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

<u>Name</u>	<u>Age</u>	<u>Position</u>
Glenn L. Cooper, M.D.	59	Executive Chairman, Director
Bobby W. Sandage, Jr., Ph.D.	58	President and Chief Executive Officer, Director
Noah D. Beerman	50	Executive Vice President and Chief Operating Officer
Lucy Lu, M.D.	37	Executive Vice President and Chief Financial Officer
Karin M. Hehenberger, M.D., Ph.D.	39	Executive Vice President and Chief Medical Officer
Dale Ritter	61	Senior Vice President, Finance and Chief Accounting Officer
Eric K. Rowinsky, M.D.	55	Director, Vice Chairman
David J. Barrett	36	Director
Jimmie Harvey, Jr., M.D.	60	Director
J. Jay Lobell	49	Director
Michael W. Rogers	52	Director
Lindsay A. Rosenwald, M.D.	57	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 over 25 years of 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 March 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, Inc., a specialty pharmaceuticals company, including executive vice president of research and development and chief scientific officer, prior to the sale of the company to Endo Pharmaceuticals. 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

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

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

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

**Karin M. Hehenberger, M.D., Ph.D.** joined us as senior vice president of scientific affairs in December 2011 and has served as our executive vice president and chief medical officer since April 19, 2012. Dr. Hehenberger has over 12 years of experience in the healthcare industry. From January 2010 until joining our company, Dr. Hehenberger was Senior Vice President for Strategic Alliances at the Juvenile Diabetes Research Foundation, or JDRF, where she was responsible for advancing JDRF's involvement with scientific, financial, and commercial partners in the diabetes community. From February 2008 until January 2010, she served as Vice President of Metabolic Strategy and Business Development at Johnson & Johnson. From October 2005 through February 2008, Dr. Hehenberger served as Senior Investment Director and Partner at Scandinavian Life Science Venture. Dr. Hehenberger holds M.D. and Ph.D. degrees from the Karolinska Institute in Stockholm, Sweden and continued her research as a JDRF post-doctoral fellow at the Joslin Diabetes Center at Harvard Medical School.

**Dale Ritter** has served as our senior vice president, finance, and chief accounting officer since May 2011. Mr. Ritter also served as acting chief financial officer until February 2012. Mr. Ritter has over 20 years of experience in the pharmaceutical industry. From September 2009 until joining us, 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



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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. In 2010, Dr. Rowinsky became the Chief Executive Officer of Primrose Therapeutics, which developed therapies for polycystic kidney disease, until it was acquired in 2011. Since February 2012, Dr. Rowinsky has been the Head of Research and Development and Chief Medical Officer of Stemline Therapeutics, a private life science company developed therapeutics targeting cancer stem cells. 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., Navidea, 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.

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

**J. Jay Lobell** has served as a member of our board of directors since June 2006. Mr. Lobell is president of Meridian Capital Group, LLC, a commercial real estate mortgage company, which he joined as a senior officer in January 2010. Mr. Lobell also is a founder of, and since December 2009 has served as vice chairman of, Beech Street Capital, LLC, a real estate lending company. Since January 2005, Mr. Lobell has served as president and chief operating officer of Paramount Biosciences, LLC, or PBS, a biotechnology investment and development company. In that capacity, he had substantial responsibility for the assembly and oversight of

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companies founded and incubated by PBS, including Coronado and Asphelia. Mr. Lobell previously has served on the board of directors of NovaDel Pharma Inc., Innovive Pharmaceuticals, Inc. and ChemRx Corporation. Mr. Lobell was a partner in the law firm Covington & Burling LLP from October 1996 through January 2005, where he advised companies and individuals as a member of the firm's securities litigation and white collar defense practice group. Mr. Lobell received his B.A. (summa cum laude, Phi Beta Kappa) from the City University of New York and his J.D. from Yale Law School, where he was senior editor of the Yale Law Journal. Based on Mr. Lobell's biotechnology, legal and financial experience, as well as his in-depth understanding of drug commercialization and corporate governance, our board of directors believes that Mr. Lobell has the appropriate set of skills to serve as a member of the board.

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

## **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.

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

### **Board Committees**

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 the audit committee include, among other things:

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

Our board of directors has determined that each member of the audit committee meets the financial literacy requirements under the applicable NASDAQ 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.

In September 2011, we established a compensation committee of the board originally comprised of Mr. Rogers and Drs. Cooper, Harvey and Rosenwald. Dr. Cooper served as the chair of the compensation committee. The compensation committee operates under a charter approved by our board. In December 2011, in connection with the listing of our shares of common stock on the NASDAQ Capital Market, or NASDAQ, Dr. Cooper resigned from the compensation committee and Mr. Rogers was appointed chair of the compensation committee.

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

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

In September 2011, we established a nominating and corporate governance committee of the board originally comprised of Mr. Lobell and Drs. Cooper, Rowinsky and Rosenwald. Mr. Lobell serves as the chair of the nominating and corporate governance committee. The nominating and corporate governance committee operates under a charter approved by our board. In December 2011, in connection with the listing of our shares of common stock on NASDAQ, Drs. Cooper and Rowinsky resigned from the nominating and corporate governance committee.

The functions of the nominating and corporate governance committee include, among other things:

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

### *Code of Ethics*

We adopted a Code of Ethics in September 2011 that applies to all directors, officers and employees. Our Code of Ethics is available on our website at [www.coronadobiosciences.com](http://www.coronadobiosciences.com). A copy of our code of ethics will also be provided to any person without charge, upon written request sent to us at our offices located at 15 New England Executive Park, Burlington, MA 01803.

### *Promoters and Certain Control Persons*

Our only "promoter" (within the meaning of Rule 405 under the Securities Act) during the last five years has been Lindsay A. Rosenwald, M.D.

### *Compensation Discussion and Analysis Introduction*

This Compensation Discussion and Analysis explains our compensation philosophy, policies and practices with respect to our named executive officers. To date, executive compensation decisions have been made by the entire board of directors considering the evaluation and recommendations of our compensation committee. In September 2011, we established a compensation committee of the board that is responsible for creating and reviewing the compensation of our executive officers, as well as overseeing our compensation and benefit plans and policies and administering our equity incentive plans.

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### *Compensation Philosophy*

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

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

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

### *Setting Executive Compensation*

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

### *Elements of Executive Compensation*

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

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

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

We hired 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

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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 and 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 our former chief executive officer 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.

We hired Bobby W. Sandage, Jr., Ph.D. to serve as our president and chief executive officer in March 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. In February 2012, Dr. Sandage's base salary was increased to \$395,000.

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

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

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

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. In February 2012, Mr. Ritter's base salary was increased by the board of directors to \$275,000.

*Discretionary Bonuses.* In addition to the payment of base salaries, we believe that discretionary bonuses can play an important role in providing appropriate incentives to our executives to achieve our strategic objectives. As part of the annual performance reviews, the 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 objective

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targets as established in advance, as well as a subjective evaluation, in each case as approved by the compensation committee. Dr. Sandage, Mr. Beerman, Dr. Lu, Dr. Hehenberger and Mr. Ritter are eligible for a maximum discretionary bonus of 50%, 45%, 40%, 40% and 40%, respectively, of their respective salaries pursuant to the terms of their employment agreements. In addition, Dr. Sandage is eligible for additional bonuses of \$137,500, \$125,000, \$250,000, and \$500,000 based on milestones tied to reaching a market capitalization, as defined in his employment agreement, of \$125 million, \$250 million, \$500 million and \$1 billion, respectively. Mr. Beerman and Dr. Lu are also eligible for additional discretionary bonuses of \$46,875, \$93,750, \$187,500, and \$375,000 based on milestones tied to reaching a market capitalization, as defined in each employment agreement, 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 in 2011 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.

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

*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 a means to acquire equity or equity-linked interests in our company. We do not have any program, plan or obligation that requires us to grant our executive officers 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 compensation committee, as well as the executive chairman and the chief executive officer for officers other than themselves.

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

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.

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.

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

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

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

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

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

In the absence of a public trading market for our common stock at the time of the grants described above prior to November 2011, the board of directors determined the fair market value of our common stock in good faith based upon consideration of a number of relevant factors including the status of development efforts, financial status and market conditions and valuations obtained from an independent valuation firm. The options granted to Dr. Lu and Mr. Ritter in February 2012 and Dr. Hehenberger in December 2011 and April 2012 were granted at the fair market value of our common stock, which was determined based on the closing price of our shares on NASDAQ on the date of grant.

All option grants typically vest over three years, with one third of the shares subject to the stock option vesting on each 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 in April 2011 and Dr. Sandage in March 2011, with Mr. Ritter in May 2011, with Mr. Beerman in September 2011, with Dr. Lu in February 2012 and with Dr. Hehenberger in April 2012. 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 September 2010 with retroactive effect to July 2010.



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Dr. Sandage, Mr. Beerman, Dr. Lu, Dr. Hehenberger 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 in 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.

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*Summary Compensation Table.* The following table provides information regarding the compensation paid during the years ended December 31, 2011 and 2010 to our principal executive officer and certain of our other executive officers, who are collectively referred to as “named executive officers” elsewhere in this prospectus.

<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.	2011	\$225,000	\$ –	\$ –	\$ 97,500	\$322,500
Executive Chairman, Director(2)	2010			453,695	137,500	591,195
Bobby W. Sandage, Jr., Ph.D.	2011	284,135	140,000	257,280	133,929	815,344
President and Chief Executive Officer, Director(3)						
Noah D. Beerman	2011	87,500	39,000	484,425	–	610,925
Executive Vice President and Chief Operating Officer(4)						
Gary Gemignani	2011	177,625	–	36,500	295,212	509,337
Former Executive Vice President, Chief Operating Officer, Chief Financial Officer(5)	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 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 and “All Other Compensation” amounts are compensation that Dr. Cooper earned pursuant to a consulting agreement with us. Initially, Dr. Cooper was compensated as a consultant for a monthly fee of \$25,000. Dr. Cooper’s 2010 “Option Awards” and “All Other Compensation” in 2010 and \$75,000 in 2011 was paid to Dr. Cooper pursuant to the consulting arrangement. In April 2011, Dr. Cooper’s consulting arrangement was transitioned into an employment arrangement at an annual base salary of \$300,000. Also included in Dr. Cooper’s “All Other Compensation” in 2011 was \$22,500 of director compensation earned by Dr. Cooper.
- (3) Dr. Sandage’s bonus represents the amount awarded for 2011 and paid in 2012. “All Other Compensation” for Dr. Sandage includes \$130,321 related to reimbursement of moving expenses Dr. Sandage owed his prior employer pursuant to his termination of employment and \$3,608 for reimbursement of life insurance premiums provided for in Dr. Sandage’s employment agreement.
- (4) Mr. Beerman’s bonus represents the amount awarded for 2011 and paid in 2012.
- (5) 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. Mr. Gemignani’s salary represents amounts paid to him during his employment and included in “All Other Compensation” is \$267,750 paid pursuant to his separation agreement and \$27,462 of vacation accrued to his separation date.

*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

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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 May 2011, we entered into an employment agreement with Mr. Ritter, our senior vice president, finance, chief accounting officer and then-acting chief financial officer, which provides 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.

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

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

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

We have granted and expect to 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, 2011 and, if applicable, a change in control also occurred on such date.

Name	Upon Termination without Cause or Resignation for Good Cause Reason—No Change in Control			Upon Termination without Cause or Resignation for Good Reason— Change in Control		
	Cash Severance	Value of		Cash Severance	Value of	
		Accelerated Vesting(1)	Total		Accelerated Vesting(1)	Total
Glenn L. Cooper, M.D.	\$ —	\$ —	\$ —	\$ —	\$ —	\$ —
Bobby W. Sandage, Jr., Ph.D.(2)	375,000	457,000	832,000	375,000	1,371,000	1,746,000
Noah D. Beerman(3)	162,500	266,250	428,750	325,000	798,750	1,123,750

- (1) The value of accelerated vesting is equal to \$6.50 per share, the closing price per share of our common stock as quoted on NASDAQ on December 30, 2011 for the purposes hereof, multiplied by the number of shares subject to accelerated vesting, less the stock option exercise price.

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

*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 2011.

<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>
Bobby W. Sandage, Jr., Ph.D.	4/14/2011	300,000	\$ 1.93	\$ 257,280
Noah D. Beerman	9/26/2011	225,000	2.95	484,425
Gary Gemignani(3)	2/12/2011	25,000	1.37	36,500

- (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) Mr. Gemignani served as our executive vice president, chief operating officer and chief financial officer from May 2010 to May 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, 2011.

<u>Name</u>	<u>Number of Securities Underlying Unexercised Options (#) Unexercisable</u>	<u>Number of Securities Underlying Unexercised Options (#) Exercisable</u>	<u>Option Exercise Price</u>	<u>Option Expiration Date(1)</u>
Bobby W. Sandage, Jr., Ph.D.	300,000	–	\$ 1.93	4/12/2021
Noah D. Beerman	225,000	–	2.95	9/25/2021
Glenn L. Cooper	193,490	96,745	1.37	10/4/2020

- (1) 1/3rd of the total of number of shares subject to each option vest on each annual anniversary of the applicable grant.

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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, 2011 except for Mr. Gemignani, a former executive officer, who exercised options to purchase 75,000 shares in 2011.

*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 March 31, 2012, 138,040 shares of common stock have been issued under the 2007 plan pursuant to the exercise of options, 1,517,960 shares, net of cancellations, of common stock were issued as restricted stock awards under the 2007 plan, 2,342,110 options to purchase shares of common stock, net of cancellations, were granted and options to purchase an aggregate of 2,204,070 shares of common stock were outstanding.

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

There are 6,000,000 shares of common stock reserved for issuance under the 2007 plan, of which 2,139,930 shares were available for issuance as of March 31, 2012.

### *Administration.*

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

### *Available Shares.*

Subject to adjustment upon certain corporate transactions or events, a maximum of 6,000,000 shares of our common stock may be issued under the 2007 plan. In addition, subject to adjustment upon certain corporate transactions or events, a participant in the 2007 plan may not receive awards with respect to more than 1,000,000 shares of common stock in any year (and an additional 500,000 shares in connection with a grantee's commencement of continuous service). Any shares covered by an award which is forfeited, canceled or expires

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shall be deemed to have not been issued for purposes of determining the maximum aggregate number of shares which may be issued under the 2007 plan, except that the maximum aggregate number of shares which may be issued pursuant to the exercise of incentive stock options shall not exceed 6,000,000. Shares that actually have been issued under the 2007 plan pursuant to an award shall not be returned to the 2007 plan and shall not become available for future issuance under the 2007 plan. To the extent not prohibited by the listing requirements of any established stock exchange or national market system on which our common stock may be traded and any applicable law, any shares covered by an award which are surrendered (i) in payment of the award exercise or purchase price or (ii) in satisfaction of tax withholding obligations incident to the exercise of an award shall be deemed not to have been issued for purposes of determining the maximum number of shares which may be issued pursuant to all awards under the 2007 plan, unless otherwise determined by the plan administrator.

### *Eligibility and Types of Awards.*

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

### *Stock Options*

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

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

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

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

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

### *Corporate Transactions.*

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

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

### *Amendment and Termination.*

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

### *Stock Awards and Restricted Stock.*

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

### *Other Awards.*

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

## **Employee Stock Purchase Plan**

On December 19, 2011, our board of directors approved the 2012 Coronado Employee Stock Purchase Plan, or ESPP, providing for the issuance of up to 200,000 shares of common stock to eligible employees, including our executive officers, subject to stockholder approval of the ESPP. Assuming stockholder approval of the ESPP, eligible employees can purchase our common stock at the end of a predetermined offering period at a price



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equal to 85% of the lesser of the fair market value at the beginning or end of the offering period. The first period commenced February 1, 2012 and will end on November 30, 2012. Thereafter, offerings will be six months in duration and will commence on December 1 and June 1 of each year. Employee contributions will be made through payroll deductions throughout the offering period and, subject to certain limitations, will be used to purchase shares at the end of each offering period. As of December 31, 2011, all the shares were available for issuance under the ESPP. The ESPP is compensatory and will result in stock-based compensation expense.

### Securities Authorized for Issuance under Equity Compensation Plans

The following table sets forth, as of December 31, 2011, certain information related to our compensation plans under which shares of our common stock are authorized for issuance.

<u>Plan Category</u>	<u>Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (a)</u>	<u>Weighted Average Exercise Price of Outstanding Options Warrants and Rights (b)</u>	<u>Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column(a)) (c)</u>
Equity compensation plans approved by stockholders	1,814,070	\$ 2.17	2,529,930
Equity compensation plans not approved by stockholders	1,068,798	\$ 6.19	—
<b>Total</b>	<b>2,882,868</b>		<b>2,529,930</b>

### Non-Executive Director Compensation

The following table and related footnotes show the compensation paid to or accrued for the benefit of our non-executive directors during the fiscal year ended December 31, 2011.

<u>Name</u>	<u>Fees Earned or paid in Cash(1)</u>	<u>Option Awards(2)</u>	<u>All Other Compensation</u>	<u>Total</u>
Eric K. Rowinsky, M.D.	\$ 17,500	\$ —	\$ 250,000(3)	\$267,500
David J. Barrett	22,500	21,345	—	43,845
Jimmie Harvey, M.D.	42,500	—	—	42,500
J. Jay Lobell	47,500	—	—	47,500
Michael W. Rogers	27,500	21,345	—	48,845
Lindsay A. Rosenwald, M.D.	45,000	—	—	45,000

- (1) Represents director and committee fees accrued in or paid for 2011.
- (2) Represents the aggregate fair value amount computed as of the grant date in accordance with FASB ASC Topic 718. Assumptions used in the calculation of this amount are included in Note 14, Stock- Based Compensation, of the Notes to Financial Statements. As required by SEC rules, the amount shown excludes the impact of estimated forfeitures related to service-based vesting conditions. Our directors will only realize compensation to the extent the trading price of our common stock is greater than the exercise price of such stock options. The aggregate number of shares subject to each of Messrs. Barrett and Rogers outstanding option awards as of December 31, 2011 was 25,000 shares. One-third of the total of number of shares subject to these options vest on each annual anniversary of the applicable grant date for so long each of Messrs. Barrett and Rogers continue to serve on our board.
- (3) Represents amount earned and paid in 2011 pursuant to his consulting arrangement.

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In September 2010, we entered into a consulting agreement with Dr. Rowinsky, one of our directors, pursuant to which Dr. Rowinsky is paid at an annual rate of \$250,000 for his services as our vice chairman.

In October 2010, our board of directors adopted a compensation program for our non-employee directors, or the Non-Employee Director Compensation Policy. Pursuant to the Non-Employee Director Compensation Policy, each member of our board of directors who is not our employee and who is not otherwise receiving compensation from us pursuant to another arrangement, will receive an annual cash retainer of \$30,000, payable quarterly, and will receive an initial option grant to purchase up to 25,000 shares of our common stock. Such stock options vest in three annual installments. In July 2011, the Non-Employee Director Compensation Policy was modified to include additional fees for committee participation whereby compensation committee and nominating and corporate governance committee members and committee chairs will receive additional annual cash retainers of \$5,000 and \$10,000, respectively, payable quarterly, and audit committee members and the audit committee chair will receive additional annual cash retainers of \$7,500 and \$15,000, respectively, payable quarterly. The Non-Employee Director Compensation Policy was further amended in February 2012 to provide for annual option grants.

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

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

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

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

The limitation of liability and indemnification provisions in our amended and restated certificate of incorporation and amended and restated bylaws may discourage stockholders from bringing a lawsuit against directors for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against

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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.

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### Principal Stockholders

The following table sets forth, as of June 20, 2012, 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</u>		<u>Percentage Total Voting Power(2)</u>
	<u>Owned</u>		
Glenn L. Cooper, M.D.	126,745(3)(4)		*
Bobby W. Sandage, Jr., Ph.D.	112,000(3)(5)		*
Noah D. Beerman	5,000(6)		*
Lucy Lu, M.D.	-(7)		
Karin M. Hehenberger, M.D., Ph.D.	925(9)		*
Dale Ritter	45,000(3)(8)		*
David J. Barrett	8,333(11)		*
Jimmie Harvey, Jr., M.D.	8,333(10)		*
J. Jay Lobell	345,120(10)		1.8%
Michael W. Rogers	8,333(11)		*
Lindsay A. Rosenwald, M.D.	3,381,178(8)(12)		18.1%
Eric K. Rowinsky, M.D.	64,497(3)(13)		*
Hillel Gross(14)	1,000,000		5.4%
Manchester Securities Corp.	1,731,279(15)		9.3%
Brookline Investments Inc.	1,052,825(16)		5.7%
All officers and directors as a group (12 persons)(17)	4,092,431		22.0%

\* 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 18,625,749 shares of common stock issued and outstanding as of June 20, 2012.
- (3) Includes common stock, as well as options that are exercisable in the next 60 days.
- (4) Does not include options to purchase an aggregate of 238,490 shares of common stock that are not exercisable in the next 60 days.
- (5) Does not include options to purchase an aggregate of 200,000 shares of common stock that are not exercisable in the next 60 days.
- (6) Does not include options to purchase an aggregate of 225,000 shares of common stock that are not exercisable in the next 60 days.
- (7) Does not include options to purchase 225,000 shares of common stock that are not exercisable in the next 60 days.
- (8) Includes shares held jointly by Mr. Ritter and his spouse. Does not include options to purchase an aggregate of 110,000 shares of common stock that are not exercisable in the next 60 days.
- (9) Includes common stock and excludes options to purchase 225,000 shares of common stock that are not exercisable in the next 60 days.
- (10) Includes options that are exercisable in the next 60 days and does not include options to purchase 16,667 shares of common stock that are not exercisable in the next 60 days.
- (11) Includes options that are exercisable in the next 60 days and does not include options to purchase 31,667 shares of common stock that are not exercisable in the next 60 days.

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- (12) Includes 3,372,845 shares of common stock, of which 2,467,334 shares are held directly by Dr. Rosenwald, 170,983 shares are held by Capretti Grandi, LLC and 742,861 shares are held by PBS, and 8,333 shares issuable upon the exercise of options exercisable in the next 60 days. 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 held by the LAR Family Trusts and the Lindsay A. Rosenwald M.D. 2000 Family Trust 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.
- (13) Does not include options to purchase 143,993 shares of common stock that are not exercisable in the next 60 days.
- (14) 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.
- (15) Includes 178,890 shares held by Elliot Associates, L.P. and 268,336 shares held by Elliot International, each affiliates of Manchester Securities Corp., or Manchester. Manchester's address is 712 Fifth Avenue, New York, NY 10019. Mr. Paul E. Singer has voting and dispositive power over these shares.
- (16) These shares are held by Brookline Coronado Investment Fund LLC, CSA Biotechnology Fund I, LLC and CSA Biotechnology Fund II, or 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.
- (17) Includes the shares referred to in footnotes (3), (4), (5), (6), (7), (8), (9), (10), (11), (12) and (13) above.

## Certain Transactions

### Director Independence

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

### Transactions with Related Parties

The following is a description of transactions since January 1, 2011 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.”

### 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, or 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, M.D.	214,669
Manchester Securities Corp.(2)	447,226

- (1) Additional detail regarding these stockholders and their equity holdings is provided in “Principal Stockholders.”
- (2) Represents 178,890 Series C shares purchased by Elliot Associates and 268,336 Series C shares 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 promissory note, or the PCP Note, dated January 2009 issued by Asphelia to PCP, an entity affiliated with Dr. Rosenwald and Mr. Lobell, in the principal amount of \$750,000. Interest on the PCP Note is at the rate of 10% per annum payable quarterly, in arrears, 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.

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 had 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

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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 PBC \$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, or 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 the Series C Financing, National received commissions of \$2.6 million and five-year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of \$5.59 per share, which were subsequently transferred by National to other individuals and entities and are now exercisable to purchase 458,276 shares of common stock. National is acting as an underwriter in this offering. See "Underwriting—Conflicts of Interest."

### *Services Agreements*

In July 2011, the board approved an employment agreement with Evan Renov, a nephew of Dr. 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. In February 2012, Mr. Renov's monthly salary was increased to \$12,692 and he is eligible for a maximum discretionary bonus of 25% of his base salary.

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."

### **Reserved Shares**

The underwriters have reserved for sale at the public offering price up to 200,000 shares offered by this prospectus for Lindsay A. Rosenwald, M.D., a principal stockholder and a director. In addition, the underwriters have reserved for sale at the public offering price up to 75,000 shares offered by this prospectus for our other officers and directors, including Bobby W. Sandage, Jr., Ph.D., our president, chief executive officer and a director. Each of these individuals has entered into lock-agreements. See "Underwriting."

## Description of Capital Stock

### Common Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 50,000,000 shares of common stock, par value \$0.001 per share. As of June 20, 2012, there were 18,625,749 shares of common stock outstanding, as well as 3,394,884 shares of common stock subject to outstanding options and warrants. 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 we may designate and issue in the future. All of our outstanding shares of common stock are fully paid and nonassessable.

### Preferred Stock

We are authorized to issue 15,000,000 shares of preferred stock, par value \$0.001 per share. In November 2011, all of our outstanding shares of preferred stock were converted, on a one-for-one basis, into 11,496,186 shares of our common stock. As of June 20, 2012, there were no shares of preferred stock outstanding and 458,276 shares of preferred stock subject to outstanding warrants that will automatically convert into shares of common stock immediately upon exercise of such warrants.

Following the date of this prospectus, our board of directors is empowered, without stockholder approval, to issue shares of preferred stock with dividend, liquidation, redemption, voting or other rights which could adversely affect the voting power or other rights of the holders of common stock. The preferred stock could be utilized as a method of discouraging, delaying or preventing a change in control of us. Although we do not currently intend to issue any shares of preferred stock, we cannot assure you that we will not do so in the future.

### Our Transfer Agent

The transfer agent for our common stock is VStock Transfer, LLC, Cedarhurst, New York.

### Quotation of Securities

Our common stock is listed on the NASDAQ Capital Market under the symbol "CNDO."

### Holdings

As of June 20, 2012, there were 18,625,749 shares of common stock outstanding held by 434 shareholders of record.



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### **Delaware Anti-Takeover Law**

We are subject to the provisions of Section 203 of the DGCL regulating corporate takeovers. This statute prevents certain Delaware corporations, under certain circumstances, from engaging in a “business combination” with:

- a stockholder who owns 15% or more of our outstanding voting stock (otherwise known as an “interested stockholder”);
- an affiliate of an interested stockholder; or
- an associate of an interested stockholder, for three years following the date that the stockholder became an interested stockholder.

A “business combination” includes a merger or sale of more than 10% of our assets. However, the above provisions of Section 203 do not apply if:

- our board of directors approves the transaction that made the stockholder an “interested stockholder,” prior to the date of the transaction;
- after the completion of the transaction that resulted in the stockholder becoming an interested stockholder, that stockholder owned at least 85% of our voting stock outstanding at the time the transaction commenced, other than statutorily excluded shares of common stock; or
- on or subsequent to the date of the transaction, the business combination is approved by our board of directors and authorized at a meeting of our stockholders, and not by written consent, by an affirmative vote of at least two-thirds of the outstanding voting stock not owned by the interested stockholder.

### **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 May 15, 2013. The “pro rata percentage” is 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.

### **Registration Rights**

Holders of the 11,496,186 shares of our common stock that were issued in November 2011 upon the conversion of our outstanding preferred stock were granted registration rights with respect to such shares of common stock. In addition, certain holders of our outstanding warrants have the right to require us to register the shares of common stock underlying such warrants for resale to the public. All of such shares were included in a registration statement on Form S-1 declared effective by the Securities and Exchange Commission on November 15, 2011. We intend to maintain the effectiveness of such registration statement as required.

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## Underwriting

We have entered into an underwriting agreement with the underwriters named below. Oppenheimer & Co. Inc. and Roth Capital Partners, LLC are acting as representatives of the underwriters.

The underwriting agreement provides for the purchase of a specific number of shares of common stock by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specified number of shares, but is not responsible for the commitment of any other underwriter to purchase shares. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares of common stock set forth opposite its name below:

<u>Underwriter</u>	<u>Number of Shares</u>
Oppenheimer & Co. Inc.	
Roth Capital Partners, LLC	
National Securities Corporation	
Total	

The underwriters have agreed to purchase all of the shares offered by this prospectus (other than those covered by the over-allotment option described below) if any are purchased. Under the underwriting agreement, if an underwriter defaults in its commitment to purchase shares, the commitments of non-defaulting underwriters may be increased or the underwriting agreement may be terminated, depending on the circumstances.

The shares should be ready for delivery on or about \_\_\_\_\_, 2012 against payment in immediately available funds. The underwriters are offering the shares subject to various conditions and may reject all or part of any order. The representatives have advised us that the underwriters propose to offer the shares directly to the public at the public offering price that appears on the cover page of this prospectus. In addition, the representatives may offer some of the shares to other securities dealers at such price less a concession of \$ \_\_\_\_\_ per share. The underwriters may also allow, and such dealers may reallow, a concession not in excess of \$ \_\_\_\_\_ per share to other dealers. After the shares are released for sale to the public, the representatives may change the offering price and other selling terms at various times.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus, permits the underwriters to purchase a maximum of 690,000 additional shares from us to cover overallotments. If the underwriters exercise all or part of this option, they will purchase shares covered by the option at the initial public offering price that appears on the cover page of this prospectus, less the underwriting discount. If this option is exercised in full, the total price to public will be \$ \_\_\_\_\_ and the total proceeds to us will be \$ \_\_\_\_\_. The underwriters have severally agreed that, to the extent the over-allotment option is exercised, they will each purchase a number of additional shares proportionate to the underwriter's initial amount reflected in the foregoing table.

The underwriters have reserved for sale at the public offering price up to 200,000 shares offered by this prospectus for Lindsay A. Rosenwald, M.D., a principal stockholder and a director. In addition, the underwriters have reserved for sale at the public offering price up to 75,000 shares offered by this prospectus for our other officers and directors, including Bobby W. Sandage, Jr., Ph.D., our president, chief executive officer and a director. Each of these individuals has entered into lock-up agreements, as described below.

The following table provides information regarding the amount of the discount to be paid to the underwriters by us:

<u>Per Share</u>	<u>Total Without Exercise of Over-Allotment Option</u>	<u>Total With Full Exercise of Over-Allotment Option</u>
\$ _____	\$ _____	\$ _____

In addition, we have agreed to reimburse the underwriters for certain out-of-pocket expenses incurred by them in connection with this offering up to \$75,000 in the aggregate.

We estimate that our total expenses of the offering, excluding the underwriting discount, will be approximately \$ \_\_\_\_\_.

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We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

We and our officers and directors have agreed to a 90-day “lock up” with respect to \_\_\_\_\_ shares of common stock that they beneficially own, including securities that are convertible into shares of common stock and securities that are exchangeable or exercisable for shares of common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus, we and such persons may not offer, sell, pledge or otherwise dispose of these securities without the prior written consent of the representatives.

The representatives have informed us that they do not expect discretionary sales by the underwriters to exceed five percent of the shares offered by this prospectus.

If the underwriters sell more shares than the above number, the underwriters have an option for 30 days to buy up to an additional 690,000 shares from us at the public offering price, less the underwriting commissions and discounts, to cover these sales.

Rules of the Securities and Exchange Commission may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

- Stabilizing transactions—The representatives may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.
- Over-allotments and syndicate covering transactions—The underwriters may sell more shares of our common stock in connection with this offering than the number of shares that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either “covered” short sales or “naked” short sales. Covered short sales are short sales made in an amount not greater than the underwriters’ over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.
- Penalty bids—If the representatives purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the underwriters and selling group members who sold those shares as part of this offering.
- Passive market making—Market makers in the shares who are underwriters or prospective underwriters may make bids for or purchases of shares, subject to limitations, until the time, if ever, at which a stabilizing bid is made.

Similar to other purchase transactions, the underwriters’ purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither we nor the underwriters makes any representation or prediction as to the effect that the transactions described above may have on the price of the shares. These transactions may occur on the NASDAQ Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

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Our common stock is traded on the NASDAQ Capital Market under the symbol “CNDO.”

*Electronic Delivery of Preliminary Prospectus:* A prospectus in electronic format may be delivered to potential investors by one or more of the underwriters participating in this offering. The prospectus in electronic format will be identical to the paper version of such preliminary prospectus. Other than the prospectus in electronic format, the information on any underwriter’s web site and any information contained in any other web site maintained by an underwriter is not part of the prospectus or the registration statement of which this prospectus forms a part.

### **Conflicts of Interest**

National Securities Corporation, one of the underwriters in this offering, is affiliated with Lindsay A. Rosenwald, M.D., a principal stockholder and a member of our board of directors. Under the rules of the Financial Industry Regulatory Authority, Inc., a conflict of interest is deemed to exist with respect to National because Dr. Rosenwald is deemed to control both National (as a beneficial owner of in excess of 10% of the outstanding capital stock of National) and us. As described above under “Certain Transactions – 2011 Series C Financing,” in connection with our Series C Financing, National received commissions of \$2.6 million and five-year warrants to purchase an aggregate of 461,263 Series C shares at an exercise price of \$5.59, which were subsequently transferred by National to other individuals and entities and are now exercisable to purchase 458,276 shares of common stock. The underwriters have reserved for sale at the public offering price up to 200,000 shares offered by this prospectus for Dr. Rosenwald.

### **Notice to Non-US Investors**

#### *United Kingdom/Germany/Norway/The Netherlands*

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive, or a Relevant Member State, an offer to the public of any securities which are the subject of the offering contemplated by this prospectus may not be made in that Relevant Member State except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

(a) to legal entities which are authorised or regulated to operate in the financial markets or, if not so authorized or regulated, whose corporate purpose is solely to invest in securities;

(b) to any legal entity which has two or more of (1) an average of at least 250 employees during the last financial year; (2) a total balance sheet of more than €43,000,000 and (3) an annual net turnover of more than €50,000,000, as shown in its last annual or consolidated accounts;

(c) by the representatives to fewer than 100 natural or legal persons (other than qualified investors as defined in the Prospectus Directive); or

(d) in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided, that no such offer of securities shall result in a requirement for the publication by us or any representative of a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, the expression an “offer to the public” in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase any securities, as the same may be varied in that Member State by any measure implementing the Prospectus Directive in that Member State and the expression “Prospectus Directive” means Directive 2003/71/EC and includes any relevant implementing measure in each Relevant Member State.

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Each underwriter has represented, warranted and agreed that:

(a) it has only communicated or caused to be communicated and will only communicate or cause to be communicated any invitation or inducement to engage in investment activity (within the meaning of section 21 of the Financial Services and Markets Act 2000, or the FSMA, received by it in connection with the issue or sale of any securities in circumstances in which section 21(1) of the FSMA does not apply to us; and

(b) it has complied with and will comply with all applicable provisions of the FSMA with respect to anything done by it in relation to the securities in, from or otherwise involving the United Kingdom.

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### **Legal Matters**

The validity of the shares of our common stock offered hereby has been passed upon for us by Loeb & Loeb LLP, New York, New York. Lowenstein Sandler PC, Roseland, New Jersey, is acting as counsel for the underwriters in this offering.

### **Experts**

The financial statements as of December 31, 2011 and 2010 and for each of the three years in the period ended December 31, 2011 and cumulatively, for the period from June 28, 2006 (date of inception) to December 31, 2011 included in this prospectus have been so included in reliance on the report (which contains an explanatory paragraph relating to the Company's ability to continue as a going concern as described in Note 1 of the financial statements) of PricewaterhouseCoopers LLP, an independent registered public accounting firm, given on the authority of said firm as experts in auditing and accounting.

### **Where You Can Find More Information**

We have filed a registration statement on Form S-1 with the Securities and Exchange Commission in connection with this offering. In addition, we file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission. You may read and copy the registration statement and any other documents we have filed at the Securities and Exchange Commission'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 Securities and Exchange Commission filings are also available to the public at the Securities and Exchange Commission's Internet site 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.

This prospectus is part of the registration statement and does not contain all of the information included in the registration statement. Whenever a reference is made in this prospectus to any of our contracts or other documents, the reference may not be complete and, for a copy of the contract or document, you should refer to the exhibits that are a part of the registration statement.

You may request a copy of these filings, at not cost, by contacting us at:

Coronado Biosciences, Inc.  
15 New England Executive Park  
Burlington, Massachusetts 01803  
(781) 238-6621  
Attention: Chief Accounting Officer

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

CONSOLIDATED FINANCIAL STATEMENTS  
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**Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of  
Coronado Biosciences, Inc.  
(a development stage enterprise)

In our opinion, the accompanying consolidated balance sheets and the related consolidated statements of operations, of changes in convertible preferred stock and stockholders' equity (deficit) and of cash flows present fairly, in all material respects, the financial position of Coronado Biosciences, Inc. and its subsidiary (a development stage enterprise) at December 31, 2011 and December 31, 2010, and the results of their operations and their cash flows for each of the three years in the period ended December 31, 2011 and, cumulatively, for the period from June 28, 2006 (date of inception) to December 31, 2011 in conformity with accounting principles generally accepted in the United States of America. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. We conducted our audits of these statements in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, and evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

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

/s/ PricewaterhouseCoopers LLP  
Boston, Massachusetts  
March 29, 2012



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

	<u>December 31,</u> <u>2011</u>	<u>December 31,</u> <u>2010</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 23,160	\$ 14,862
Prepaid and other current assets	215	55
Total current assets	23,375	14,917
Computer equipment, net of accumulated depreciation	—	22
Total Assets	<u>\$ 23,375</u>	<u>\$ 14,939</u>
<b>LIABILITIES, CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIT)</b>		
Current Liabilities:		
Accounts payable	\$ 575	\$ 476
Accounts payable—related party	—	46
PCP interest payable—related party	19	—
Accrued expenses	2,899	1,037
Total current liabilities	3,493	1,559
PCP notes payable—related party	750	—
Total Liabilities	<u>4,243</u>	<u>1,559</u>
Commitments and Contingencies (Note 6)		
Convertible Preferred Stock, \$.001 par value, 587,376 Series C Shares authorized, 0 shares issued and outstanding as of December 31, 2011; 10,000,000 shares authorized, 4,357,885 Series A Shares issued and outstanding as of December 31, 2010, net of issuance costs (liquidation value of \$54,844 as of December 31, 2010)	—	29,277
Stockholders' Equity (Deficit):		
Common Stock, \$.001 par value, 50,000,000 shares authorized, 18,604,245 shares issued and outstanding as of December 31, 2011; 4,791,102 shares issued and outstanding as of December 31, 2010;	19	5
Additional paid-in capital	75,687	4,312
Deficit accumulated during development stage	(56,574)	(20,214)
Total Stockholders' Equity (Deficit)	<u>19,132</u>	<u>(15,897)</u>
Total Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)	<u>\$ 23,375</u>	<u>\$ 14,939</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 for share and per share amounts)**

	<u>For the year ended December 31,</u>			<u>Period from</u>
	<u>2011</u>	<u>2010</u>	<u>2009</u>	<u>June 28, 2006</u>
				<u>(Date of</u>
				<u>Inception) to</u>
				<u>December 31,</u>
				<u>2011</u>
Operating expenses:				
Research and development	\$ 8,583	\$ 8,341	\$ 2,270	\$ 24,542
General and administrative	5,755	900	343	7,614
In-process research and development	20,706	—	—	20,706
Loss from operations	(35,044)	(9,241)	(2,613)	(52,862)
Interest income	165	61	—	244
Interest expense	(74)	(1,535)	(1,053)	(3,282)
Other income	—	733	—	733
Warrant expense	(1,407)	—	—	(1,407)
Net loss	(36,360)	(9,982)	(3,666)	(56,574)
Common Stock dividend to Series A Convertible Preferred Stockholders	(5,861)	—	—	(5,861)
Net loss attributed to Common Stockholders	\$ (42,221)	\$ (9,982)	\$ (3,666)	\$ (62,435)
Basic and diluted net loss per common share	\$ (5.51)	\$ (2.24)	\$ (1.01)	
Weighted average common shares outstanding—basic and diluted	7,662,984	4,453,786	3,612,769	

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

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)**

**Period from June 28, 2006 (date of inception) through December 31, 2011**

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

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional paid-in capital</u>	<u>Deficit accumulated during development stage</u>	<u>Total Stockholders' (deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Balances at June 28, 2006 (Date of Inception)	-	\$ -	-	\$ -	\$ -	\$ -	\$ -
Net loss	-	-	-	-	-	(123)	(123)
Balances at December 31, 2006	-	-	-	-	-	(123)	(123)
Issuance of Common Stock to founders	-	-	2,125,096	2	-	-	2
Issuance of restricted Common Stock to non-employees	-	-	2,180,000	2	-	-	2
Issuance of restricted Common Stock to employees	-	-	457,170	1	-	-	1
Stock-based compensation expense	-	-	-	-	13	-	13
Net loss	-	-	-	-	-	(2,645)	(2,645)
Balances at December 31, 2007	-	-	4,762,266	5	13	(2,768)	(2,750)
Stock-based compensation expense	-	-	-	-	25	-	25
Contribution of services by stockholder	-	-	-	-	20	-	20
Net loss	-	-	-	-	-	(3,798)	(3,798)
Balances at December 31, 2008	-	-	4,762,266	5	58	(6,566)	(6,503)
Issuance of Common Stock to non-employees for services	-	-	5,000	-	-	-	-
Stock-based compensation expense	-	-	-	-	39	-	39
Contribution of services by stockholder	-	-	-	-	40	-	40
Net loss	-	-	-	-	-	(3,666)	(3,666)
Balances at December 31, 2009	-	-	4,767,266	5	137	(10,232)	(10,090)
Issuance of Convertible Preferred Stock Series A for cash	2,584,166	21,681	-	-	-	-	-
Issuance of Convertible Preferred Stock Series A upon conversion of debt and accrued interest	1,773,719	10,508	-	-	-	-	-
Costs related to issuance of Convertible Preferred Stock Series A, including Common Stock warrants	-	(2,912)	-	-	621	-	621
Reclassification of fair value of warrant liability	-	-	-	-	234	-	234
Change in fair value of embedded conversion feature related to convertible debt	-	-	-	-	831	-	831
Issuance of Common Stock to non-employees for services	-	-	23,836	-	82	-	82
Issuance of Common Stock warrants to non-employees for services	-	-	-	-	38	-	38
Stock-based compensation expense	-	-	-	-	2,329	-	2,329
Contribution of services by stockholder	-	-	-	-	40	-	40
Net loss	-	-	-	-	-	(9,982)	(9,982)
Balances at December 31, 2010	4,357,885	29,277	4,791,102	5	4,312	(20,214)	(15,897)

**CORONADO BIOSCIENCES, INC. AND SUBSIDIARY**

(A development stage enterprise)

**Consolidated Statements of Changes in Convertible Preferred Stock and Stockholders' Equity (Deficit)—  
(Continued)****Period from June 28, 2006 (date of inception) through December 31, 2011****(\$ in thousands except for share amounts)**

	<u>Preferred Stock</u>		<u>Common Stock</u>		<u>Additional paid-in capital</u>	<u>Deficit accumulated during development stage</u>	<u>Total Stockholders' (deficit)</u>
	<u>Shares</u>	<u>Amount</u>	<u>Shares</u>	<u>Amount</u>			
Issuance of Convertible Preferred Stock Series B for purchase of Asphelia assets	2,525,677	16,114	—	—	—	—	—
Issuance of Convertible Preferred Stock Series C for cash	4,612,624	25,785	—	—	—	—	—
Costs related to issuance of Convertible Preferred Stock Series C, including the fair value of Preferred Stock Series C warrants	—	(4,171)	—	—	—	—	—
Issuance of Common Stock for conversion of Convertible Preferred Stock Series A	(4,357,885)	(29,277)	4,357,885	4	29,273	—	29,277
Issuance of Common Stock for conversion of Convertible Preferred Stock Series B	(2,525,677)	(16,114)	2,525,677	2	16,111	—	16,113
Issuance of Common Stock for conversion of Convertible Preferred Stock Series C	(4,612,624)	(21,614)	4,612,624	5	21,609	—	21,614
Issuance of Common Stock dividend to Preferred Stock Series A stockholders	—	—	2,178,917	2	(2)	—	—
Exercise of stock options	—	—	138,040	1	192	—	193
Warrant liability	—	—	—	—	2,693	—	2,693
Stock-based compensation expense	—	—	—	—	1,469	—	1,469
Contribution of services by stockholder	—	—	—	—	30	—	30
Net loss	—	—	—	—	—	(36,360)	(36,360)
Balances at December 31, 2011	—	\$ —	18,604,245	\$ 19	\$ 75,687	\$ (56,574)	\$ 19,132

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

**Coronado Biosciences, Inc. and Subsidiary**  
(A development stage enterprise)  
**Consolidated Statements of Cash Flows**  
**(\$ in thousands)**

	For the Year Ended December 31,			Period from June 28, 2006 (Date of Inception) to December 31, 2011
	2011	2010	2009	2011
<b>Cash flows from operating activities:</b>				
Net loss	\$(36,360)	\$ (9,982)	\$(3,666)	\$ (56,574)
Adjustments to reconcile net loss to net cash used in operating activities:				
Stock-based compensation expense	1,469	2,329	39	3,874
Acquired in-process research and development	20,706	—	—	20,706
Noncash interest	—	236	493	1,031
Noncash interest—related parties	—	34	101	286
Contribution of services by stockholder	30	40	40	130
Issuance of Common Stock to non-employee for services	—	121	—	121
Change in fair value of common stock warrant liability	—	234	—	234
Change in fair value of embedded conversion feature	—	831	—	831
Change in fair value of preferred stock warrant liability	1,407	—	—	1,407
Amortization of deferred financing costs	—	157	415	737
Depreciation expense	22	5	5	41
Changes in operating assets and liabilities:				
Other current assets	(160)	(51)	203	(215)
Interest payable—related parties	19	(38)	38	19
Accounts payable and accrued expenses-related parties	(46)	46	—	—
Accounts payable and accrued expenses	1,961	361	(19)	3,474
Net cash used in operating activities	<u>(10,952)</u>	<u>(5,677)</u>	<u>(2,351)</u>	<u>(23,898)</u>
<b>Cash flows from investing activities:</b>				
Purchase of computer equipment	—	(13)	(2)	(41)
Purchase of in-process research and development	(3,843)	—	—	(3,843)
Net cash used in investing activities	<u>(3,843)</u>	<u>(13)</u>	<u>(2)</u>	<u>(3,884)</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	2,221
Proceeds from issuance of Convertible Preferred Stock Series A	—	21,681	—	21,681
Payment of costs related to the issuance of Convertible Preferred Stock Series A	—	(2,291)	—	(2,291)
Proceeds from issuance of Convertible Preferred Stock Series C	25,784	—	—	25,784
Payment of costs related to the issuance of Convertible Preferred Stock Series C	(2,884)	—	—	(2,884)
Proceeds from borrowings under line of credit	—	—	40	80
Payment of line of credit	—	(80)	—	(80)
Proceeds from Senior Convertible Notes	—	—	3,500	7,570
Payment of debt issue costs	—	—	(344)	(737)
Payment of notes payable—related parties	—	—	—	(600)
Proceeds from issuance of Common Stock	193	—	—	198
Net cash provided by financing activities	<u>23,093</u>	<u>19,042</u>	<u>3,856</u>	<u>50,942</u>
<b>Increase in cash and cash equivalents</b>	<u>8,298</u>	<u>13,352</u>	<u>1,503</u>	<u>23,160</u>
Cash and cash equivalents—beginning of period	<u>14,862</u>	<u>1,510</u>	<u>7</u>	<u>—</u>
Cash and cash equivalents—end of period	<u>\$ 23,160</u>	<u>\$ 14,862</u>	<u>\$ 1,510</u>	<u>\$ 23,160</u>

**Coronado Biosciences, Inc. and Subsidiary**  
(A development stage enterprise)  
**Consolidated Statements of Cash Flows—(Continued)**  
**(\$ in thousands)**

	<u>For the Year Ended</u> <u>December 31,</u>			<u>Period from</u> <u>June 28, 2006</u> <u>(Date of</u> <u>Inception) to</u> <u>December 31,</u> <u>2011</u>
	<u>2011</u>	<u>2010</u>	<u>2009</u>	
<b>Supplemental disclosure of cash flow information:</b>				
Cash paid for interest	\$ 53	\$ 81	\$ 7	\$ 141
<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
Assumption of PCP Note related to Asphelia Asset Purchase	750	—	—	750
Issuance of Convertible Preferred Stock Series C warrants	1,286	—	—	1,286
Issuance of Common Stock warrants related to the Convertible Preferred Stock Series A financing	—	621	—	621
Conversion of Senior Convertible Notes into Convertible Preferred Stock Series A	—	8,601	—	8,601
Conversion of notes payable—related parties into Convertible Preferred Stock Series A	—	1,907	—	1,907
Issuance of Common Stock for Convertible Preferred Stock Series A, B and C	67,004	—	—	67,004

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

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

**1. Organization and Description of Business**

Coronado Biosciences, Inc. (the “Company”), incorporated in Delaware on June 28, 2006 (date of inception), is a biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer.

*Development-Stage Risks and Liquidity*

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

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit of \$56.6 million as of December 31, 2011. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates. To date, the Company’s operations have been funded primarily by issuing equity securities and debt securities. During 2010, the Company issued 4,357,885 shares of Series A Convertible Preferred Stock (“Series A Shares”) resulting in net proceeds to the Company of \$19.4 million (see Note 12). All debt securities were either repaid or converted into Series A Shares as of December 31, 2010. During 2011, the Company completed an offering of 4,612,624 shares of Series C Convertible Preferred Stock (“Series C Shares”) resulting in net proceeds to the Company of approximately \$22.9 million (see Note 12). On November 15, 2011, the Company’s Resale Registration Statement on Form S-1 was declared effective resulting in the conversion of 4,357,855 Series A Shares, 2,525,677 shares of Series B Convertible Preferred Stock (“Series B Shares”) and 4,612,624 Series C Shares to Common Stock.

The Company expects to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its product candidates. Management believes that cash and cash equivalents on hand, including cash raised in the Series C Shares financing (see Note 12) are sufficient to sustain operations into the fourth quarter of 2012 based on its existing business plan and given the ability to control the timing of significant expense commitments. The Company will require additional financing to develop and obtain regulatory approvals for its product candidates, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. The Company will seek funds through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to the Company on acceptable terms or at all. The Company’s failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company will be required to delay, reduce or eliminate research and development programs, and pursue merger or acquisition strategies. These circumstances raise substantial doubt about the Company’s ability to continue as a going concern.

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

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

### **2. Summary of Significant Accounting Policies**

#### *Basis of Presentation and Principles of Consolidation*

The Company's consolidated financial statements have been prepared in conformity with accounting principles generally accepted in the United States of America ("GAAP"). The Company's consolidated financial statements include the accounts of the Company and its 100% owned subsidiary, Innmune Limited. All intercompany balances and transactions have been eliminated.

#### *Use of Estimates*

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

#### *Segment Reporting*

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

#### *Concentration of Risk*

The Company is completely dependent on third party manufacturers for product supply. In particular the Company relies and expects to continue to rely exclusively on OvaMed to supply it with its requirements of TSO. OvaMed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it is also producing product for clinical trials by third parties, including Falk. Similarly, the Company relies on BioReliance and PCT for its CNDO-109 requirements and its CNDO-109 clinical program would be adversely affected by a significant interruption in the supply of this product.

#### *Cash and Cash Equivalents and Concentration of Credit Risk*

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

#### *Computer Equipment*

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

#### *Deferred Financing Costs*

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



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### *Impairment of Long-Lived Assets*

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

### *Research and Development*

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

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

### *Government Grant*

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

### *Contingencies*

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

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

### *Stock-Based Compensation*

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

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

- Arm's length private transactions involving the Company's Preferred Stock;

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- Financial and operating performance;
- Market conditions;
- Developmental milestones achieved;
- Business risks; and
- Management and board experience.

The assumptions used in calculating the fair value of stock-based awards represent management's best estimates and involve inherent uncertainties and the application of management's judgment. As of November 17, 2011, the Company utilizes its public trading price in determining the fair value of its stock-based awards.

### *Income Taxes*

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

### *Comprehensive Loss*

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

### *Recently Issued Accounting Standards*

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

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

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

## **3. Net Loss Per Common Share**

The Company calculates earnings (loss) per share using the two-class method, which is an earnings allocation formula that determines earnings per share for Common Stock and participating securities according to dividends declared and non-forfeitable participation rights in undistributed earnings. Under this method, all earnings (distributed and undistributed) are allocated to common shares and participating securities based on their respective rights to receive dividends. Holders of the Series A Shares were entitled to and did receive in May 2011, a Common Stock dividend equal to 50% of Series A Shares held. Additionally, holders of restricted

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Common Stock were entitled to all cash dividends, when and if declared, and such dividends are non-forfeitable. The participating securities do not have a contractual obligation to share in any losses of the Company. As a result, net losses are not allocated to the participating securities for any periods presented.

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of Common Stock outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of Common Stock and Common Stock equivalents outstanding for the period. For purposes of this calculation, Common Stock equivalents are only included in the calculation of diluted net loss per share when the effect is dilutive. As of November 15, 2011, the Company issued 11,496,186 shares of Common Stock as a result of the conversion of its Series A, Series B and Series C Shares. For the year ended December 31, 2011, a weighted percentage of this Common Stock was included in the common shares outstanding.

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

	For the year ended December 31,		
	2011	2010	2009
<i>(\$ in thousands except share and per share amounts)</i>			
<b>Historical net loss per share:</b>			
<i>Numerator</i>			
Net loss	\$ (36,360)	\$ (9,982)	\$ (3,666)
Common Stock dividend to Series A Preferred Stockholders	(5,861)	—	—
Net loss attributed to Common Stockholders	<u>\$ (42,221)</u>	<u>\$ (9,982)</u>	<u>\$ (3,666)</u>
<i>Denominator</i>			
Weighted-average common shares outstanding—Denominator for basic and diluted net loss per share	<u>7,662,984</u>	<u>4,453,786</u>	<u>3,612,769</u>
Basic and diluted net loss per share attributed to common stockholders	<u>\$ (5.51)</u>	<u>\$ (2.24)</u>	<u>\$ (1.01)</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 effect of including such securities would be antidilutive:

	For the year ended December 31,		
	2011	2010	2009
Series A Shares	3,796,733	2,617,243	—
Series B Shares	2,158,935	—	—
Series C Shares	1,966,635	—	—
Unvested restricted Common Stock	—	322,900	1,146,980
Warrants to purchase Common Stock	533,249	261,861	87,002
Warrants to purchase Series C Shares	256,059	—	—
Options to purchase Common Stock	<u>1,479,291</u>	<u>296,112</u>	<u>—</u>
	<u>10,190,902</u>	<u>3,498,116</u>	<u>1,233,982</u>

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### 4. Computer Equipment

Computer equipment consisted of the following:

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

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

### 5. Accrued Liabilities

Accrued expenses consisted of the following:

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

### 6. Commitments and Contingencies

#### *Operating Lease Obligations*

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

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

#### *Indemnification*

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

#### *Legal Proceedings*

In the ordinary course of business, the Company and its subsidiary may be subject to both insured and uninsured litigation. Suits and claims may be brought against the Company by customers, suppliers, partners

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and/or third parties (including tort claims for personal injury arising from clinical trials of the Company's product candidates and property damage) alleging deficiencies in performance, breach of contract, etc., and seeking resulting alleged damages. During the years ended December 31, 2011, 2010 and 2009, no claims have been brought by or against the Company and its subsidiary.

### **7. Asphelia Asset Purchase**

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

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

*(\$ in thousands)*

Fair value of 2,525,677 Series B Shares	\$16,114
Cash payment	3,809
Fair value of PCP Note	750
Other transaction costs	33
<b>Total asset acquisition cost</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 year ended December 31, 2011.

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

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

The OvaMed Supply Agreement currently expires in March 2013 but will automatically renew for successive one-year periods, unless the Company gives 12 months prior notice of its election not to renew. The OvaMed

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Supply Agreement is subject to early termination by either party under certain customary conditions of breach and by the Company in the event of specified failures to supply or regulatory or safety failures.

### **8. Employee Benefit Plans**

On January 1, 2008, the Company adopted a defined contribution 401(k) plan which allows employees to contribute up to a percentage of their compensation, subject to IRS limitations and provides for a discretionary Company match up to a maximum of 4% of employee compensation. In 2011 the Company paid a matching contribution of \$77,000. No match was paid in prior years.

### **9. Fair Value Measurement**

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

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

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

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

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

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

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

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

### **10. Related Party Transactions**

#### *Services Agreement*

In November 2006, the Company entered into a consulting contract with Paramount BioSciences, LLC ("PBS") an affiliate of a principal stockholder and director of the Company (the "Principal Stockholder/Director"), under

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which PBS provided certain drug development, professional, administrative and accounting services. Total fees for the period from inception to December 31, 2008 were \$550,000. Since December 31, 2008 no fees have been incurred.

### *Placement Agent*

Paramount BioCapital, Inc. ("PBC"), an affiliate of the Principal Stockholder/Director of the Company, acted as placement agent for the private placement of the Company's Senior Convertible Notes, PCP Notes, and Series A Shares (see Note 11). For the services rendered, PBC received cash payments for commissions and reimbursement of expenses as well as warrants to purchase Common Stock (see Notes 11 and 13).

### *Other Related Parties*

The Principal Stockholder/Director, individually and through certain trusts owned in excess of 10% of the Company's issued and outstanding Common Stock as of December 31, 2011. In addition, certain trusts established for the benefit of family members of the Principal Stockholder/Director beneficially owned an aggregate of approximately 7.9% of the Company's outstanding capital stock as of December 31, 2011.

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

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

## **11. Debt**

### *Related Party Notes*

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

The Related Party Notes mature and were payable on or upon the occurrence of certain events defined in the agreement. Certain events include either the consummation of an equity financing in which gross proceeds to the Company equal or exceed 250% of the outstanding principal amount, an initial public offering or a sale of the Company. On September 4, 2008, the Company amended the Related Party Notes to provide that all unpaid principal and accrued interest shall be automatically converted into the Company's Common Stock upon the initial closing of a private placement of the Company's Common Stock at a conversion price equal to 100% of the lowest price paid by investors of the offering. On July 7, 2009, the Company amended the Related Party Notes to change the maturity date to February 20, 2010 and to provide that all unpaid principal and accrued interest shall be automatically converted upon the occurrence of certain events including a qualified financing, a reverse merger or a sale of the Company, as defined.

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

In 2010, the Company completed a qualified financing defined as an equity financing or series of related financings greater than \$10 million at a conversion price equal to 75% of the lowest price per unit paid for such

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securities in cash by investors. This qualified equity financing resulted in the Related Party Notes, principal and accrued interest totaling \$1.6 million to automatically convert into 273,046 shares of Series A Shares at a per share price of \$5.87. In addition, under the PBS Note, all principal borrowed and interest accrued subsequent to January 20, 2010 totaling \$0.3 million was converted into 36,194 Series A Shares at a per share price of \$8.39.

### *PCP Promissory Notes (the "PCP Notes")*

In 2009, the Company issued 10% promissory notes to PCP for aggregate gross proceeds of \$570,000. PCP is a related party due to common ownership by the Principal Stockholder/Director. All unpaid principal and accrued interest outstanding under the PCP Notes were payable on December 31, 2013 or earlier in the event of either the consummation of an equity financing in which gross proceeds to the Company equal or exceed 250% of the outstanding principal amount or a reverse merger or sale of the Company. The outstanding principal and accrued interest totaling \$0.6 million was repaid in cash in 2010.

In conjunction with entering into the PCP Notes, the Company issued warrants to purchase 27,175 shares of Common Stock (see Note 13). A portion of the proceeds was allocated to the fair value of the warrants and recorded as a debt discount and was amortized to interest expense in the consolidated statement of operations over the term of the PCP Notes. This amount was not material.

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

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

### *Senior Convertible Notes*

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

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

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

In 2010, the Company amended the Senior Convertible Notes to extend the maturity date to September 30, 2010 and modify the conversion price factor for certain events. The amendment was accounted for as a



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modification and the change in the fair value of the conversion feature, in the amount of \$0.7 million, was recorded as a debt discount. The debt discount was amortized to interest expense in the consolidated statement of operations over the remaining term of the Senior Convertible Notes.

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

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

PBC was entitled to receive commissions equal to 7% of the gross proceeds of the Senior Convertible Notes, expense reimbursements, and warrants to purchase Common Stock (as defined in Note 13) as compensation for its services as the placement agent for the Senior Convertible Notes. These issuance costs of \$0.7 million were capitalized as deferred financing costs and were amortized to interest expense in the consolidated statements of operations over the estimated life of the Senior Convertible Notes. For the years ended December 31, 2010, 2009 and the period from inception to December 31, 2011, amortization of deferred financing costs was \$0.2 million, \$0.4 million, and \$0.7 million, respectively.

### *Line of Credit Facility*

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

Interest expense for all debt is as follows:

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

## 12. Equity

### *Convertible Preferred Stock*

*Series A Shares.* The Company's Certificate of Incorporation, as amended, authorizes the Company to issue 15,000,000 shares of \$0.001 par value Preferred Stock. As of December 31, 2011 and 2010, there were 0 Series A Shares and 4,357,885 Series A Shares outstanding, respectively.

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

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

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

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

- (1) April 26, 2012, or
- (2) if the Company's capital stock becomes publicly traded, then the date upon which such capital stock has a publicly traded value of \$12.59 or more per share, as adjusted for any stock splits, stock exchanges, recapitalizations, dividends and the like (such date, the "Valuation Milestone Date"). The Valuation Milestone Date shall be deemed to have occurred: (i) on the date which the Company's capital stock first becomes publicly traded, if such capital stock has an initial quoted value greater than or equal to \$12.59 per share, or (ii) the date that is the twentieth (20th) consecutive or non-consecutive trading day where the volume-weighted average price for the Company's capital stock as reported by Bloomberg Financial L.P. is greater than or equal to \$12.59 per share, in each case as adjusted for any stock splits, stock exchanges, recapitalizations and dividends as determined by the Company's board of directors in its reasonable discretion.

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

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

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

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

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

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

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The Series A Shares were redeemable upon a liquidation event, including liquidation, winding up, and dissolution of the Company. Additionally, the holders would be entitled to receive cash in the event of an acquisition, including a merger or consolidation or asset transfer. Certain of these events would not be considered solely within the Company's control. As a result, outstanding Series A Shares have been classified as mezzanine equity in the consolidated balance sheet at December 31, 2010.

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

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

### *Voting Rights*

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

### *Liquidation*

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

### *Conversion*

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

### *Dividends*

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

### *Fully Paid and Nonassessable*

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

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

### *Voting Rights*

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

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### *Liquidation*

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

### *Conversion*

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

### *Dividends*

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

### *Fully Paid and Nonassessable*

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

### *Conversion of Series A, B and C Shares*

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

### *Common Stock*

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

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

### *Voting Rights*

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

### *Dividends*

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

### *Liquidation*

In the event of the Company's liquidation, dissolution or winding up, holders of Common Stock will be entitled to share ratably in the net assets legally available for distribution to stockholders after the payment of all of the Company's debts and other liabilities, subject to the satisfaction of any liquidation preference granted to the holders of any outstanding shares of Preferred Stock.

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### *Rights and Preference*

Holders of the Company's Common Stock have no preemptive, conversion or subscription rights, and there are no redemption or sinking fund provisions applicable to our Common Stock. The rights, preferences and privileges of the holders of Common Stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of the Company's Preferred Stock that are or may be issued.

### *Fully Paid and Nonassessable*

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

On June 1, 2007, the Company issued the following shares of Common Stock:

- 2,125,096 shares of fully vested Common Stock to its founders at par value of \$0.001.
- 457,170 shares of restricted Common Stock were granted to certain employees of the Company under the Company's 2007 Stock Incentive Plan, for payment of par value (see Note 14). The shares vest annually in equal amounts over three years and the fair value of the awards was determined and fixed on the grant date. Compensation expense is recorded on a straight-line basis over the vesting period.
- 2,180,000 shares of restricted Common Stock were issued to certain employees of PBS at par value of \$0.001 that vest annually in equal amounts over three years (see Note 14). PBS provides various services to the Company. The fair value of the awards was determined on the grant date and the unvested awards were remeasured each reporting period. Compensation expense is recorded on a straight-line basis over the vesting period.

Compensation expense related to the restricted Common Stock for the years ended December 31, 2011, 2010, 2009, and for the period from inception to December 31, 2011 was \$0.0 million, \$2.0 million, \$39,000 and \$2.1 million, respectively, and was recorded as research and development expense in the consolidated statements of operations. All shares were fully vested as of December 31, 2010 and no restricted Common Stock issuances were made for the year ended December 31, 2011.

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

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

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

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

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

## **13. Warrants to Purchase Common Stock**

### *Debt Placement Agent Warrants*

In connection with the issuance of the Senior Convertible Notes (see Note 11), the Company issued seven-year warrants to purchase the Company's Common Stock to PBC as partial consideration for its services as the placement agent. The number of warrants and the exercise price were dependent upon i) the lowest price paid in

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a qualified financing, ii) consideration received in a sale of the company, or iii) consideration received in a reverse merger. If none of these events occurred before the second anniversary of the issuance date, the Debt Placement Warrants would be exercisable for a number of shares of Common Stock equal to 10% of the principal amount of the Senior Convertible Notes divided by \$1.00, at a per share exercise price of \$1.00.

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

In connection with the Series A Shares offering on April 26, 2010, a qualified financing, both the number of warrants and the exercise price became known. The placement agent received warrants for shares of the Company's Common Stock equal to 10% of the principal amount of the Senior Convertible Notes divided by the lowest price paid for securities in the Series A Shares offering, at an exercise price of 110% of the lowest price paid for securities in a qualified financing. Pursuant to the Series A Shares offering, PBC was issued warrants for an aggregate of 48,510 shares of Common Stock at an exercise price of \$9.23 per share with a fair value of \$0.1 million related to the 2008 Senior Convertible Notes and warrants for an aggregate of 41,716 shares of Common Stock at an exercise price of \$9.23 per share with a fair value of \$0.1 million related to the 2009 Senior Convertible Notes. The fair value of the warrants related to the 2008 Senior Convertible Notes was determined using an option pricing model assuming a 95.4% volatility, a 1.7% risk-free rate of interest, a term of 4.8 years and an estimated per share fair value of the Company's Common Stock of \$3.45. The fair value of the warrants related to the 2009 Senior Convertible Notes was determined using an option pricing model assuming a 93.4% volatility, a 2.9% risk-free rate of interest, a term of 6.2 years and an estimated per share fair value of the Company's Common Stock of \$3.45. In April 2010, the total fair value \$0.2 million of the warrants was reclassified from a liability to additional paid-in capital in the consolidated balance sheets.

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

### *PCP Warrants*

In connection with the issuance of the PCP Notes in 2009 (see Note 11), the Company also issued to PCP warrants to purchase shares of the Company's Common Stock. The number of warrants and the exercise five-year price were dependent upon i) the lowest price paid in a qualified financing or ii) consideration received in a reverse merger. If none of these events occurred before the second anniversary of the issuance date, the number of warrants would equal 40% of the principal amount of the PCP Notes divided by \$1.00, at a per share exercise price of \$1.00.

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

In connection with the Series A Shares offering, a qualified financing, both the number of PCP warrants and the exercise price became known. The placement agent received warrants for the number of shares of the Company's Common Stock equal to 40% of the principal amount of the PCP Notes divided by the lowest price paid for securities in the Series A Shares offering, at an exercise price of 110% of the lowest price paid for securities in the offering. The Company issued warrants to purchase an aggregate of 27,175 shares of Common Stock at an exercise price of \$9.23 per share for a fair value of \$47,000. The fair value of the warrants was

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determined using an option pricing model assuming a 98.3% volatility, an average 2.1% risk-free rate of interest, a term of 3.8 – 4.2 years and an estimated per share fair value of the Company's Common Stock of \$3.45. The fair value on April 26, 2010 totaling \$47,000 was reclassified from a liability to additional paid-in capital in the consolidated balance sheets.

### *Preferred Stock Placement Warrants*

In connection with the issuance of the Company's Series A Shares (see Note 12), the Company issued seven-year warrants to purchase an aggregate of 258,418 shares of the Company's Common Stock at an exercise price of \$8.39 per share to PBC as partial consideration for its services as the placement agent.

The fair value of the warrants was \$0.6 million measured on the respective date of issuance and were recorded as a reduction in the carrying value of the Preferred Stock and an increase to additional paid in capital. The fair values were determined using an option pricing model assuming 92.0% – 94.4% volatility, a 2.0% – 3.3% risk-free rate of interest, a term of seven years and an estimated fair value of the Company's Common Stock of \$3.45 per share. The warrants were accounted for as stock issuance costs; and the fair value was recorded as a reduction to the carrying amount of the Series A Shares (see Note 12) with a corresponding increase to additional paid-in capital.

### *Non-Employee Warrants*

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

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

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

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

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the consolidated statements of operations. The fair value of these awards will be mark-to-marketed on each valuation date using the Black Scholes pricing model until such time that these awards are fully vested.

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

### *Warrants to Purchase Series C Shares*

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

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

## **14. Stock Plans and Stock-Based Compensation**

In 2007, the Company's board of directors adopted and stockholders approved the Coronado Biosciences, Inc. 2007 Stock Incentive Plan (the "Plan") authorizing the Company to grant up to 6,000,000 shares of Common Stock to eligible employees, directors, and consultants in the form of restricted stock, stock options and other types of grants. The amount, terms, and exercisability provisions of grants are determined by the Board of Directors.

The purpose of the Plan is to provide the Company with the flexibility to use shares, options or other awards based on the Company's Common Stock as part of an overall compensation package to provide performance-based rewards to attract and retain qualified personnel. Such awards include, without limitation, options, stock appreciation rights, sales or bonuses of restricted stock, restricted stock units or dividend equivalent rights, and an award may consist of one such security or benefit, or two or more of them in any combination or alternative. Vesting of awards may be based upon the passage of time, the occurrence of one or more events, or the satisfaction of performance criteria or other conditions. There are 6,000,000 shares of Common Stock reserved for issuance under the Plan, of which 3,470,610 were granted, net of cancellations, and 2,529,930 shares were available for issuance as of December 31, 2011.

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



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

- *Risk-Free Interest Rate:* The Company determined the risk-free interest rate by using a weighted average assumption equivalent to the expected term based on the U.S. Treasury constant maturity rate.
- *Expected Volatility:* The Company determined its future stock price volatility based on the average historical stock price volatility of comparable peer companies.
- *Expected Term:* Due to the limited exercise history of the Company's stock options, the Company determined the expected term based on the stratification of employee groups and the expected effect of events that have indications on future exercise activity. Expected life for options granted to employees uses the Simplified Method, while option granted to non-employees uses an expected term equal to the life of the contract.
- *Expected Dividend Rate:* The Company has not paid and does not anticipate paying any cash dividends in the near future.

The fair value of each option award was estimated on the grant date using the Black Scholes option pricing model and expensed under the straight line method. The fair value for non-employee stock based awards are mark-to-marketed on each valuation date until vested using the Black Scholes pricing model. The following assumptions were used:

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

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

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

The following table summarizes stock option activity:

(\$ in thousands except per share amounts)	Outstanding Options			Weighted Average Remaining Contractual Life (in years)
	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	
Outstanding at December 31, 2010	1,228,190	\$ 1.37	\$ 466	9.8
Options granted	1,165,000	\$ 2.65		
Options exercised	(138,040)	\$ 1.40		
Options forfeited	(441,080)	\$ 1.44		
Options expired	–	–		
Outstanding at December 31, 2011	<u>1,814,070</u>	\$ 2.17	\$ 7,852	9.2
Options vested and expected to vest	<u>1,748,763</u>	\$ 2.17	\$ 7,569	9.2
Options vested and exercisable	254,690	\$ 1.43	\$ 1,291	9.2

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As of December 31, 2011, the Company had unrecognized stock-based compensation expense related to all unvested stock options of \$3.7 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.2 years.

### *Employee Stock Purchase Plan*

On December 19, 2011, the Board of Directors approved the 2012 Coronado Employee Stock Purchase Plan the (“ESPP”) for the issuance of up to 200,000 shares of common stock to eligible employees. Eligible employees can purchase the Company’s Common Stock at the end of a predetermined offering period at 85% of the lower of the fair market value at the beginning or end of the offering period. The first period commences February 1, 2012 and will end on November 30, 2012. Thereafter offerings will be six months in duration and will commence on each December 1 and June 1. Employee contributions will be made through payroll deductions over the offering period and subject to certain limitations will be used to purchase shares at the end of each offering period. As of December 31, 2011 all the shares were available for issuance under the plan. The ESPP is compensatory and will result in stock-based compensation expense. The ESPP is subject to shareholder approval.

## **15. License Agreements**

### *TSO*

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

### *Terms of Agreement and Collaboration Agreement with OvaMed and Falk*

In December 2011, the Company entered into a binding Terms of Agreement with Falk and OvaMed to agree to enter into a collaboration agreement relating to the development of TSO for Crohn’s disease (the “Collaboration Agreement”). In March 2012, the parties entered into the Collaboration Agreement under which Falk granted the Company exclusive rights and licenses under certain Falk patent rights, pre-clinical data, and clinical data from Falk’s clinical trials of TSO in Crohn’s disease, including the ongoing Falk Phase 2 clinical trial, for use in North America, South America and Japan. In exchange, the Company granted Falk exclusive rights and licenses to its pre-clinical data and data from planned clinical trials of TSO in Crohn’s disease for use in Europe.

In addition, the Company agreed to pay Falk a total of €5 million (approximately \$6.5 million) after receipt of certain preclinical and clinical data, all of which is currently expected to be paid by the first half of 2013, and a royalty equal to 1% of net sales of TSO in North America, South America and Japan.

Under the Collaboration Agreement, a Steering Committee comprised of Coronado, Falk and OvaMed representatives will oversee the development program, under which Coronado and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn’s disease in the United States and Europe and will share in certain preclinical development costs.

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

### *CNDO-109*

In November 2007, the Company entered into a license agreement with UCL Business PCL (“UCLB”) under which the Company received an exclusive, worldwide license to develop and commercialize CNDO-109 for the treatment of cancer-related and other conditions. In consideration for the license, the Company made upfront payments totaling \$0.1 million and may be required to make future milestone payments totaling up to

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approximately \$22 million upon the achievement of various milestones related to regulatory or commercial events. In March 2012, the Company recognized a milestone payment of \$250,000 to UCLB related to its February 2012 IND filing for CNDO-109. In the event that CNDO-109 is commercialized, the Company is obligated to pay to UCLB annual royalties ranging from 3% to 5% based upon various levels of net sales of the product. Under the terms of the agreement, the Company must use diligent and reasonable efforts to develop and commercialize CNDO-109 worldwide.

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

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

### *CNDO-101*

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

### *BcL-2*

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

## **16. Income Taxes**

The Company has incurred net operating losses since inception. The Company has not reflected any benefit of such net operating loss carryforwards in the accompanying consolidated financial statements and has established a full valuation allowance of \$20.6 million against its deferred tax assets.

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

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

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

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

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

(1) —Other consists of: nondeductible items (2%), prior year NOL true-up (3%) and state rate change 1%.

Realization of the future tax benefits is dependent on the Company's ability to generate sufficient taxable income within the carryforward period. Due to the Company's recent history of operating losses, management believes that the deferred tax assets arising from the above-mentioned future tax benefits are currently uncertain with respect to realization and, accordingly, has provided a full valuation allowance.

As of December 31, 2011, the Company has federal net operating loss carryforwards and research and development tax credit carryforwards of approximately \$27.9 million and \$0.7 million, respectively, which expire beginning in 2026 and 2028, respectively. As of December 31, 2011, the Company has state net operating loss carryforwards of approximately \$20.0 million, which expires beginning in 2021 to 2030. Utilization of the net operating loss carryforwards and credits may be subject to a substantial annual limitation due to the ownership change limitations provided by the Internal Revenue Code of 1986, as amended, or the IRC, and similar state provisions. The Company has not performed a detailed analysis to determine whether an ownership change under Section 382 of the IRC has occurred. The effect of an ownership change would be the imposition of an annual limitation on the use of net operating loss carryforwards attributable to periods before the change. Any limitation may result in expiration of a portion of the NOL or research and development credit carryforwards before utilization.

As of December 31, 2011, the Company had no unrecognized tax benefits and does not anticipate any significant change to the unrecognized tax benefit balance. The Company would classify interest and penalties related to uncertain tax positions in income tax expense, if applicable. There was no interest expense or

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penalties related to unrecognized tax benefits recorded through December 31, 2011. The tax years 2006 through 2011 remain open to examination by one or more major taxing jurisdictions to which the Company is subject.

### 17. Selected Quarterly Financial Data (Unaudited)

The following table contains quarterly financial information for fiscal years 2011 and 2010. The Company believes that the following information reflects all normal recurring adjustments necessary for a fair statement of the information for the periods presented.

<i>(in thousands, except per share data)</i>	<u>First Quarter</u>	<u>Second Quarter</u>	<u>Third Quarter</u>	<u>Fourth Quarter</u>
<b>2011</b>				
Operating expenses	\$(22,545)	\$(3,736)	\$(3,531)	\$(5,232)
Other income/(expense)	\$ 2	\$ 3	\$ 166	\$(1,487)
Net loss	\$(22,543)	\$(3,733)	\$(3,365)	\$(6,719)
Basic and diluted net loss per common share	\$ (4.71)	\$ (0.64)	\$ (0.48)	\$ (0.52)
<b>2010</b>				
Operating expenses	\$ (2,302)	\$(2,468)	\$(2,083)	\$(2,389)
Other income/(expense)	\$ (1,114)	\$ (351)	\$ (37)	\$ 761
Net loss	\$ (3,416)	\$(2,819)	\$(2,120)	\$(1,628)
Basic and diluted net loss per common share	\$ (0.86)	\$ (0.66)	\$ (0.44)	\$ (0.34)

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

	<u>March 31,</u> <u>2012</u>	<u>December 31,</u> <u>2011</u>
<b>ASSETS</b>		
Current Assets:		
Cash and cash equivalents	\$ 17,735	\$ 23,160
Prepaid and other current assets	308	215
Total current assets	<u>18,043</u>	<u>23,375</u>
Total Assets	<u>\$ 18,043</u>	<u>\$ 23,375</u>
<b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>		
Current Liabilities:		
Accounts payable	\$ 1,001	\$ 575
PCP interest payable—related party	19	19
Accrued expenses	<u>2,823</u>	<u>2,899</u>
Total current liabilities	3,843	3,493
PCP notes payable—related party	<u>750</u>	<u>750</u>
Total Liabilities	<u>4,593</u>	<u>4,243</u>
Commitments and Contingencies		
Convertible Preferred Stock, \$.001 par value, 587,376 Series C Shares authorized, 0 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively	—	—
Stockholders' Equity:		
Common Stock, \$.001 par value, 50,000,000 shares authorized, 18,604,245 shares issued and outstanding as of March 31, 2012 and December 31, 2011, respectively	19	19
Additional paid-in capital	76,561	75,687
Deficit accumulated during development stage	<u>(63,130)</u>	<u>(56,574)</u>
Total Stockholders' Equity	<u>13,450</u>	<u>19,132</u>
Total Liabilities and Stockholders' Equity	<u>\$ 18,043</u>	<u>\$ 23,375</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 for share and per share amounts)**  
**(Unaudited)**

	<u>Three Months Ended</u> <u>March 31,</u>		<u>Period from</u> <u>June 28, 2006</u> <u>(Date of</u> <u>Inception) to</u> <u>March 31,</u> <u>2012</u>
	<u>2012</u>	<u>2011</u>	<u>2012</u>
Operating expenses:			
Research and development	\$ 4,581	\$ 1,246	\$ 29,122
General and administrative	2,000	593	9,614
In-process research and development	—	20,706	20,706
Loss from operations	(6,581)	(22,545)	(59,442)
Interest income	44	19	288
Interest expense	(19)	(17)	(3,302)
Other income	—	—	733
Warrant expense	—	—	(1,407)
Net loss	(6,556)	(22,543)	(63,130)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	—	(5,861)
Net loss attributed to Common Stockholders	<u>\$ (6,556)</u>	<u>\$ (22,543)</u>	<u>\$ (68,991)</u>
Basic and diluted net loss per common share	<u>\$ (0.35)</u>	<u>\$ (4.71)</u>	
Weighted average common shares outstanding—basic and diluted	<u>18,604,245</u>	<u>4,791,102</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 Cash Flows**  
(\$ in thousands)  
(Unaudited)

	For the Three Months Ended March 31,		Period from June 28, 2006 (Date of Inception) to March 31, 2012
	2012	2011	2012
<b>Cash flows from operating activities:</b>			
Net loss	\$ (6,556)	\$ (22,543)	\$ (63,130)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	874	210	4,748
Acquired in-process research and development	—	20,706	20,706
Noncash interest	—	—	1,031
Noncash interest—related parties	—	—	286
Contribution of services by stockholder	—	10	130
Issuance of Common Stock to non-employee for services	—	—	121
Change in fair value of common stock warrant liability	—	—	234
Change in fair value of embedded conversion feature	—	—	831
Change in fair value of preferred stock warrant liability	—	—	1,407
Amortization of deferred financing costs	—	—	737
Depreciation expense	—	2	41
Changes in operating assets and liabilities:			
Other assets	(93)	(28)	(308)
Interest payable—related parties	—	18	19
Accounts payable and accrued expenses	350	(159)	3,824
Net cash used in operating activities	(5,425)	(1,784)	(29,323)
<b>Cash flows from investing activities:</b>			
Purchase of computer equipment	—	—	(41)
Purchase of in-process research and development	—	(3,809)	(3,843)
Net cash used in investing activities	—	(3,809)	(3,884)
<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	—	—	2,221
Proceeds from issuance of Series A Convertible Preferred Stock	—	—	21,681
Payment of costs related to the issuance of Series A Convertible Preferred Stock	—	—	(2,291)
Proceeds from issuance of Series C Convertible Preferred Stock	—	—	25,784
Payment of costs related to the issuance of Series C Convertible Preferred Stock	—	—	(2,884)
Proceeds from borrowings under line of credit	—	—	80
Payment of line of credit	—	—	(80)
Proceeds from senior convertible notes	—	—	7,570
Payment of debt issue costs	—	—	(737)
Payment of notes payable—related parties	—	—	(600)
Proceeds from issuance of Common Stock	—	—	198
Net cash provided by financing activities	—	—	50,942
<b>(Decrease) Increase in cash and cash equivalents</b>	(5,425)	(5,593)	17,735
Cash and cash equivalents—beginning of period	23,160	14,862	—
Cash and cash equivalents—end of period	\$ 17,735	\$ 9,269	\$ 17,735



**Coronado Biosciences, Inc. and Subsidiary**  
(A development stage enterprise)  
**Consolidated Statements of Cash Flows—(Continued)**  
**(\$ in thousands)**  
**(Unaudited)**

	<u>For the Three Months Ended</u> <u>March 31,</u>		<u>Period from</u> <u>June 28, 2006</u> <u>(Date of</u> <u>Inception) to</u> <u>March 31,</u> <u>2012</u>
	<u>2012</u>	<u>2011</u>	
<b>Supplemental disclosure of cash flow information:</b>			
Cash paid for interest	\$ 18	\$ —	\$ 159
<b>Supplemental disclosure of non-cash financing and investing activities:</b>			
Issuance of Series B Convertible Preferred Stock for purchase of assets	—	16,114	16,114
Assumption of PCP note related to Asphelia Asset Purchase	—	750	750
Issuance of Series C Convertible Preferred Stock warrants	—	—	1,286
Issuance of Common Stock warrants related to the Series A Convertible Preferred Stock financing	—	—	621
Conversion of senior convertible notes into Series A Convertible Preferred Stock	—	—	8,601
Conversion of notes payable—related parties into Series A Convertible Preferred Stock	—	—	1,907
Issuance of Common Stock for Series A, B and C Convertible Preferred Stock	—	—	67,004

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

## Coronado Biosciences, Inc. and Subsidiary

(A development stage enterprise)

### Notes to the Consolidated Financial Statements

#### 1. Organization and Description of Business

Coronado Biosciences, Inc. (the "Company"), incorporated in Delaware on June 28, 2006 (date of inception), is a biopharmaceutical company focused on the development of novel immunotherapy biologic agents for the treatment of autoimmune diseases and cancer.

##### *Development-Stage Risks and Liquidity*

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

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit of \$63.1 million as of March 31, 2012. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales of its product candidates. To date, the Company's operations have been funded primarily by issuing equity securities and debt securities.

The Company expects to incur substantial expenditures in the foreseeable future for the research, development and potential commercialization of its product candidates. Management believes that cash and cash equivalents on hand are sufficient to sustain operations into the fourth quarter of 2012 based on its existing business plan and given the ability to control the timing of significant expense commitments. The Company will require additional financing to develop and obtain regulatory approvals for its product candidates, fund operating losses and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. The Company will seek funds through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to the Company on acceptable terms or at all and any equity financings, if available, will result in dilution to existing stockholders. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company will be required to delay, reduce or eliminate research and development programs. These circumstances raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might result from this uncertainty.

#### 2. 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 Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP 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.

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The consolidated balance sheet at December 31, 2011 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 Company's Form 10-K which was filed with the United States Securities and Exchange Commission, or SEC, on March 29, 2012.

The Company's unaudited consolidated financial statements include the accounts of the Company and its 100% owned subsidiary, Innmune 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 consolidated financial statements and the reported amounts of expenses during the reporting period.

### *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, common 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.

### *Concentration of Risk*

The Company is completely dependent on third party manufacturers for product supply. In particular the Company relies and expects to continue to rely exclusively on OvaMed GmbH ("OvaMed") to supply it with its requirements of Trichuris suis ova ("TSO" or "CNDO-201"). OvaMed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it is also producing product for clinical trials by third parties, including Dr. Falk Pharma GmbH ("Falk"). OvaMed also relies on certain other suppliers for materials and services. Similarly, the Company currently relies on BioReliance and PCT for its CNDO-109 product requirements. The Company's clinical development programs would be adversely affected by a significant interruption in obtaining clinical trial supplies.

### *Cash and Cash Equivalents and Concentration of Credit Risk*

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

### *Contingencies*

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

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

### *Stock-Based Compensation*

The Company expenses stock-based compensation to employees over the requisite service period based on the estimated grant-date fair value of the awards and forfeiture rates. For stock-based compensation awards to

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non-employees, the Company remeasures the fair value of the non-employee awards at each reporting period prior to vesting and finally at the vesting date of the award. Changes in the estimated fair value of these non-employee awards are recognized as compensation expense in the period of change.

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

### *Income Taxes*

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

### *Comprehensive Loss*

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

### *Recently Issued Accounting Standards*

In May 2011, the Financial Accounting Standards Board ("FASB") issued a new standard on fair value measurement and disclosure requirements. The new standard changes fair value measurement principles and disclosure requirements including measuring the fair value of financial instruments that are managed within a portfolio, the application of applying premiums and discounts in a fair value measurement, and additional disclosure about fair value measurements. The adoption of this guidance in the first quarter of 2012 did not have an impact on the Company's consolidated financial statements.

In June 2011, the FASB issued a new standard on the presentation of comprehensive income. The new standard eliminated the alternative to report other comprehensive income and its components in the statement of changes in equity. Under the new standard, companies can elect to present items of net income and other comprehensive income in one continuous statement or in two separate, but consecutive statements. The Company adopted the provisions of this guidance during the first quarter of 2012, and it did not have an impact on the Company's consolidated financial statements.

## **3. Net Loss Per Common Share**

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

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

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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. During the quarter ended March 31, 2012, the Company did not issue any shares of Common Stock.

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

<i>(\$ in thousands except share and per share amounts)</i>	<b>For the three months ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
<b>Historical net loss per share:</b>		
<i>Numerator</i>		
Net loss attributed to Common Stockholders	\$ (6,556)	\$ (22,543)
<i>Denominator</i>		
Weighted-average common shares outstanding—Denominator for basic and diluted net loss per share	18,604,245	4,791,102
Basic and diluted net loss per share attributed to common stockholders	\$ (0.35)	\$ (4.71)

The Company's potential dilutive securities which include convertible preferred 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:

	<b>For the three months ended March 31,</b>	
	<b>2012</b>	<b>2011</b>
Series A Convertible Preferred Stock	–	4,357,885
Series B Convertible Preferred Stock	–	2,357,299
Warrants to purchase Common Stock	1,068,800	460,536
Options to purchase Common Stock	1,999,015	1,174,246
	<u>3,067,815</u>	<u>8,349,966</u>

#### 4. Accrued Liabilities

Accrued expenses consisted of the following:

<i>(\$ in thousands)</i>	<b>As of March 31,</b>	<b>As of December 31,</b>
	<b>2012</b>	<b>2011</b>
Salaries, bonuses and related benefits	\$ 347	\$ 493
Professional fees	206	215
Research and development expenses	232	653
Accrued milestones	1,950	1,500
Other	88	38
Total accrued expenses	<u>\$ 2,823</u>	<u>\$ 2,899</u>

Accrued milestones at March 31, 2012 include milestones due to OvaMed for \$1.7 million and a milestone payment due to University College of London Business PLC, ("UCLB") for \$250,000.

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### 5. TSO

#### *Asphelia Asset Purchase*

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

In exchange, the Company issued 2,525,677 Series B Convertible Preferred Stock with a fair value of \$6.38 per share, assumed the Paramount Credit Partners, LLC note (the “PCP Note”) in the principal amount of \$750,000 and paid cash of approximately \$3.8 million, including a \$3.4 million payment to OvaMed and \$0.4 million for repayment of Asphelia’s debt, \$61,000 of which was paid to a related party. The total consideration paid in connection with the Asphelia Asset Purchase is as follows:

*(\$ in thousands)*

Fair value of 2,525,677 Series B Convertible Preferred Stock	\$16,114
Cash payment	3,809
Fair value of PCP Note	750
Other transaction costs	33
<b>Total asset acquisition cost</b>	<b>\$20,706</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 year ended December 31, 2011.

In connection with the Asphelia Asset Purchase, Asphelia assigned the Exclusive Sublicense Agreement, dated December 2005, between Asphelia and OvaMed (as amended, the “OvaMed License”) and Manufacturing and Supply Agreement dated March 2006, between Asphelia and OvaMed (as amended, the “OvaMed Supply Agreement”) to the Company and the Company assumed Asphelia’s obligations under these agreements. Under the OvaMed License, the Company has exclusive rights under certain patents (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 \$5.4 million, contingent upon the achievement of various regulatory milestones for the first product that incorporates TSO, and additional milestone payments contingent upon the achievement of regulatory milestones relating to subsequent indications. In 2011, the IND filed by the Company with the United States Federal Food and Drug Administration (“FDA”) became effective, resulting in the recognition during 2011 of a \$1.5 million obligation to OvaMed, reflecting the associated milestone payment payable in November 2012. In March 2012, upon the receipt of pre-clinical data from Falk, a \$200,000 milestone payment became payable to OvaMed. In the event that TSO is commercialized, the Company is obligated to pay to OvaMed royalties based on net sales and, if sublicensed, a varying percentage of certain consideration received from the sublicensee.

The OvaMed Supply Agreement currently expires in March 2014, but will automatically renew for successive one-year periods, unless the Company gives 12 months prior notice of its election not to renew. The OvaMed Supply Agreement is subject to early termination by either party under certain customary conditions of breach and by the Company in the event of specified failures to supply or regulatory or safety failures.

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### *Collaboration Agreement with OvaMed and Falk*

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

The Company agreed to pay Falk a total of €5 million (approximately \$6.5 million) after receipt of certain preclinical and clinical data, and a royalty equal to 1% of net sales of TSO in North America, South America and Japan. In March 2012, the Company paid Falk €1 million (approximately \$1.4 million) upon receipt of Falk's pre-clinical data package and recorded this payment as a TSO milestone expense. In April 2012, the Company paid and expensed an additional €1.5 million (approximately \$2.0 million) upon receipt from Falk of the recommendation from the independent data monitoring committee that conducted an interim analysis of the Falk Phase 2 trial. The Company currently expects to pay the remaining €2.5 million (approximately \$3.3 million) in the second half of 2013.

Under the Collaboration Agreement, a steering committee comprised of the Company, Falk and OvaMed representatives oversees the TSO development program in Crohn's disease, under which the Company and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's disease in the United States and Europe and will share in certain preclinical development costs.

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

### **6. Debt and Interest**

The \$750,000 PCP Note is classified as a long-term liability at March 31, 2012 on the consolidated balance sheet.

Interest expense consisted of the following:

(\$ in thousands)	For the three months ended		Period from June 28, 2006 (Date of Inception) to March 31, 2012
	2012	2011	
Interest expense	\$ —	\$ —	\$ 1,032
Interest expense—related parties	19	17	468
Amortization of embedded conversion feature	—	—	831
Change in fair value of Common Stock warrant liability	—	—	234
Amortization of deferred financing fees	—	—	737
Total interest expense	<u>\$ 19</u>	<u>\$ 17</u>	<u>\$ 3,302</u>

### **7. 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

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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.

Some of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate fair value due to their liquid or short-term nature, such as cash and cash equivalents, prepaid expenses, other current assets, other long-term assets, accounts payable, accrued expenses and other current liabilities. The carrying amount of the Company's debt obligation approximates fair value. The fair value of the company's debt obligation was determined using Level 2 inputs, which include current interest rates on similar borrowings.

## **8. Stock-based Compensation**

### *Stock-based Compensation Plans*

As of March 31, 2012, the Company has two equity compensation plans, the Coronado Biosciences, Inc. 2007 Stock Incentive Plan, for employees, non-employees and outside directors and, subject to stockholder approval, the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (the "ESPP"). Although the ESPP is still subject to stockholders approval, eligible employees began to participate in the ESPP effective February 1, 2012.

*Compensation Expense.* The following table summarizes the stock-based compensation expense from awards, including stock options and restricted Common Stock awards to employees and non-employees, and warrants to non-employees for the three months ended March 31, 2012 and 2011, and from the period June 28, 2006 (Date of Inception) to date.

	<u>For the three months ended</u> <u>March 31,</u>		<u>Period from</u> <u>June 28, 2006</u> <u>(Date of</u> <u>Inception) to</u> <u>March 31,</u> <u>2012</u>
	<u>2012</u>	<u>2011</u>	
<i>(\$ in thousands)</i>			
Employee awards	\$ 313	\$ 99	\$ 1,048
Non-employee awards	445	34	3,258
Non-employee warrants	116	77	442
Total stock-based compensation expense	<u>\$ 874</u>	<u>\$ 210</u>	<u>\$ 4,748</u>



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The following table summarizes stock option activity as of March 31, 2012:

	<u>Outstanding Options</u>			<u>Weighted Average Remaining Contractual Life (in years)</u>
	<u>Number of Shares</u>	<u>Weighted Average Exercise Price</u>	<u>Total Weighted Average Intrinsic Value</u>	
<i>(\$ in thousands except per share amounts)</i>				
At December 31, 2011	1,814,070	\$ 2.17	\$ 7,852	9.2
Options granted	390,000	6.64		
Options exercised	—			
Options cancelled	—			
At March 31, 2012	<u>2,204,070</u>	\$ 2.96	\$12,117	9.1
Options vested and expected to vest	2,124,723	\$ 2.96	\$11,680	9.1
Options vested and exercisable	254,690	\$ 1.43	\$ 1,790	9.1

As of March 31, 2012, the Company had unrecognized stock-based compensation expense related to unvested stock options granted to employees of \$4.3 million, which is expected to be recognized over the remaining weighted-average vesting period of 2.1 years.

**4,600,000 Shares**

**coronado**

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BIOSCIENCES

**Common Stock**

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**PROSPECTUS**

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, 2012

**Oppenheimer & Co.**

**Roth Capital Partners**

**National Securities Corporation**

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You should rely only on the information contained in this prospectus. No dealer, salesperson or other person is authorized to give information that is not contained in this prospectus. This prospectus is not an offer to sell nor is it seeking an offer to buy these securities in any jurisdiction where the offer or sale is not permitted. The information contained in this prospectus is correct only as of the date of this prospectus, regardless of the time of the delivery of this prospectus or any sale of these securities.

**PART II**  
**INFORMATION NOT REQUIRED IN PROSPECTUS**

**Item 13. Other Expenses of Issuance and Distribution.**

The following table sets forth the various expenses, all of which will be borne by the registrant, in connection with the sale and distribution of the securities being registered, other than the underwriting discounts and commissions. All amounts shown are estimates except for the SEC registration fee.

SEC registration fee	\$ 3,560
FINRA fees	\$ 3,605
Printing and engraving expenses	\$ 50,000
Accounting fees and expenses	\$ 50,000
Legal fees and expenses	\$250,000
Miscellaneous	\$ 42,835
Total	<u>\$400,000</u>

**Item 14. 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 15. Recent Sales of Unregistered Securities.**

The information below lists all of the securities sold by us during the past three years which were not registered under the Securities Act:

1. In January 2009, May 2009 and June 2009, in connection with borrowings under 10% senior promissory notes, we agreed to issue warrants to purchase an aggregate of 40,787 shares of our common stock with an exercise price of \$6.15 per share to PCP (as adjusted).
2. 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.
3. 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.
4. 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 (3) above).
5. 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.
6. 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.
7. 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 are being distributed to Asphelia's designees.

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8. 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. Of these warrants, 25,000 have been exercised to purchase 20,790 shares of common stock pursuant to cashless exercise provisions.
9. 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.
10. In September 2011, we issued warrants to purchase an aggregate of 75,000 shares at an exercise price of \$2.95 per share to three investor and public relations firms. In December 2011, we issued a warrant to purchase 5,000 shares of common stock with an exercise price of \$6.00 per share to a public relations firm.
11. 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.
12. 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. Of these warrants, 2,986 have been exercised through June 20, 2012 to purchase 534 shares of common stock pursuant to cashless exercise provisions.
13. From January 1, 2008 to June 20, 2012, we granted stock options under our 2007 plan to purchase an aggregate of 2,492,110 shares of our common stock (net of cancellations) to our employees, directors and consultants, having exercise prices ranging from \$1.37 to \$7.98 per share. Of these, options to purchase 138,040 shares of common stock have been exercised through June 20, 2012 for aggregate consideration of \$193,000, each at an exercise price of \$1.40 per share.
14. In July 2009, we issued 5,000 shares of common stock to a consultant as compensation for services rendered.
15. In April 2010, we issued 23,836 shares of common stock to a consultant as compensation for services rendered.
16. 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), (14), (15) and (16) 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.

The offers, sales and issuances of the securities described in paragraph (13) 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.

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### **Item 16. Exhibits and Financial Statement Schedules.**

(a) The following exhibits are filed as part of this Registration Statement:

- 1.1\*\* Form of Underwriting Agreement
- 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.(1)
- 4.9 Form of Consultant/Agent Warrant to Purchase Common Stock.(1)
- 5.1\*\* Opinion of Loeb & Loeb LLP re: legality.
- 10.1 Form of Note Purchase Agreement relating to the 2008 bridge financing.(1)
- 10.2 Form of Note Purchase Agreement relating to the 2009 bridge financing.(1)
- 10.3 Form of Subscription Agreement relating to the initial Series A financing.(1)
- 10.4 Form of Subscription Agreement relating to the second Series A financing.(1)
- 10.5 Form of Subscription Agreement relating to the Series C financing.(1)
- 10.6 Form of Consent and Support Agreement.(1)
- 10.7 Letter Agreement, dated April 29, 2011, by and between the Registrant and Manchester Securities Corp.(1)
- 10.8\* 2007 Stock Incentive Plan.(1)
- 10.9\* Form of Stock Option Award Agreement.(1)
- 10.10† Exclusive Sublicense Agreement, dated December 12, 2005, by and between OvaMed GmbH and Collingwood Pharmaceuticals, Inc.(1)
- 10.11† Manufacturing and Supply Agreement, dated March 29, 2006, by and among OvaMed GmbH and Collingwood Pharmaceuticals, Inc.(1)
- 10.12† License Agreement, dated November 5, 2007, by and between UCL Business PLC and the Registrant.(1)

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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.(1)
10.16†	Term Sheet in causa OvaMed/Asphelia, dated June 8, 2010, by and between OvaMed GmbH and Asphelia Pharmaceuticals, Inc.(1)
10.17†	Amendment and Agreement, dated January 7, 2011, by and among Asphelia Pharmaceuticals, Inc., the Registrant and OvaMed GmbH.(1)
10.18	Asset Purchase Agreement, dated January 7, 2011, by and between the Registrant and Asphelia Pharmaceuticals, Inc.(1)
10.19*	Employment Agreement, dated March 21, 2011, by and among Registrant and Bobby W. Sandage, Jr., Ph.D.(1)
10.20*	Employment Agreement, dated April 1, 2011, by and among the Registrant and Glenn L. Cooper. M.D.(1)
10.21*	Employment Agreement, dated May 16, 2011, by and between the Registrant and Dale Ritter.(1)
10.22*	Separation Agreement, dated June 3, 2011, by and between the Registrant and Gary G. Gemignani.(1)
10.23*	Separation Agreement, dated December 2, 2010, by and between the Registrant and Raymond J. Tesi, M.D.(1)
10.24*	Consulting Agreement, dated September 21, 2010, by and between the Registrant and Eric Rowinsky, M.D.(1)
10.25	Form of Indemnification Agreement by and between the Registrant and its officers and directors.(1)
10.26	Lease Agreement dated May 26, 2011 relating to the Registrant's premises located at 15 New England Executive Park, Burlington, Massachusetts 01803.(1)
10.27	Master Contract Services Agreement, dated March 12, 2008, by and between the Registrant and BioReliance Corporation, as amended.(1)
10.28	Consulting Agreements between the Registrant and each of Dr. Mark Lowdell and UCL Consultants Limited.(1)
10.29	10% Senior Promissory Note, as amended, issued by Asphelia Pharmaceuticals, Inc. to Paramount Credit Partners, LLC.(1)
10.30	Employment Agreement, dated September 26, 2011, by and between the Registrant and Noah D. Beerman(3)
10.31	Consulting Agreement, dated September 27, 2011, by and between the Registrant and Joel Weinstock, M.D.(2)
10.32	Terms of Agreement among the Registrant, OvaMed and Falk effective as of December 22, 2011.(4)
10.33*	Amendment to Employment Agreement between the Registrant and Bobby W. Sandage, Jr., Ph.D. effective as of December 19, 2011.(4)
10.34	Side Agreement among the Registrant, UIRF and OvaMed effective as of November 15, 2011.(4)
10.35*	Employment Agreement, dated February 21, 2012, by and between the Registrant and Lucy Lu, M.D.(5)



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10.36†	Collaboration Agreement among the Registrant, Dr. Falk Pharma GmbH and OvaMed GmbH dated March 20, 2012.(7)
10.37*	Employment Agreement, dated as of April 19, 2012, by and between the Registrant and Karin M. Hehenberger.(8)
10.38†	Amendment No. 2 to License Agreement, dated May 16, 2012, by and between the Registrant and UCL Business PLC.(9)
14.1	Code of Ethics of Coronado Biosciences, Inc. Applicable To Directors, Officers And Employees.(6)
21.1	Subsidiaries of the Registrant.(1)
23.1**	Consent of PricewaterhouseCoopers LLP.
23.2**	Consent of Loeb & Loeb LLP (included in Exhibit 5.1).
24.1	Power of Attorney (included on signature page).
101	Interactive Data Files.

† Confidential treatment has been granted with respect to portions of this exhibit.

\* Indicates management contract or compensatory plan.

\*\* Filed herewith.

(1) Filed as an exhibit with the same number to the Registrant's Registration Statement on Form 10-12G (File No. 000-54463) initially filed on July 15, 2011.

(2) Filed as an exhibit with the same number to the Registrant's Amendment No. 1 to Registration Statement on Form S-1 (File No. 333-177041) filed on October 7, 2011.

(3) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on September 26, 2011.

(4) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on December 22, 2011.

(5) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on February 23, 2012.

(6) Filed as an exhibit with the same number to the Registrant's Registration Statement on Form S-1 (File No. 333-177041) filed on September 28, 2011.

(7) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on March 23, 2012.

(8) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on April 25, 2012.

(9) Filed as an exhibit with the same number to the Registrant's Current Report on Form 8-K filed on May 25, 2012.

### **Item 17. Undertakings.**

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

i. To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

ii. To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than 20 percent change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement.

iii. To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement.

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(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That for the purpose of determining any liability under the Securities Act of 1933 in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser

(b) The undersigned hereby undertakes to provide to the underwriter at the closing specified in the underwriting agreements, certificates in such denominations and registered in such names as required by the underwriter to permit prompt delivery to each purchaser.

(c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

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**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the Registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this registration statement or amendment thereto to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Burlington, State of Massachusetts, on June 21, 2012.

**CORONADO BIOSCIENCES, INC.**

By: /s/ Bobby W. Sandage, Jr.

Name: Bobby W. Sandage, Jr., Ph.D.

Title: Chief Executive Officer

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities held on the dates indicated.

<u>Signature</u>	<u>Title</u>	<u>Date</u>
* _____ Glenn L. Cooper, M.D.	Executive Chairman of the Board of Directors	June 21, 2012
<u>/s/ Bobby W. Sandage</u> Bobby W. Sandage, Jr., Ph.D.	Chief Executive Officer, President and Director (principal executive officer)	June 21, 2012
* _____ Lucy Lu, M.D.	Chief Financial Officer (principal financial officer)	June 21, 2012
<u>/s/ Dale Ritter</u> Dale Ritter	Senior Vice President, Finance, Chief Accounting Officer (principal accounting officer)	June 21, 2012
* _____ Eric K. Rowinsky, M.D.	Vice Chairman of the Board of Directors	June 21, 2012
* _____ David J. Barrett	Director	June 21, 2012
* _____ Jimmie Harvey, Jr., M.D.	Director	June 21, 2012
* _____ J. Jay Lobell	Director	June 21, 2012
* _____ Michael W. Rogers	Director	June 21, 2012
* _____ Lindsay A. Rosenwald, M.D.	Director	June 21, 2012

\*By: Dale Ritter, as attorney-in-fact

**4,600,000 Shares**  
**CORONADO BIOSCIENCES, INC.**  
**Common Stock**  
**UNDERWRITING AGREEMENT**

June [ ], 2012

Oppenheimer & Co. Inc.  
Roth Capital Partners, LLC,  
as Representatives of the several  
Underwriters named in Schedule I hereto  
c/o Oppenheimer & Co. Inc.  
85 Broad Street  
New York, New York 10004

Ladies and Gentlemen:

Coronado Biosciences, Inc., a Delaware corporation (the “Company”), proposes, subject to the terms and conditions contained herein, to sell to you and the other underwriters named on Schedule I to this Agreement (the “Underwriters”), for whom you are acting as Representatives (the “Representatives”), an aggregate of 4,600,000 shares (the “Firm Shares”) of the Company’s common stock, \$0.001 par value per share (the “Common Stock”). The respective amounts of the Firm Shares to be purchased by each of the several Underwriters are set forth opposite their names on Schedule I hereto. In addition, the Company proposes to grant to the Underwriters an option to purchase up to an additional 690,000 shares (the “Option Shares”) of Common Stock from the Company for the purpose of covering over-allotments in connection with the sale of the Firm Shares. The Firm Shares and the Option Shares are collectively called the “Shares.”

The Company has prepared and filed in conformity with the requirements of the Securities Act of 1933, as amended (the “Securities Act”), and the published rules and regulations thereunder (the “Rules”) adopted by the Securities and Exchange Commission (the “Commission”) a Registration Statement (as hereinafter defined) on Form S-1 (No. 333-181856), including a preliminary prospectus relating to the Shares, and such amendments thereof as may have been required to the date of this Agreement. Copies of such Registration Statement (including all amendments thereof) and of the related Preliminary Prospectus (as hereinafter defined) have heretofore been delivered by the Company to you. The term “Preliminary Prospectus” means any preliminary prospectus included at any time as a part of the Registration Statement or filed with the Commission by the Company pursuant to Rule 424(a) of the Rules.

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The term “Registration Statement” as used in this Agreement means the initial registration statement (including all exhibits, financial schedules and all documents and information deemed to be a part of the Registration Statement through incorporation by reference or otherwise), as amended at the time and on the date it becomes effective (the “Effective Date”), including the information (if any) contained in the form of final prospectus filed with the Commission pursuant to Rule 424(b) of the Rules and deemed to be part thereof at the time of effectiveness pursuant to Rule 430A of the Rules. If the Company has filed an abbreviated registration statement to register additional Shares pursuant to Rule 462(b) under the Rules (the “462(b) Registration Statement”), then any reference herein to the Registration Statement shall also be deemed to include such 462(b) Registration Statement. The term “Prospectus” as used in this Agreement means the prospectus in the form included in the Registration Statement at the time of effectiveness or, if Rule 430A of the Rules is relied on, the term Prospectus shall also include the final prospectus filed with the Commission pursuant to and within the time limits described in Rule 424(b) of the Rules.

The Company understands that the Underwriters propose to make a public offering of the Shares, as set forth in and pursuant to the Statutory Prospectus (as hereinafter defined) and the Prospectus, as soon after the Effective Date and the date of this Agreement as the Representatives deem advisable. The Company hereby confirms that the Underwriters and dealers have been authorized to distribute or cause to be distributed each Preliminary Prospectus, and each Issuer Free Writing Prospectus (as hereinafter defined) and are authorized to distribute the Prospectus (as from time to time amended or supplemented if the Company furnishes amendments or supplements thereto to the Underwriters).

1. Sale, Purchase, Delivery and Payment for the Shares. On the basis of the representations, warranties and agreements contained in, and subject to the terms and conditions of, this Agreement:

(a) The Company agrees to issue and sell to each of the Underwriters, and each of the Underwriters agrees, severally and not jointly, to purchase from the Company, at a purchase price of \$[ ] per share (the “Initial Price”), the number of Firm Shares set forth opposite the name of such Underwriter under the column “Number of Firm Shares to be Purchased from the Company” on Schedule I to this Agreement, subject to adjustment in accordance with Section 8 hereof.

(b) The Company hereby grants to the several Underwriters an option to purchase, severally and not jointly, all or any part of the Option Shares at the Initial Price. The number of Option Shares to be purchased by each Underwriter shall be the same percentage (adjusted by the Representatives to eliminate fractions) of the total number of Option Shares to be purchased by the Underwriters as such Underwriter is purchasing of the Firm Shares. Such option may be exercised only to cover over-allotments in the sales of the Firm Shares by the Underwriters and may be exercised in whole or in part at any time on or before 12:00 noon, New York City time, on the business day before the Firm Shares Closing Date (as defined below), and from time to time thereafter within 30 days after the date of this Agreement, in each case upon written, facsimile or telegraphic notice, or verbal or telephonic notice confirmed by written, facsimile or telegraphic notice, by the Representatives to the Company no later than 12:00 noon, New York City time, on the business day before the Firm Shares Closing Date or at least one business day before the Option Shares Closing Date (as defined below), as the case may be, setting forth the number of Option Shares to be purchased and the time and date (if other than the Firm Shares Closing Date) of such purchase.

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(c) Payment of the purchase price for, and delivery of certificates for, the Firm Shares shall be made at the offices of Oppenheimer & Co. Inc., 300 Madison Avenue, New York, New York 10017, at 10:00 a.m., New York City time, on the third (or if the Shares are priced, as contemplated by Rule 15c6-1(c) under the Securities and Exchange Act of 1934, as amended (the “Exchange Act”), after 4:30 p.m. New York City time, fourth) business day following the date of this Agreement or at such time on such other date, not later than ten (10) business days after the date of this Agreement, as shall be agreed upon by the Company and the Representatives (such time and date of delivery and payment are called the “Firm Shares Closing Date”). In addition, in the event that any or all of the Option Shares are purchased by the Underwriters, payment of the purchase price, and delivery of the certificates, for such Option Shares shall be made at the above-mentioned offices, or at such other place as shall be agreed upon by the Representatives and the Company, on each date of delivery as specified in the notice from the Representatives to the Company (such time and date of delivery and payment are called the “Option Shares Closing Date”). The Firm Shares Closing Date and any Option Shares Closing Date are called, individually, a “Closing Date” and, together, the “Closing Dates.”

(d) Payment shall be made to the Company by wire transfer of immediately available funds or by certified or official bank check or checks payable in New York Clearing House (same day) funds drawn to the order of the Company, against delivery of the respective certificates to the Representatives for the respective accounts of the Underwriters of certificates for the Shares to be purchased by them.

(e) Certificates evidencing the Shares shall be registered in such names and shall be in such denominations as the Representatives shall request at least two full business days before the Firm Shares Closing Date or, in the case of Option Shares, on the day of notice of exercise of the option as described in Section 1(b) and shall be delivered by or on behalf of the Company to the Representatives through the facilities of the Depository Trust Company (“DTC”) for the account of such Underwriter. The Company will cause the certificates representing the Shares to be made available for checking and packaging, at such place as is designated by the Representatives, on the full business day before the Firm Shares Closing Date (or the Option Shares Closing Date in the case of the Option Shares).

2. Representations and Warranties of the Company. The Company represents and warrants to each Underwriter as of the date hereof, as of the Firm Shares Closing Date and as of each Option Shares Closing Date (if any), as follows:

(a) On the Effective Date, the Registration Statement complied, and on the date of the Prospectus, the date any post-effective amendment to the Registration Statement becomes effective, the date any supplement or amendment to the Prospectus is filed with the Commission and each Closing Date, the Registration Statement, the Prospectus (and any amendment thereof or supplement thereto) will comply, in all material respects, with the requirements of the Securities Act and the Rules and the Exchange Act and the rules and regulations of the Commission thereunder. The Registration Statement did not, as of the Effective Date, contain

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any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading; and on the Effective Date and the other dates referred to above neither the Registration Statement nor the Prospectus, nor any amendment thereof or supplement thereto, will contain any untrue statement of a material fact or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. When any Preliminary Prospectus was first filed with the Commission (whether filed as part of the Registration Statement or any amendment thereto or pursuant to Rule 424(a) of the Rules) and when any amendment thereof or supplement thereto was first filed with the Commission, such Preliminary Prospectus as amended or supplemented complied in all material respects with the applicable provisions of the Securities Act and the Rules and did not contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary in order to make the statements therein not misleading. If applicable, each Preliminary Prospectus and the Prospectus delivered to the Underwriters for use in connection with this offering was identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T. Notwithstanding the foregoing, none of the representations and warranties in this paragraph 2(a) shall apply to statements in, or omissions from, the Registration Statement, any Preliminary Prospectus or the Prospectus made in reliance upon, and in conformity with, information herein or otherwise furnished in writing by the Representatives on behalf of the several Underwriters specifically for use in the Registration Statement, any Preliminary Prospectus or the Prospectus, as the case may be. With respect to the preceding sentence, the Company acknowledges that the only information furnished in writing by the Representatives on behalf of the several Underwriters for use in the Registration Statement, any Preliminary Prospectus or the Prospectus is the statements contained in the tenth paragraph under the caption “Underwriting” in the Prospectus (the “Underwriter Information”).

(b) As of the Applicable Time (as hereinafter defined), neither (i) the price to the public and the number of shares offered and sold, as indicated on the cover page of the Prospectus and the Statutory Prospectus (as hereinafter defined), all considered together (collectively, the “General Disclosure Package”), nor (ii) any individual Issuer Free Writing Prospectus (as hereinafter defined) when considered together with the General Disclosure Package, included, includes or will include any untrue statement of a material fact or omitted, omits or will omit to state any material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements in or omissions in the General Disclosure Package made in reliance upon and in conformity with the Underwriter Information.

Each Issuer Free Writing Prospectus, including any electronic road show (including without limitation any “bona fide electronic road show” as defined in Rule 433(h)(5) under the Securities Act) (each, a “Road Show”) (i) is identified in Schedule III hereto and (ii) complied when issued, and complies, in all material respects with the requirements of the Securities Act and the Rules and the Exchange Act and the rules and regulations of the Commission thereunder.

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As used in this Section and elsewhere in this Agreement:

“Applicable Time” means 6:00 pm (Eastern time) on the date of this Underwriting Agreement.

“Statutory Prospectus” as of any time means the Preliminary Prospectus relating to the Shares that is included in the Registration Statement immediately prior to the Applicable Time.

“Issuer Free Writing Prospectus” means each “free writing prospectus” (as defined in Rule 405 of the Rules) prepared by or on behalf of the Company or used or referred to by the Company in connection with the offering of the Shares, including, without limitation, each Road Show.

(c) The Registration Statement is effective under the Securities Act and no stop order preventing or suspending the effectiveness of the Registration Statement or suspending or preventing the use of any Preliminary Prospectus, the Prospectus or any “free writing prospectus”, as defined in Rule 405 under the Rules, has been issued by the Commission and no proceedings for that purpose have been instituted or are threatened under the Securities Act. Any required filing of any Preliminary Prospectus and/or the Prospectus and any supplement thereto pursuant to Rule 424(b) of the Rules has been or will be made in the manner and within the time period required by such Rule 424(b). Any material required to be filed by the Company pursuant to Rule 433(d) or Rule 163(b)(2) of the Rules has been or will be made in the manner and within the time period required by such Rules.

(d) Each Issuer Free Writing Prospectus, as of its issue date and at all subsequent times through the completion of the public offer and sale of the Shares or until any earlier date that the Company notified or notifies the Representatives as described in the next sentence, did not, does not and will not include any information that conflicted, conflicts or will conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus.

If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement, the Statutory Prospectus or the Prospectus or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company has promptly notified or will promptly notify the Representatives and has promptly amended or will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(e) The financial statements of the Company (including all notes and schedules thereto) included in the Registration Statement, the Statutory Prospectus and Prospectus present fairly the financial position of the Company and its consolidated subsidiary at the dates indicated and the statement of operations, stockholders’ equity and cash flows of the Company and its consolidated subsidiary for the periods specified; and such financial statements and related schedules and notes thereto, and the unaudited financial information filed with the Commission



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as part of the Registration Statement, have been prepared in conformity with generally accepted accounting principles, consistently applied throughout the periods involved. The summary consolidated financial data included in the Statutory Prospectus and Prospectus present fairly the information shown therein as at the respective dates and for the respective periods specified and have been presented on a basis consistent with the consolidated financial statements set forth in the Prospectus and other financial information.

(f) PricewaterhouseCoopers LLP (the “Auditor”) whose reports are filed with the Commission as a part of the Registration Statement, are and, during the periods covered by their reports, were independent public accountants as required by the Securities Act and the Rules.

(g) Each of the Company and Innmune Limited (its “subsidiary”), is duly organized, validly existing and in good standing under the laws of their respective jurisdictions of incorporation or organization and each such entity has all requisite power and authority to carry on its business as is currently being conducted as described in the Statutory Prospectus and the Prospectus, and to own, lease and operate its properties. All of the issued shares of capital stock of, or other ownership interests in, each subsidiary have been duly and validly authorized and issued and are fully paid and non-assessable and are owned, directly or indirectly, by the Company, free and clear of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever. The Company and its subsidiary is duly qualified to do business and is in good standing as a foreign corporation in each jurisdiction in which the nature of the business conducted by it or location of the assets or properties owned, leased or licensed by it requires such qualification, except for such jurisdictions where the failure to so qualify individually or in the aggregate would not have a material adverse effect on the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiary considered as a whole (a “Material Adverse Effect”); and to the Company’s knowledge, no proceeding has been instituted in any such jurisdiction revoking, limiting or curtailing, or seeking to revoke, limit or curtail, such power and authority or qualification. Except for its subsidiary, neither the Company nor its subsidiary own any equity interest in any corporation, partnership, joint venture, association or other business organization.

(h) The Company and its subsidiary has all requisite corporate power and authority, and all necessary authorizations, approvals, consents, orders, licenses, certificates and permits of and from all governmental or regulatory bodies or any other person or entity (collectively, the “Permits”), to own, lease and license its assets and properties and conduct its business, all of which are valid and in full force and effect, except where the lack of such Permits, individually or in the aggregate, would not have a Material Adverse Effect. The Company and its subsidiary have fulfilled and performed in all material respects all of their respective obligations with respect to such Permits and no event has occurred that allows, or after notice or lapse of time would allow, revocation or termination thereof or results in any other material impairment of the rights of the Company thereunder. Except as may be required under the Securities Act and state and foreign Blue Sky laws, no other Permits are required to enter into, deliver and perform this Agreement and to issue and sell the Shares.

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(i) (i) At the time of filing the Registration Statement, and (ii) at the date hereof, the Company was not and is not an “ineligible issuer,” as defined in Rule 405 of the Rules, including (but not limited to) the Company or any other subsidiary in the preceding three years not having been convicted of a felony or misdemeanor or having been made the subject of a judicial or administrative decree or order as described in Rule 405 of the Rules.

(j) The Company and its subsidiary owns or possesses legally enforceable rights to use all patents, patent rights, inventions, trademarks, trademark applications, trade names, service marks, copyrights, copyright applications, licenses, know-how and other similar rights and proprietary knowledge (collectively, “Intangibles”) necessary for the conduct of its business. Neither the Company nor its subsidiary has received any notice of, or is not aware of, any infringement of or conflict with asserted rights of others with respect to any Intangibles.

(k) The Company and its subsidiary has good and marketable title in fee simple to all real property, and good and marketable title to all other property owned by it, in each case free and clear of all liens, encumbrances, claims, security interests and defects, except such as do not materially affect the value of such property and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiary. All property held under lease by the Company and its subsidiary is held by them under valid, existing and enforceable leases, free and clear of all liens, encumbrances, claims, security interests and defects, except such as are not material and do not materially interfere with the use made or proposed to be made of such property by the Company and its subsidiary.

(l) Subsequent to the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus and the Prospectus, (i) there has not been any event which would reasonably be expected to result in a Material Adverse Effect; (ii) neither the Company nor its subsidiary has sustained any loss or interference with its assets, businesses or properties (whether owned or leased) from fire, explosion, earthquake, flood or other calamity, whether or not covered by insurance, or from any labor dispute or any court or legislative or other governmental action, order or decree which would reasonably be expected to result in a Material Adverse Effect. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, since the date of the latest balance sheet included in the Registration Statement, the Statutory Prospectus and the Prospectus, neither the Company nor its subsidiary has (A) issued any securities or incurred any liability or obligation, direct or contingent, for borrowed money, except such liabilities or obligations incurred in the ordinary course of business, (B) entered into any transaction not in the ordinary course of business or (C) declared or paid any dividend or made any distribution on any shares of its stock or redeemed, purchased or otherwise acquired or agreed to redeem, purchase or otherwise acquire any shares of its capital stock.

(m) There is no document, contract or other agreement required to be described in the Registration Statement, the Statutory Prospectus or the Prospectus or to be filed as an exhibit to the Registration Statement which is not described or filed as required by the Securities Act or Rules. Each description of a contract, document or other agreement in the Registration Statement, the Statutory Prospectus or the Prospectus accurately reflects in all material respects the terms of the underlying contract, document or other agreement. Each contract, document or other agreement described in the Registration Statement, the Statutory Prospectus or the

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Prospectus or listed in the Exhibits to the Registration Statement is in full force and effect and is valid and enforceable by and against the Company or its subsidiary, as the case may be, in accordance with its terms, except (i) such contracts or other agreements that have terminated or expired in accordance with their terms as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, and (ii) where the failure to be in full force and effect and so valid and enforceable would not reasonably be expected to result in a Material Adverse Effect, individually or in the aggregate. Neither the Company nor its subsidiary, if its subsidiary is a party, nor to the Company's knowledge, any other party is in default in the observance or performance of any term or obligation to be performed by it under any such agreement, and no event has occurred which with notice or lapse of time or both would constitute such a default, in any such case which default or event, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect. No default exists, and no event has occurred which with notice or lapse of time or both would constitute a default, in the due performance and observance of any term, covenant or condition, by the Company or its subsidiary, if a subsidiary is a party thereto, of any other agreement or instrument to which the Company or its subsidiary is a party or by which the Company or its properties or business or a subsidiary or its properties or business may be bound or affected which default or event, individually or in the aggregate, would reasonably be expected to have a Material Adverse Effect.

(n) The statistical and market related data included in the Registration Statement, the Statutory Prospectus or the Prospectus are based on or derived from sources that the Company believes to be reliable and accurate.

(o) Neither the Company nor its subsidiary (i) is in violation of its certificate or articles of incorporation, by-laws or other organizational documents, (ii) is in default under, and no event has occurred which, with notice or lapse of time, or both, would constitute a default under, or result in the creation or imposition of any lien, charge, mortgage, pledge, security interest, claim, limitation on voting rights, equity, trust or other encumbrance, preferential arrangement, defect or restriction of any kind whatsoever, upon, any property or assets of the Company or its subsidiary pursuant to, any bond, debenture, note, indenture, mortgage, deed of trust, loan agreement or other agreement or instrument to which it is a party or by which it is bound or to which any of its properties or assets is subject or (iii) is in violation of any statute, law, rule, regulation, ordinance, directive, judgment, decree or order of any judicial, regulatory or other legal or governmental agency or body, foreign or domestic, except (in the case of clauses (ii) and (iii) above) for violations or defaults that could not (individually or in the aggregate) reasonably be expected to have a Material Adverse Effect.

(p) This Agreement has been duly authorized, executed and delivered by the Company.

(q) Neither the execution, delivery and performance of this Agreement by the Company nor the consummation of any of the transactions contemplated hereby (including, without limitation, the issuance and sale by the Company of the Shares) will give rise to a right to terminate or accelerate the due date of any payment due under, or conflict with or result in the breach of any term or provision of, or constitute a default (or an event which with notice or lapse of time or both would constitute a default) under, or require any consent or waiver under, or result in the execution or imposition of any lien, charge or encumbrance upon any properties or assets of the Company or its subsidiary pursuant to the terms of, (i) any indenture, mortgage,

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deed of trust or other agreement or instrument to which the Company or its subsidiary is a party or by which either the Company or its subsidiary or any of their properties or businesses is bound, or any franchise, license, permit, judgment, decree, order, statute, rule or regulation applicable to the Company or its subsidiary, or (ii) violate any provision of the charter or by-laws of the Company or its subsidiary, except (A) in the case of clause (i) above, for violations or defaults that would not, individually or in the aggregate, reasonably be expected to result in a Material Adverse Effect, and (B) for such consents or waivers which have already been obtained and are in full force and effect.

(r) The Company has authorized and outstanding capital stock as set forth under the caption "Capitalization" in the Statutory Prospectus and the Prospectus. The certificates evidencing the Shares are in due and proper legal form and have been duly authorized for issuance by the Company. All of the issued and outstanding shares of Common Stock have been duly and validly issued and are fully paid and nonassessable. Except as set forth in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no statutory preemptive or other similar rights to subscribe for or to purchase or acquire any shares of Common Stock of the Company or its subsidiary or any such rights pursuant to its certificate of incorporation or by-laws or any agreement or instrument to or by which the Company or its subsidiary is a party or bound. The Shares, when issued and sold pursuant to this Agreement, will be duly and validly issued, fully paid and nonassessable and none of them will be issued in violation of any preemptive or other similar right. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there is no outstanding option, warrant or other right calling for the issuance of, and there is no commitment, plan or arrangement to issue, any share of stock of the Company or its subsidiary or any security convertible into, or exercisable or exchangeable for, such stock. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, the exercise price of each option to acquire Common Stock (each, a "Company Stock Option") is no less than the fair market value of a share of Common Stock as determined on the date of grant of such Company Stock Option. All grants of Company Stock Options were validly issued and properly approved by the Board of Directors of the Company or the compensation committee of the Company's Board of Directors in material compliance with all applicable laws and the terms of the plans under which such Company Stock Options were issued and were recorded on the Company financial statements, in accordance with U.S. generally accepted accounting principles, and no such grants involved any "back dating", "forward dating," "spring loading" or similar practices with respect to the effective date of grant. The Common Stock and the Shares conform in all material respects to all statements in relation thereto contained in the Registration Statement and the Statutory Prospectus and the Prospectus. All outstanding shares of capital stock of the Company's subsidiary have been duly authorized and validly issued, and are fully paid and nonassessable and are owned directly by the Company free and clear of any security interests, liens, encumbrances, equities or claims, other than those described in the Statutory Prospectus and the Prospectus.

(s) No holder of any security of the Company has any right, which has not been waived or satisfied prior to the date hereof, to have any security owned by such holder included in the Registration Statement or to demand registration of any security owned by such holder for a period of 180 days after the date of this Agreement. Each director and executive officer of the Company and each stockholder of the Company listed on Schedule II hereto has delivered to the Representatives his enforceable written lock-up agreement in the form attached to this Agreement as Exhibit A hereto ("Lock-Up Agreement").

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(t) Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no legal or governmental proceedings pending to which the Company or its subsidiary is a party or of which any property of the Company or its subsidiary is the subject which, if determined adversely to the Company or its subsidiary could individually or in the aggregate have a Material Adverse Effect; and, to the knowledge of the Company, no such proceedings are threatened or contemplated by governmental authorities or threatened by others.

(u) All necessary corporate action has been duly and validly taken by the Company to authorize the execution, delivery and performance of this Agreement and the issuance and sale of the Shares by the Company.

(v) Neither the Company nor its subsidiary is involved in any labor dispute or, to the knowledge of the Company, is any such dispute threatened, which dispute would reasonably be expected to result in a Material Adverse Effect. The Company is not aware of any existing or imminent labor disturbance by the employees of any of its principal suppliers or contractors which would reasonably be expected to result in a Material Adverse Effect. The Company is not aware of any threatened or pending litigation between the Company or its subsidiary and any of its executive officers which, if adversely determined, could have a Material Adverse Effect and has no reason to believe that such officers will not remain in the employment of the Company.

(w) No transaction has occurred between or among the Company and any of its officers or directors, or five percent stockholders or any affiliate or affiliates of any such officer or director or five percent stockholders that is required to be described in and is not described in the Registration Statement, the Statutory Prospectus and the Prospectus.

(x) The Company has not taken, nor will it take, directly or indirectly, any action designed to or which might reasonably be expected to cause or result in, or which has constituted or which might reasonably be expected to constitute, the stabilization or manipulation of the price of the Common Stock or any security of the Company to facilitate the sale or resale of any of the Shares.

(y) The Company and its subsidiary has filed all Federal, state, local and foreign tax returns which are required to be filed through the date hereof, which returns are true and correct in all material respects or has received timely extensions thereof, and has paid all taxes shown on such returns and all assessments received by it to the extent that the same are material and have become due. There are no tax audits or investigations pending, which if adversely determined would reasonably be expected to result in a Material Adverse Effect; nor are there any material proposed additional tax assessments against the Company or its subsidiary.

(z) The Shares have been duly authorized for listing on the NASDAQ Capital Market (the "NASDAQ Capital Market").

(aa) The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the Common Stock under the Exchange Act or the listing of the Common Stock on the NASDAQ Capital Market, nor has the Company received any notification that the Commission or the NASDAQ Capital Market is contemplating terminating such registration or listing.

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(bb) The books, records and accounts of the Company and its subsidiary accurately and fairly reflect, the transactions in, and dispositions of, the assets of, and the results of operations of, the Company and its subsidiary. The Company and its subsidiary maintains a system of internal accounting controls sufficient to provide reasonable assurances that (i) transactions are executed in accordance with management's general or specific authorizations, (ii) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles and to maintain asset accountability, (iii) access to assets is permitted only in accordance with management's general or specific authorization and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

(cc) The Company has established and maintains disclosure controls and procedures (as such term is defined in Rule 13a-15 under the Exchange Act), which: (i) are designed to ensure that material information relating to the Company is made known to the Company's principal executive officer and its principal financial officer by others within the Company, particularly during the periods in which the periodic reports required under the Exchange Act are required to be prepared; (ii) provide for the periodic evaluation of the effectiveness of such disclosure controls and procedures at the end of the periods in which the periodic reports are required to be prepared; and (iii) are effective in all material respects to perform the functions for which they were established.

(dd) Based on the evaluation of its disclosure controls and procedures, the Company is not aware of (i) any material weakness or significant deficiency in the design or operation of internal controls which could adversely affect the Company's ability to record, process, summarize and report financial data or any material weaknesses in internal controls; or (ii) any fraud, whether or not material, that involves management or other employees who have a role in the Company's internal controls.

(ee) Except as described in the Statutory Prospectus and the Prospectus and as preapproved in accordance with the requirements set forth in Section 10A of the Exchange Act, the Auditor has not been engaged by the Company to perform any "prohibited activities" (as defined in Section 10A of the Exchange Act).

(ff) Except as described in the Statutory Prospectus and the Prospectus, there are no material off-balance sheet arrangements (as defined in Item 303 of Regulation S-K) that have or are reasonably likely to have a material current or future effect on the Company's financial condition, revenues or expenses, changes in financial condition, results of operations, liquidity, capital expenditures or capital resources.

(gg) The Company's Board of Directors has validly appointed an audit committee whose composition satisfies the requirements of Rule 5605 of the NASDAQ Stock Market and the Board of Directors and/or the audit committee of the Board of Directors has adopted a charter that satisfies the requirements of Rule 5605 of the NASDAQ Stock Market.

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(hh) There is and has been no failure on the part of the Company or any of its directors or officers, in their capacities as such, to comply with any applicable provision of the Sarbanes-Oxley Act of 2002, as amended (the “Sarbanes-Oxley Act”), including, without limitation, Section 402 related to loans and Sections 302 and 906 related to certifications.

(ii) The Company and its subsidiary are insured by insurers of recognized financial responsibility against such losses and risks and in such amounts as are, in the Company’s reasonable judgment, customary in the businesses in which they are engaged; all policies of insurance and fidelity or surety bonds insuring the Company or its subsidiary or the Company’s or its subsidiary’s respective businesses, assets, employees, officers and directors are in full force and effect; the Company and its subsidiary are in compliance with the terms of such policies and instruments in all material respects; and neither the Company nor its subsidiary has any reason to believe that it will not be able to renew its existing insurance coverage as and when such coverage expires or to obtain similar coverage from similar insurers as may be necessary to continue its business at a cost that is not materially greater than the current cost. Neither the Company nor its subsidiary has been denied any insurance coverage which it has sought or for which it has applied.

(jj) Each approval, consent, order, authorization, designation, declaration or filing of, by or with any regulatory, administrative or other governmental body necessary in connection with the execution and delivery by the Company of this Agreement and the consummation of the transactions herein contemplated required to be obtained or performed by the Company (except such additional steps as may be required by the Financial Industry Regulatory Authority (“FINRA”) or may be necessary to qualify the Shares for public offering by the Underwriters under the state securities or Blue Sky laws) has been obtained or made and is in full force and effect.

(kk) There are no affiliations with FINRA among the Company’s officers, directors or, to the best of the knowledge of the Company, any five percent or greater stockholder of the Company, except as set forth in the Registration Statement or otherwise disclosed in writing to the Representatives.

(ll) The Company does not expect to be a Passive Foreign Investment Company (“PFIC”) within the meaning of Section 1297(a) of the United States Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder for the year ending December 31, 2011, and has no plan or intention to conduct its business in a manner that would be reasonably expected to result in the Company becoming a PFIC in the future under current laws and regulations.

(mm) (i) Each of the Company and its subsidiary is in compliance in all material respects with all rules, laws and regulation relating to the use, treatment, storage and disposal of toxic substances and protection of health or the environment (“Environmental Law”) which are applicable to its business; (ii) neither the Company nor its subsidiary has received any notice from any governmental authority or third party of an asserted claim under Environmental Laws; (iii) each of the Company and its subsidiary has received all permits, licenses or other approvals required of it under applicable Environmental Laws to conduct its business and is in compliance in all material respects with all terms and conditions of any such permit, license or approval; (iv)

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to the Company's knowledge, no facts currently exist that will require the Company or its subsidiary to make future material capital expenditures to comply with Environmental Laws; and (v) no property which is or has been owned, leased or occupied by the Company or its subsidiary has been designated as a Superfund site pursuant to the Comprehensive Environmental Response, Compensation of Liability Act of 1980, as amended (42 U.S.C. Section 9601, et. seq.) ("CERCLA"), or otherwise designated as a contaminated site under applicable state or local law. Neither the Company nor its subsidiary has been named as a "potentially responsible party" under CERCLA.

(nn) The Company is not and, after giving effect to the offering and sale of the Shares and the application of proceeds thereof as described in the Statutory Prospectus and the Prospectus, will not be an "investment company" within the meaning of the Investment Company Act of 1940, as amended.

(oo) The Company or any other person associated with or acting on behalf of the Company including, without limitation, any director, officer, agent or employee of the Company or its subsidiary, has not, directly or indirectly, while acting on behalf of the Company or its subsidiary (i) used any corporate funds for unlawful contributions, gifts, entertainment or other unlawful expenses relating to political activity; (ii) made any unlawful payment to foreign or domestic government officials or employees or to foreign or domestic political parties or campaigns from corporate funds; (iii) violated any provision of the Foreign Corrupt Practices Act of 1977, as amended; or (iv) made any other unlawful payment.

(pp) The operations of the Company and its subsidiary are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any governmental agency (collectively, the "Money Laundering Laws") and no action, suit or proceeding by or before any court or governmental agency, authority or body or any arbitrator involving the Company or its subsidiary with respect to the Money Laundering Laws is pending, or to the knowledge of the Company, threatened.

(qq) Neither the Company nor its subsidiary nor, to the knowledge of the Company, any director, officer, agent, employee or affiliate of the Company or its subsidiary is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Treasury Department ("OFAC"); and the Company will not directly or indirectly use the proceeds of the offering, or lend, contribute or otherwise make available such proceeds to its subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person currently subject to any U.S. sanctions administered by OFAC.

(rr) Except as described in the Statutory Prospectus and the Prospectus, the Company has not sold or issued any shares of Common Stock during the six-month period preceding the date of the Prospectus, including any sales pursuant to Rule 144A under, or Regulations D or S of, the Securities Act, other than shares issued pursuant to employee benefit plans, qualified stock options plans or other employee compensation plans or pursuant to outstanding options, rights or warrants.



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(ss) The Company has fulfilled its obligations, if any, under the minimum funding standards of Section 302 of the U.S. Employee Retirement Income Security Act of 1974 (“ERISA”) and the regulations and published interpretations thereunder with respect to each “plan” as defined in Section 3(3) of ERISA and such regulations and published interpretations in which its employees are eligible to participate and each such plan is in compliance in all material respects with the presently applicable provisions of ERISA and such regulations and published interpretations. No “Reportable Event” (as defined in 12 ERISA) has occurred with respect to any “Pension Plan” (as defined in ERISA) for which the Company could have any liability.

(tt) None of the Company, its directors or its officers has distributed nor will distribute prior to the later of (i) the Firm Shares Closing Date, or the Option Shares Closing Date, and (ii) completion of the distribution of the Shares, any offering material in connection with the offering and sale of the Shares other than any Preliminary Prospectus, the Prospectus, the Registration Statement and other materials, if any, permitted by the Securities Act and consistent with Section 3(d) below.

(uu) Except as described in the Registration Statement, the General Disclosure Package, the Statutory Prospectus and the Prospectus, the Company and its subsidiary: (A) are and at all times have been in material compliance with all statutes, rules or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labelling, promotion, sale, offer for sale, storage, import, export or disposal of any product under development, manufactured or distributed by the Company or its subsidiary (“Applicable Laws”); (B) have not received any Form 483 from the United States Food and Drug Administration (the “FDA”), notice of adverse finding, warning letter, or other correspondence or written notice from the FDA, the DEA or any other federal, state, local or foreign governmental or regulatory authority alleging or asserting material noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances, authorizations, permits and supplements or amendments thereto required by any such Applicable Laws (“Authorizations”), which would, individually or in the aggregate, result in a Material Adverse Effect; (C) possess all material Authorizations necessary for its business as conducted on the date of the Registration Statement, and such Authorizations are valid and in full force and effect and neither the Company nor its subsidiary is in material violation of any term of any such Authorizations; (D) have not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party alleging that any product, operation or activity is in material violation of any Applicable Laws or Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) have not received notice that the FDA or any other federal, state, local or foreign governmental or regulatory authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any material Authorizations and has no knowledge that the FDA or any other federal, state, local or foreign governmental or regulatory authority is considering such action; and (F) have filed, obtained, maintained or submitted all reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations, except where exempt from such requirements under Applicable Law or Authorizations or where the failure to file such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments would not

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result in a Material Adverse Effect, and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were materially complete and correct on the date filed (or were corrected or supplemented by a subsequent submission).

(vv) The animal and other preclinical studies and clinical trials conducted by the Company or on behalf of the Company that the Company intends to rely on in support of its regulatory submissions to the FDA or foreign regulatory agencies were, and, if still pending are, to the Company's knowledge, being conducted, to the extent applicable, in material compliance with the requirements of "Good Laboratory Practices" and "Good Clinical Practices;" the descriptions of the results of such preclinical studies and clinical trials contained in the Registration Statement, the General Disclosure Package, the Statutory Prospectus and the Prospectus are accurate and complete in all material respects, and, except as set forth in the Registration Statement, the General Disclosure Package, the Statutory Prospectus and the Prospectus, the Company has no knowledge of any other clinical trials or preclinical studies, the results of which the Company believes reasonably call into question the clinical trial or preclinical study results described or referred to in the Registration Statement, the General Disclosure Package, the Statutory Prospectus and the Prospectus when viewed in the context in which such results are described; and the Company has not received any written notices or correspondence from the FDA or any other domestic or foreign governmental agency requiring the termination, suspension or modification of any preclinical studies or clinical trials conducted by or on behalf of the Company that are described in the Registration Statement, the General Disclosure Package, the Statutory Prospectus and the Prospectus or the results of which are referred to in the Registration Statement, the General Disclosure Package, the Statutory Prospectus and the Prospectus.

3. Conditions of the Underwriters' Obligations. The obligations of the Underwriters under this Agreement are several and not joint. The respective obligations of the Underwriters to purchase the Shares are subject to each of the following terms and conditions:

(a) Notification that the Registration Statement has become effective shall have been received by the Representatives and the Prospectus shall have been timely filed with the Commission in accordance with Section 4(a) of this Agreement and any material required to be filed by the Company pursuant to Rule 433(d) of the Rules shall have been timely filed with the Commission in accordance with such rule.

(b) No order preventing or suspending the use of any Preliminary Prospectus, the Prospectus or any "free writing prospectus" (as defined in Rule 405 of the Rules), shall have been or shall be in effect and no order suspending the effectiveness of the Registration Statement shall be in effect and no proceedings for such purpose shall be pending before or threatened by the Commission, and any requests for additional information on the part of the Commission (to be included in the Registration Statement or the Prospectus or otherwise) shall have been complied with to the satisfaction of the Commission and the Representatives. If the Company has elected to rely upon Rule 430A, Rule 430A information previously omitted from the effective Registration Statement pursuant to Rule 430A shall have been transmitted to the Commission for filing pursuant to Rule 424(b) within the prescribed time period and the Company shall have provided evidence satisfactory to the Underwriters of such timely filing, or a post-effective amendment providing such information shall have been promptly filed and declared effective in accordance with the requirements of Rule 430A.

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(c) The representations and warranties of the Company contained in this Agreement and in the certificates delivered pursuant to Section 3(d) shall be true and correct when made and on and as of each Closing Date as if made on such date. The Company shall have performed in all material respects all covenants and agreements and satisfied all the conditions contained in this Agreement required to be performed or satisfied by them at or before such Closing Date.

(d) The Representatives shall have received on each Closing Date a certificate, addressed to the Representatives and dated such Closing Date, of the chief executive or chief operating officer and the chief financial officer or chief accounting officer of the Company to the effect that: (i) the representations, warranties and agreements of the Company in this Agreement were true and correct when made and are true and correct as of such Closing Date; (ii) the Company has performed in all material respects all covenants and agreements and satisfied all conditions contained herein; (iii) they have carefully examined the Registration Statement, the Prospectus, the General Disclosure Package, and any individual Issuer Free Writing Prospectus and, in their opinion (A) as of the Effective Date the Registration Statement and Prospectus did not include, and as of the Applicable Time, neither (i) the General Disclosure Package, nor (ii) any individual Issuer Free Writing Prospectus, when considered together with the General Disclosure Package, included, any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading, and (B) since the Effective Date no event has occurred which should have been set forth in a supplement or otherwise required an amendment to the Registration Statement, the Statutory Prospectus or the Prospectus; (iv) no stop order suspending the effectiveness of the Registration Statement has been issued and, to their knowledge, no proceedings for that purpose have been instituted or are pending under the Securities Act; and (v) there has not occurred any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiary considered as a whole.

(e) The Representatives shall have received: (i) simultaneously with the execution of this Agreement a signed letter from the Auditor addressed to the Representatives and dated the date of this Agreement, in form and substance reasonably satisfactory to the Representatives, containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the Disclosure Package, and (ii) on each Closing Date, a signed letter from the Auditor addressed to the Representatives and dated the date of such Closing Date(s), in form and substance reasonably satisfactory to the Representatives containing statements and information of the type ordinarily included in accountants' "comfort letters" to underwriters with respect to the financial statements and certain financial information contained in the Registration Statement and the Prospectus.

(f) The Representatives shall have received on each Closing Date from Loeb & Loeb LLP, counsel for the Company, an opinion, addressed to the Representatives and dated such Closing Date, and stating in effect that:

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(i) Each of the Company and its subsidiary has been duly organized and is validly existing as a corporation in good standing under the laws of the State of Delaware and the United Kingdom, respectively. Each of the Company and its subsidiary is duly qualified to transact business and is in good standing as a foreign corporation in each jurisdiction in which the character or location of its assets or properties or the nature of its business makes such qualification necessary, except where the failure to so qualify or to be in good standing, individually or in the aggregate, would not have a Material Adverse Effect.

(ii) Each of the Company and its subsidiary has all requisite corporate power and authority to own, lease and operate its properties and to conduct its business as now being conducted and as described in the Registration Statement, the Statutory Prospectus and the Prospectus and with respect to the Company to enter into and perform its obligations under this Agreement and to issue and sell the Shares.

(iii) The authorized, issued and outstanding capital stock of the Company is as set forth in the Registration Statement, the Statutory Prospectus and the Prospectus under the caption "Capitalization" as of the dates stated therein and, since such dates, there has been no change in the capital stock of the Company except for subsequent issuances, if any, pursuant to this Agreement or pursuant to reservations, agreements or employee benefit plans referred to in the Statutory Prospectus and the Prospectus or pursuant to the exercise of convertible securities or options referred to in the Statutory Prospectus and the Prospectus; all of the outstanding shares of capital stock of the Company have been duly and validly authorized and issued and are fully paid and nonassessable and none of them was issued in violation of any preemptive or other similar right. The Shares to be issued and sold by the Company pursuant to this Agreement have been duly authorized for issuance and sale to the Underwriters pursuant to this Agreement and, when issued and delivered by the Company pursuant to this Agreement against payment of the consideration set forth herein, will be validly issued, fully paid and nonassessable, and no holder of the Shares is or will be subject to personal liability by reason of being such a holder. Except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, the issuance and sale of the Shares by the Company is not subject to any preemptive or other similar rights of any securityholder of the Company. To the best of such counsel's knowledge, except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no preemptive or other rights to subscribe for or to purchase or any restriction upon the voting or transfer of any securities of the Company pursuant to the Company's certificate of incorporation or by-laws or other governing documents or any agreements or other instruments to which the Company is a party or by which it is bound. To the best of such counsel's knowledge, except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there is no outstanding option, warrant or other right calling for the issuance of, and no commitment, plan or arrangement to issue, any share of stock of the Company or any security convertible into,

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exercisable for, or exchangeable for stock of the Company. The Common Stock and the Shares conform in all material respects to the descriptions thereof contained in the Registration Statement, the Statutory Prospectus and the Prospectus. The form of certificate used to evidence the Common Stock complies in all material respects with all applicable statutory requirements, with any applicable requirements of the certificate of incorporation or by-laws of the Company and the requirements of the NASDAQ Capital Market. To the best of such counsel's knowledge, except as disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus, there are no persons with registration rights or other similar rights to have any securities registered pursuant to the Registration Statement or otherwise registered by the Company under the Securities Act.

(iv) All necessary corporate action has been duly and validly taken by the Company to authorize the execution, delivery and performance of this Agreement and the issuance and sale of the Shares. This Agreement has been duly and validly authorized, executed and delivered by the Company and this Agreement constitutes the legal, valid and binding obligation of the Company enforceable against the Company in accordance with its terms except as such enforceability may be limited by applicable bankruptcy, insolvency, fraudulent conveyance, reorganization, moratorium and other similar laws affecting the enforcement of creditors' rights generally and by general equitable principles, and except as any rights to indemnification may be limited by public policy concerns.

(v) Neither the execution, delivery and performance of this Agreement by the Company nor the consummation of any of the transactions contemplated hereby (including, without limitation, the issuance and sale by the Company of the Shares) nor the execution, delivery or performance of any other agreement or instrument entered into or to be entered into by the Company in connection with the transactions contemplated by the Registration Statement, the Statutory Prospectus and the Prospectus will give rise to a right to terminate or accelerate the due date of any payment due under, or conflict with or result in the breach of any term or provision of, or constitute a default (or any event which with notice or lapse of time, or both, would constitute a default) under, or require consent or waiver under, or result in the execution or imposition of any lien, charge, claim, security interest or encumbrance upon any properties or assets of the Company or its subsidiary pursuant to the terms of, any indenture, mortgage, deed trust, note or other agreement or instrument of which such counsel is aware and to which the Company or its subsidiary is a party or by which either the Company or its subsidiary or any of its assets or properties or businesses is bound, or any franchise, license, permit, judgment, decree, order, statute, rule or regulation, domestic or foreign, of which such counsel is aware or violate any provision of the charter or by-laws of the Company or its subsidiary.

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(vi) No consent, approval, authorization, license, registration, qualification or order of any court or governmental agency or regulatory body is required for the due authorization, execution, delivery or performance of this Agreement by the Company or the consummation of the transactions contemplated hereby or thereby, except such as have been obtained under the Securities Act and such as may be required under state securities or Blue Sky laws in connection with the purchase and distribution of the Shares by the several Underwriters.

(vii) To the best of such counsel's knowledge, there is no any action, suit, proceeding or other investigation, before any court or before or by any public body or board pending or threatened against, or involving the assets, properties or businesses of, the Company which is required to be disclosed in the Registration Statement, the Statutory Prospectus and the Prospectus and is not so disclosed or which could reasonably be expected to have a Material Adverse Effect.

(viii) The statements in the Statutory Prospectus and the Prospectus under the captions "Description of Capital Stock," "Business – Legal Proceedings," and "Certain Transactions," and in the Registration Statement under Item 15 of Part II, insofar as such statements constitute a summary of documents referred to therein or matters of law, are accurate in all material respects and accurately present the information with respect to such documents and matters. Accurate copies of all contracts and other documents known to such counsel and required to be filed as exhibits to, or described in, the Registration Statement have been so filed with the Commission or are fairly described in the Registration Statement, as the case may be.

(ix) The Registration Statement, all Preliminary Prospectuses (including the Statutory Prospectus) and the Prospectus and each amendment or supplement thereto (except for the financial statements and schedules and other financial data included therein, as to which such counsel expresses no opinion) comply as to form in all material respects with the requirements of the Securities Act and the Rules, all Preliminary Prospectuses (including the Statutory Prospectus) and the Prospectuses and any further amendment or supplement to any such incorporated document made by the Company (except for the financial statements and schedules and other financial data included therein, as to which such counsel expresses no opinion) when they became effective or were filed with the Commission, as the case may be, complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder.

(x) The Registration Statement is effective under the Securities Act, and to such counsel's knowledge no stop order suspending the effectiveness of the Registration Statement has been issued and no proceedings for that purpose have been instituted or are threatened, pending or contemplated. Any required filing of the Prospectus and any supplement thereto pursuant to Rule 424(b) under the Securities Act has been made in the manner and within the time period required by such Rule 424(b).

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(xi) The Shares have been approved for listing on the NASDAQ Capital Market.

(xii) The capital stock of the Company conforms in all material respects to the description thereof contained in the Statutory Prospectus and the Prospectus under the caption "Description of Capital Stock."

(xiii) The Company is not an "investment company" or an entity controlled by an "investment company" as such terms are defined in the Investment Company Act of 1940, as amended.

To the extent deemed advisable by such counsel, such counsel may rely as to matters of fact on certificates of responsible officers of the Company and public officials and on the opinions of other counsel satisfactory to the Representatives as to matters which are governed by laws other than the laws of the State of New York, the General Corporation Law of the State of Delaware and the Federal laws of the United States; provided that such counsel shall state that in their opinion the Underwriters and they are justified in relying on such other opinions. Copies of such certificates and other opinions shall be furnished to the Representatives and counsel for the Underwriters.

In addition, such counsel shall state that such counsel has participated in conferences with officers and other representatives of the Company, representatives of the Representatives and representatives of the independent certified public accountants of the Company, at which conferences the contents of the Registration Statement, the Prospectus and Issuer Free Writing Prospectuses and related matters were discussed and, although such counsel is not passing upon and does not assume any responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement, the Prospectus (except as specified in the foregoing opinion), and any Issuer Represented General Free Writing Prospectus on the basis of the foregoing, no facts have come to the attention of such counsel which lead such counsel to believe that (i) the Registration Statement at the time it became effective and at the time of the latest amendment thereto (except with respect to the financial statements and notes and schedules thereto and other financial data, as to which such counsel need express no belief) contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, or that the Prospectus as amended or supplemented (except with respect to the financial statements, notes and schedules thereto and other financial data, as to which such counsel need make no statement) on the date thereof and on the Closing Date contained or as of the date hereof contains any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading and (ii) the Statutory Prospectus, when considered together with the price to the public and the number of shares as set forth on the cover page of the Prospectus, as of the Applicable Time, contained any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading.

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(g) The Representatives shall have received on each Closing Date from each of (i) Foley & Lardner LLP, with respect to TSO, and (ii) Arnold & Porter LLP, with respect to CNDO-109, both firms serving as intellectual property counsel for the Company, an opinion, addressed to the Representatives and dated such Closing Date, and stating in effect that:

1. To such counsel's knowledge, the information in the Prospectus under (i) "Risk Factors – Our success will depend upon intellectual property, proprietary technologies and regulatory market exclusivity periods, and the intellectual property protection for our product candidates depends significantly on third parties," (ii) "Risk Factors – 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," and (iii) "Business – Intellectual Property," to the extent that they constitute matters of law, summaries of legal matters, documents or proceedings, or legal conclusions, have been reviewed by such counsel and they are accurate and complete in all material respects and present fairly the information purported to be shown.

2. To such counsel's knowledge, (i) there are no legal or governmental proceedings pending relating to patents and patent applications necessary for the conduct of the Company's business, other than the review and examination of these applications for patent by the United States Patent and Trademark Office and applicable foreign patent examining, and (ii) no such proceedings, other than the aforementioned patent office reviews and examinations, have been threatened in writing (or otherwise) or contemplated by governmental authorities or others.

3. Although such counsel has not investigated the matter, and except as set out in paragraph 5 below and in the Registration Statement, General Disclosure Package, and the Prospectus, we are not aware that the Company or any Subsidiary is a party to, or bound by, any contract, instrument, arrangement or other agreement, relating to the patents and patent applications necessary for the conduct of the Company's business, that are of a character required to be described in the Registration Statement, the General Disclosure Package or the Prospectus or to be filed as an exhibit to the Registration Statement which have not been so described or filed as required.



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4. Although such counsel has not investigated the matter, the Company has not advised such counsel, and such counsel is not aware of, any infringement that would reasonably be expected to have a Material Adverse Effect by any third party of the patents necessary for the conduct of the Company's business. Although such counsel has not investigated the matter, the Company has not advised such counsel of, and such counsel is not aware of, any facts that cause such counsel to believe that the Company is infringing any valid and enforceable patent rights of others.

5. To such counsel's knowledge, the Company (either directly or through any of its Subsidiaries) has valid license rights to the patents and patent applications necessary for the conduct of its business.

6. To such counsel's knowledge, the products in clinical development and described in the Registration Statement, the General Disclosure Package and the Prospectus are each (i) encompassed by at least one claim in one or more issued patents licensed to the Company or a Subsidiary, or (ii) encompassed by at least one claim in one or more patent applications licensed to the Company or a Subsidiary.

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To the extent deemed advisable by such counsel, such counsel may rely as to matters of fact on certificates of responsible officers of the Company and public officials and on the opinions of other counsel satisfactory to the Representatives as to matters which are governed by laws other than the laws of the State of New York, the General Corporation Law of the State of Delaware and the Federal laws of the United States; provided that such counsel shall state that in their opinion the Underwriters and they are justified in relying on such other opinions. Copies of such certificates and other opinions shall be furnished to the Representatives.

(h) The Representatives shall have received on each Closing Date from Hyman, Phelps & MacNamara, LLP, regulatory counsel for the Company, an opinion, addressed to the Representatives and dated such Closing Date and stating that the statements in the Registration

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Statement, the Statutory Prospectus and the Prospectus under the caption “Business-Government Regulation and Product Approval” insofar as such statements constitute a summary of documents referred to therein or matters of law, are accurate in all material respects and accurately present the information with respect to such documents and matters.

(i) The Representatives shall have received on each Closing Date from Lowenstein Sandler PC, counsel for the Representatives, an opinion, addressed to the Representatives and dated such Closing Date, and stating in effect that:

(i) The issuance and sale of the Shares have been duly authorized by requisite corporate action on the part of the Company and when delivered to and paid for by the Underwriters in accordance with the terms of the Underwriting Agreement, will be validly issued, fully paid and non-assessable, and to our knowledge, the issuance of such Shares will not be subject to any preemptive or similar rights: (A) contained in the Company’s certificate of incorporation and by-laws, (B) under the Delaware General Corporate Law or (C) under agreements filed as exhibits to the Registration Statement, except such as have been validly waived or complied with.

(ii) The Underwriting Agreement has been duly authorized, executed and delivered by the Company.

(iii) As of the date of the Statutory Prospectus and the Prospectus, as the case may be, the statements in the Statutory Prospectus and the Prospectus (as applicable) under the captions “Description of Capital Stock” and “Underwriting” insofar as such statements constituted summaries of the legal matters, documents or proceedings referred to therein, fairly presented the information called for with respect to such legal matters, documents and proceedings and fairly summarized the matters referred to therein.

(iv) The Registration Statement, all Preliminary Prospectuses (including the Statutory Prospectus) and the Prospectus and each amendment or supplement thereto (except for the financial statements and schedules and other financial data included therein, as to which such counsel expresses no opinion) comply as to form in all material respects with the requirements of the Securities Act and the Rules, all Preliminary Prospectuses (including the Statutory Prospectus) and the Prospectuses and any further amendment or supplement to any such incorporated document made by the Company (except for the financial statements and schedules and other financial data included therein, as to which such counsel expresses no opinion) when they became effective or were filed with the Commission, as the case may be, complied as to form in all material respects with the requirements of the Securities Act or the Exchange Act, as applicable, and the rules and regulations of the Commission thereunder.

(v) The Registration Statement is effective under the Securities Act, and to such counsel’s knowledge no stop order suspending the effectiveness of the Registration Statement has been issued and no proceedings for that purpose have

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been instituted or are threatened, pending or contemplated. Any required filing of the Prospectus and any supplement thereto pursuant to Rule 424(b) under the Securities Act has been made in the manner and within the time period required by such Rule 424(b).

To the extent deemed advisable by such counsel, such counsel may rely as to matters of fact on certificates of responsible officers of the Company and public officials and on the opinions of other counsel satisfactory to the Representatives as to matters which are governed by laws other than the laws of the State of New York, the General Corporation Law of the State of Delaware and the Federal laws of the United States; provided that such counsel shall state that in their opinion the Underwriters and they are justified in relying on such other opinions. Copies of such certificates and other opinions shall be furnished to the Representatives.

In addition, such counsel shall state that such counsel has participated in conferences with officers and other representatives of the Company, representatives of the Representatives and representatives of the independent certified public accountants of the Company, at which conferences the contents of the Registration Statement, the Prospectus and Issuer Free Writing Prospectuses and related matters were discussed and, although such counsel is not passing upon and does not assume any responsibility for the accuracy, completeness or fairness of the statements contained in the Registration Statement and the Prospectus (except as specified in the foregoing opinion) or any Issuer Free Writing Prospectuses,, on the basis of the foregoing, no facts have come to the attention of such counsel which lead such counsel to believe that (i) the Registration Statement at the time it became effective (except with respect to the financial statements and notes and schedules thereto and other financial data, as to which such counsel need express no belief) contained any untrue statement of a material fact or omitted to state a material fact required to be stated therein or necessary to make the statements therein not misleading, or that the Prospectus as amended or supplemented (except with respect to the financial statements, notes and schedules thereto and other financial data, as to which such counsel need make no statement) on the date thereof and on the Closing Date contained or as of the date hereof contains any untrue statement of a material fact or omitted to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading or (ii) the Statutory Prospectus, when considered together with the price to the public and the number of shares as set forth on the cover page of the Prospectus, as of the Applicable Time, contained any untrue statement of a material fact or omitted to state any material fact necessary in order to make the statements therein, in the light of circumstances under which they were made, not misleading.

(j) All proceedings taken in connection with the sale of the Firm Shares and the Option Shares as herein contemplated shall be reasonably satisfactory in form and substance to the Representatives, and their counsel.

(k) The Representatives shall have received copies of the Lock-up Agreements executed by each entity or person listed on Schedule II hereto.

(l) The Shares shall have been approved for listing on the NASDAQ Capital Market, subject only to official notice of issuance.

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(m) The Representatives shall be reasonably satisfied that since the respective dates as of which information is given in the Registration Statement, the Statutory Prospectus, the General Disclosure Package and the Prospectus, (i) there shall not have been any material change in the capital stock of the Company or any material change in the indebtedness (other than in the ordinary course of business) of the Company, (ii) except as set forth or contemplated by the Registration Statement, the Statutory Prospectus, the General Disclosure Package or the Prospectus, no material oral or written agreement or other transaction shall have been entered into by the Company that is not in the ordinary course of business or that could reasonably be expected to result in a material reduction in the future earnings of the Company, (iii) no loss or damage (whether or not insured) to the property of the Company shall have been sustained that had or could reasonably be expected to have a Material Adverse Effect, (iv) no legal or governmental action, suit or proceeding affecting the Company or any of its properties that is material to the Company or that affects or could reasonably be expected to affect the transactions contemplated by this Agreement shall have been instituted or threatened and (v) there shall not have been any material change in the assets, properties, condition (financial or otherwise), or in the results of operations, business affairs or business prospects of the Company or its subsidiary considered as a whole that makes it impractical or inadvisable in the Representatives' judgment to proceed with the purchase or offering of the Shares as contemplated hereby.

(n) On the Firm Shares Closing Date, FINRA shall have confirmed that it has not raised any objection with respect to the fairness and reasonableness of the underwriting terms and agreements in connection with the offering of the Shares.

(o) The Company shall have furnished or caused to be furnished to the Representatives such further certificates or documents as the Representatives shall have reasonably requested.

4. Covenants and other Agreements of the Company and the Underwriters.

(a) The Company covenants and agrees as follows:

(i) The Company will use its commercially reasonable efforts to cause the Registration Statement, if not effective at the time of execution of this Agreement, and any amendments thereto, to become effective as promptly as possible. The Company shall prepare the Prospectus in a form approved by the Representatives and file such Prospectus pursuant to Rule 424(b) under the Securities Act not later than the Commission's close of business on the second business day following the execution and delivery of this Agreement, or, if applicable, such earlier time as may be required by the Rules. The Company will file with the Commission all Issuer Free Writing Prospectuses in the time and manner required under Rules 433(d) or 163(b)(2), as the case may be.

(ii) The Company shall promptly advise the Representatives in writing (A) when any post-effective amendment to the Registration Statement shall have become effective or any supplement to the Prospectus shall have been filed, (B) of any request by the Commission for any amendment of the

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Registration Statement or the Prospectus or for any additional information, (C) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or of any order preventing or suspending the use of any preliminary prospectus or any “free writing prospectus”, as defined in Rule 405 of the Rules, or the institution or threatening of any proceeding for that purpose and (D) of the receipt by the Company of any notification with respect to the suspension of the qualification of the Shares for sale in any jurisdiction or the initiation or threatening of any proceeding for such purpose. The Company shall not file any amendment of the Registration Statement or supplement to the Prospectus or any Issuer Free Writing Prospectus unless the Company has furnished the Representatives a copy for its review prior to filing and shall not file any such proposed amendment or supplement to which the Representatives reasonably object. The Company shall use its best efforts to prevent the issuance of any such stop order and, if issued, to obtain as soon as possible the withdrawal thereof.

(iii) If, at any time when a prospectus relating to the Shares (or, in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act, any event occurs as a result of which the Prospectus as then amended or supplemented would include any untrue statement of a material fact or omit to state any material fact necessary to make the statements therein in the light of the circumstances under which they were made not misleading, or if it shall be necessary to amend or supplement the Prospectus to comply with the Securities Act or the Rules, the Company promptly shall prepare and file with the Commission, subject to the second sentence of paragraph (ii) of this Section 4(a), an amendment or supplement which shall correct such statement or omission or an amendment which shall effect such compliance.

(iv) If at any time following issuance of an Issuer Free Writing Prospectus there occurs an event or development as a result of which such Issuer Free Writing Prospectus would conflict with the information contained in the Registration Statement or would include an untrue statement of a material fact or would omit to state a material fact required to be stated therein or necessary in order to make the statements therein, in the light of the circumstances prevailing at the subsequent time, not misleading, the Company will promptly notify the Representatives and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

(v) The Company shall make generally available to its security holders and to the Representatives as soon as practicable, but not later than 45 days after the end of the 12-month period beginning at the end of the fiscal quarter of the Company during which the Effective Date occurs (or 90 days if such 12-month period coincides with the Company’s fiscal year), an earning statement (which need not be audited) of the Company, covering such 12-month period, which shall satisfy the provisions of Section 11(a) of the Securities Act or Rule 158 of the Rules.

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(vi) The Company shall furnish to the Representatives and counsel for the Underwriters, without charge, signed copies of the Registration Statement (including all exhibits thereto and amendments thereof) and to each other Underwriter a copy of the Registration Statement (without exhibits thereto) and all amendments thereof and, so long as delivery of a prospectus by an Underwriter or dealer may be required by the Securities Act or the Rules, as many copies of any Preliminary Prospectus, any Issuer Free Writing Prospectus and the Prospectus and any amendments thereof and supplements thereto as the Representatives may reasonably request. If applicable, the copies of the Registration Statement, preliminary prospectus, any Issuer Free Writing Prospectus and Prospectus and each amendment and supplement thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(vii) The Company shall cooperate with the Representatives and their counsel in endeavoring to qualify the Shares for offer and sale in connection with the offering under the laws of such jurisdictions as the Representatives may designate and shall maintain such qualifications in effect so long as required for the distribution of the Shares; provided, however, that the Company shall not be required in connection therewith, as a condition thereof, to qualify as a foreign corporation or to execute a general consent to service of process in any jurisdiction or subject itself to taxation as doing business in any jurisdiction.

(viii) The Company, during the period when the Prospectus (or in lieu thereof, the notice referred to in Rule 173(a) of the Rules) is required to be delivered under the Securities Act and the Rules or the Exchange Act, will file all reports and other documents required to be filed with the Commission pursuant to Section 13, 14 or 15 of the Exchange Act within the time periods required by the Exchange Act and the regulations promulgated thereunder.

(ix) Without the prior written consent of the Representatives, for a period of 90 days after the date of this Agreement, the Company and each of its individual directors and executive officers shall not issue, sell or register with the Commission (other than on Form S-8 or on any successor form), or otherwise dispose of, directly or indirectly, any equity securities of the Company (or any securities convertible into, exercisable for or exchangeable for equity securities of the Company), except for the issuance of the Shares pursuant to the Registration Statement and the issuance of shares pursuant to the Company's existing stock option plan, employee stock purchase plan ("ESPP") or bonus plan as described in the Registration Statement, the Statutory Prospectus and the Prospectus. In the event that during this period, (A) any shares are issued to any director or executive

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officer pursuant to the Company's existing stock option plan, ESPP or bonus plan that are exercisable during such 90 day period or (B) any registration is effected on Form S-8 or on any successor form relating to shares that are exercisable during such 90 day period, the Company shall obtain the written agreement of such director or executive officer that, for a period of 90 days after the date of this Agreement, such person will not, without the prior written consent of the Representatives, offer for sale, sell, distribute, grant any option for the sale of, or otherwise dispose of, directly or indirectly, or exercise any registration rights with respect to, any shares of Common Stock (or any securities convertible into, exercisable for, or exchangeable for any shares of Common Stock) owned by such person. Notwithstanding the foregoing, (i) the Company represents and warrants that each director and executive officer shall be subject to similar lockup restrictions as set forth on Exhibit A attached hereto and the Company shall enforce such rights and impose stop-transfer restrictions on any such sale or other transfer or disposition of such shares until the end of the applicable period and (ii) if (x) during the last 17 days of the 90 day period described in this Section 4(a)(ix) the Company issues an earnings release or material news or a material event relating to the Company occurs; or (y) prior to the expiration of such 90 day period, the Company announces that it will release earnings results during the 16 day period beginning on the last day of the 90 day period; the restrictions imposed during this Section 4(a)(ix) shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event; provided, however, that this sentence shall not apply if the research published or distributed on the Company is compliant under Rule 139 of the Securities Act and the Company's securities are actively traded as defined in Rule 101(c)(1) of Regulation M of the Exchange Act.

(x) On or before completion of this offering, the Company shall make all filings required under applicable securities laws and by the NASDAQ Capital Market (including any required registration under the Exchange Act).

(xi) Prior to the Closing Date, the Company will issue no press release or other communications directly or indirectly and hold no press conference with respect to the Company, its condition, financial or otherwise, or its earnings, business affairs or business prospects, or the offering of the Shares without the prior written consent of the Representatives unless in the judgment of the Company and its counsel, and after notification to the Representatives, such press release or communication is required by law.

(xii) The Company will apply the net proceeds from the offering of the Shares in the manner set forth under "Use of Proceeds" in the Prospectus.



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(b) The Company agrees to pay, or reimburse if paid by the Representatives, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated, all costs and expenses incident to the public offering of the Shares and the performance of the obligations of the Company under this Agreement including those relating to: (i) the preparation, printing, reproduction filing and distribution of the Registration Statement including all exhibits thereto, each Preliminary Prospectus, the Prospectus, any Issuer Free Writing Prospectus, all amendments and supplements thereto, and the printing, filing and distribution of this Agreement; (ii) the preparation and delivery of certificates for the Shares to the Underwriters; (iii) the registration or qualification of the Shares for offer and sale under the securities or Blue Sky laws of the various requisite jurisdictions, including the reasonable fees and disbursements of counsel for the Underwriters in connection with such registration and qualification and the preparation, printing, distribution and shipment of preliminary and supplementary Blue Sky memoranda; (iv) the furnishing (including costs of shipping and mailing) to the Representatives and to the Underwriters of copies of each Preliminary Prospectus, the Prospectus and all amendments or supplements to the Prospectus, any Issuer Free Writing Prospectus, and of the several documents required by this Section to be so furnished, as may be reasonably requested for use in connection with the offering and sale of the Shares by the Underwriters or by dealers to whom Shares may be sold; (v) the filing fees of FINRA in connection with its review of the terms of the public offering and reasonable fees and disbursements of counsel for the Underwriters in connection with such review; (vi) inclusion of the Shares for listing on the NASDAQ Capital Market; and (vii) all transfer taxes, if any, with respect to the sale and delivery of the Shares by the Company to the Underwriters. In addition to the foregoing, the Company will reimburse the Representatives for a maximum of \$75,000 for their expenses, including legal fees, incurred, whether pursuant to clauses (iii) and (iv) or otherwise, in connection with the purchase and sale of the Shares contemplated hereby. Subject to the provisions of Section 7, the Underwriters agree to pay, whether or not the transactions contemplated hereby are consummated or this Agreement is terminated, all costs and expenses incident to the performance of the obligations of the Underwriters under this Agreement not payable by the Company pursuant to the preceding sentence.

(c) The Company acknowledges and agrees that each of the Underwriters has acted and is acting solely in the capacity of a principal in an arm's length transaction between the Company and the Underwriters with respect to the offering of Shares contemplated hereby (including in connection with determining the terms of the offering) and not as a financial advisor, agent or fiduciary to the Company or any other person. Additionally, the Company acknowledges and agrees that the Underwriters have not and will not advise the Company or any other person as to any legal, tax, investment, accounting or regulatory matters in any jurisdiction. The Company has consulted with its own advisors concerning such matters and shall be responsible for making its own independent investigation and appraisal of the transactions contemplated hereby, and the Underwriters shall have no responsibility or liability to the Company or any other person with respect thereto, whether arising prior to or after the date hereof. Any review by the Underwriters of the Company, the transactions contemplated hereby or other matters relating to such transactions have been and will be performed solely for the benefit of the Underwriters and shall not be on behalf of the Company. The Company agrees that it will not claim that the Underwriters, or any of them, has rendered advisory services of any nature or respect, or owes a fiduciary duty to the Company or any other person in connection with any such transaction or the process leading thereto.

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(d) The Company represents and agrees that, unless it obtains the prior consent of the Representatives, and each Underwriter represents and agrees that, unless it obtains the prior consent of the Company and the Representatives, it has not made and will not make any offer relating to the Shares that would constitute an “issuer free writing prospectus,” as defined in Rule 433, or that would otherwise constitute a “free writing prospectus,” as defined in Rule 405, required to be filed with the Commission. The Company has complied and will comply with the requirements of Rule 433 under the Act applicable to any Issuer Free Writing Prospectus, including timely filing with the Commission where required, legending and record keeping. The Company represents that it has satisfied and agrees that it will satisfy the conditions set forth in Rule 433 of the Rules to avoid a requirement to file with the Commission any Road Show.

#### 5. Indemnification.

(a) The Company agrees to indemnify and hold harmless each Underwriter, its officers and employees and each person, if any, who controls any Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all losses, claims, damages and liabilities, joint or several (including any reasonable investigation, legal and other expenses incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claim asserted), to which they, or any of them, may become subject under the Securities Act, the Exchange Act or other Federal or state law or regulation, at common law or otherwise, insofar as such losses, claims, damages or liabilities arise out of or are based upon any untrue statement or alleged untrue statement of a material fact contained in any preliminary prospectus, the Registration Statement, the Statutory Prospectus, the Prospectus, any Issuer Free Writing Prospectus or any “issuer-information” filed or required to be filed pursuant to Rule 433(d) of the Rules, any amendment thereof or supplement thereto, or in any Blue Sky application or other information or other documents executed by the Company filed in any state or other jurisdiction to qualify any or all of the Shares under the securities laws thereof (any such application, document or information being hereinafter referred to as a “Blue Sky Application”) or arise out of or are based upon any omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that such indemnity shall not inure to the benefit of any Underwriter (or any person controlling such Underwriter) on account of any losses, claims, damages or liabilities arising from the sale of the Shares to any person by such Underwriter if such untrue statement or omission or alleged untrue statement or omission was made in such preliminary prospectus, the Registration Statement, the Prospectus, the Statutory Prospectus, any Issuer Free Writing Prospectus or such amendment or supplement thereto, or in any Blue Sky Application in reliance upon and in conformity with the Underwriter Information. This indemnity agreement will be in addition to any liability which the Company may otherwise have.

(b) Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, and each person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, each director of the Company, and each officer of the Company who signs the Registration Statement, against any losses, claims, damages or liabilities to which such party may become subject, under the Securities Act or otherwise, insofar as such losses, claims, damages or liabilities (or actions in respect thereof) arise out of or are based upon an untrue statement or alleged untrue statement of

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a material fact contained in any preliminary prospectus, the Registration Statement or the Prospectus, or any amendment or supplement thereto, or arise out of or are based upon the omission or alleged omission to state therein a material fact required to be stated therein or necessary to make the statements therein not misleading, in each case to the extent, but only to the extent, that such untrue statement or alleged untrue statement or omission or alleged omission was made in any Preliminary Prospectus, the Registration Statement, the Statutory Prospectus or the Prospectus or any such amendment or supplement in reliance upon and in conformity with the Underwriter Information; provided, however, that the obligation of each Underwriter to indemnify the Company (including any controlling person, director or officer thereof) shall be limited to the amount of the underwriting discount and commissions applicable to the Shares to be purchased by such Underwriter hereunder.

(c) Any party that proposes to assert the right to be indemnified under this Section will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim is to be made against an indemnifying party or parties under this Section, notify each such indemnifying party of the commencement of such action, suit or proceeding, enclosing a copy of all papers served. No indemnification provided for in Section 5(a) or 5(b) shall be available to any party who shall fail to give notice as provided in this Section 5(c) if the party to whom notice was not given was unaware of the proceeding to which such notice would have related and was prejudiced by the failure to give such notice but the omission so to notify such indemnifying party of any such action, suit or proceeding shall not relieve it from any liability that it may have to any indemnified party for contribution or otherwise than under this Section. In case any such action, suit or proceeding shall be brought against any indemnified party and it shall notify the indemnifying party of the commencement thereof, the indemnifying party shall be entitled to participate in, and, to the extent that it shall wish, jointly with any other indemnifying party similarly notified, to assume the defense thereof, with counsel reasonably satisfactory to such indemnified party, and after notice from the indemnifying party to such indemnified party of its election so to assume the defense thereof and the approval by the indemnified party of such counsel, the indemnifying party shall not be liable to such indemnified party for any legal or other expenses, except as provided below and except for the reasonable costs of investigation subsequently incurred by such indemnified party in connection with the defense thereof. The indemnified party shall have the right to employ its counsel in any such action, but the fees and expenses of such counsel shall be at the expense of such indemnified party unless (i) the employment of counsel by such indemnified party has been authorized in writing by the indemnifying parties, (ii) the indemnified party shall have been advised by counsel that there may be one or more legal defenses available to it which are different from or in addition to those available to the indemnifying party (in which case the indemnifying parties shall not have the right to direct the defense of such action on behalf of the indemnified party) or (iii) the indemnifying parties shall not have employed counsel to assume the defense of such action within a reasonable time after notice of the commencement thereof, in each of which cases the fees and expenses of counsel shall be at the expense of the indemnifying parties. An indemnifying party shall not be liable for any settlement of any action, suit, and proceeding or claim effected without its written consent, which consent shall not be unreasonably withheld or delayed.

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6. Contribution. In order to provide for just and equitable contribution in circumstances in which the indemnification provided for in Section 5(a) or 5(b) is due in accordance with its terms but for any reason is unavailable to or insufficient to hold harmless an indemnified party in respect to any losses, liabilities, claims, damages or expenses referred to therein, then each indemnifying party shall contribute to the aggregate losses, liabilities, claims, damages and expenses (including any investigation, legal and other expenses reasonably incurred in connection with, and any amount paid in settlement of, any action, suit or proceeding or any claims asserted, but after deducting any contribution received by any person entitled hereunder to contribution from any person who may be liable for contribution) incurred by such indemnified party, as incurred, in such proportion as is appropriate to reflect the relative benefits received by the Company on the one hand and the Underwriters on the other hand from the offering of the Shares pursuant to this Agreement or, if such allocation is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to above but also the relative fault of the Company on the one hand and the Underwriters on the other hand in connection with the statements or omissions which resulted in such losses, liabilities, claims, damages or expenses, as well as any other relevant equitable considerations. The Company and the Underwriters agree that it would not be just and equitable if contribution pursuant to this Section 6 were determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation which does not take account of the equitable considerations referred to above. The aggregate amount of losses, liabilities, claims, damages and expenses incurred by an indemnified party and referred to above shall be deemed to include any legal or other expenses reasonably incurred by such indemnified party in investigating, preparing or defending against any litigation, or any investigation or proceeding by any governmental agency or body, commenced or threatened, or any claim whatsoever based upon any such untrue or alleged untrue statement or omission or alleged omission. Notwithstanding the provisions of this Section 6, no Underwriter (except as may be provided in the Agreement Among Underwriters) shall be required to contribute any amount in excess of the underwriting discounts and commissions applicable to the Shares purchased by such Underwriter. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation. For purposes of this Section 6, each person, if any, who controls an Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act shall have the same rights to contribution as such Underwriter, and each director of the Company, each officer of the Company who signed the Registration Statement, and each person, if any, who controls the Company within the meaning of the Section 15 of the Securities Act or Section 20 of the Exchange Act, shall have the same rights to contribution as the Company. Any party entitled to contribution will, promptly after receipt of notice of commencement of any action, suit or proceeding against such party in respect of which a claim for contribution may be made against another party or parties under this Section 6, notify such party or parties from whom contribution may be sought, but the omission so to notify such party or parties from whom contribution may be sought shall not relieve the party or parties from whom contribution may be sought from any other obligation it or they may have hereunder or otherwise than under this Section 6. No party shall be liable for contribution with respect to any action, suit, proceeding or claim settled without its written consent. The Underwriters' obligations to contribute pursuant to this Section 6 are several in proportion to their respective underwriting commitments and not joint.

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## 7. Termination.

(a) This Agreement may be terminated with respect to the Shares to be purchased on a Closing Date by the Representatives by notifying the Company at any time at or before a Closing Date in the absolute discretion of the Representatives if: (i) there has occurred any material adverse change in the securities markets or any event, act or occurrence that has materially disrupted, or in the reasonable opinion of the Representatives, will in the future materially disrupt, the securities markets or there shall be such a material adverse change in general financial, political or economic conditions or the effect of international conditions on the financial markets in the United States is such as to make it, in the judgment of the Representatives, inadvisable or impracticable to market the Shares or enforce contracts for the sale of the Shares; (ii) there has occurred any outbreak or material escalation of hostilities or acts of terrorism or other calamity or crisis the effect of which on the financial markets of the United States is such as to make it, in the judgment of the Representatives, inadvisable or impracticable to market the Shares or enforce contracts for the sale of the Shares; (iii) trading in the Shares or any securities of the Company has been suspended or materially limited by the Commission or trading generally on the New York Stock Exchange, Inc., the American Stock Exchange, Inc. or NASDAQ has been suspended or materially limited, or minimum or maximum ranges for prices for securities shall have been fixed, or maximum ranges for prices for securities have been required, by any of said exchanges or by such system or by order of the Commission, FINRA, or any other governmental or regulatory authority; (iv) a banking moratorium has been declared by any state or Federal authority; or (v) in reasonable judgment of the Representatives, there has been, since the time of execution of this Agreement or since the respective dates as of which information is given in the Prospectus, any material adverse change in the assets, properties, condition, financial or otherwise, or in the results of operations, business affairs or business prospects of the Company and its subsidiary considered as a whole, whether or not arising in the ordinary course of business.

(b) If this Agreement is terminated pursuant to any of its provisions, the Company shall not be under any liability to any Underwriter, and no Underwriter shall be under any liability to the Company, except that (y) if this Agreement is terminated by the Representatives or the Underwriters because of any failure, refusal or inability on the part of the Company to comply with the terms or to fulfill any of the conditions of this Agreement, the Company will reimburse the Underwriters for all out-of-pocket expenses (including the reasonable fees and disbursements of their counsel) incurred by them in connection with the proposed purchase and sale of the Shares or in contemplation of performing their obligations hereunder and (z) no Underwriter who shall have failed or refused to purchase the Shares agreed to be purchased by it under this Agreement, without some reason sufficient hereunder to justify cancellation or termination of its obligations under this Agreement, shall be relieved of liability to the Company, or to the other Underwriters for damages occasioned by its failure or refusal.

8. Substitution of Underwriters. If any Underwriter shall default in its obligation to purchase on any Closing Date the Shares agreed to be purchased hereunder on such Closing Date, the Representatives shall have the right, within 36 hours thereafter, to make arrangements for one or more of the non-defaulting Underwriters, or any other underwriters, to purchase such Shares on the terms contained herein. If, however, the Representatives shall not have completed such arrangements within such 36-hour period, then the Company shall be

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entitled to a further period of 36 hours within which to procure another party or other parties reasonably satisfactory to the Underwriters to purchase such Shares on such terms. If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by the Representatives and the Company as provided above, the aggregate number of Shares which remains unpurchased on such Closing Date does not exceed one-eleventh of the aggregate number of all the Shares that all the Underwriters are obligated to purchase on such date, then the Company shall have the right to require each non-defaulting Underwriter to purchase the number of Shares which such Underwriter agreed to purchase hereunder at such date and, in addition, to require each non-defaulting Underwriter to purchase its pro rata share (based on the number of Shares which such Underwriter agreed to purchase hereunder) of the Shares of such defaulting Underwriter or Underwriters for which such arrangements have not been made; but nothing herein shall relieve a defaulting Underwriter from liability for its default. In any such case, either the Representatives or the Company shall have the right to postpone the applicable Closing Date for a period of not more than seven days in order to effect any necessary changes and arrangements (including any necessary amendments or supplements to the Registration Statement or Prospectus or any other documents), and the Company agrees to file promptly any amendments to the Registration Statement or the Prospectus which in the opinion of the Company and the Underwriters and their counsel may thereby be made necessary.

If, after giving effect to any arrangements for the purchase of the Shares of a defaulting Underwriter or Underwriters by the Representatives and the Company as provided above, the aggregate number of such Shares which remains unpurchased exceeds 10% of the aggregate number of all the Shares to be purchased at such date, then this Agreement, or, with respect to a Closing Date which occurs after the Firm Shares Closing Date, the obligations of the Underwriters to purchase and of the Company, as the case may be, to sell the Option Shares to be purchased and sold on such date, shall terminate, without liability on the part of any non-defaulting Underwriter to the Company, and without liability on the part of the Company, except as provided in Sections 4(b), 5, 6 and 7. The provisions of this Section 8 shall not in any way affect the liability of any defaulting Underwriter to the Company or the nondefaulting Underwriters arising out of such default. The term "Underwriter" as used in this Agreement shall include any person substituted under this Section 8 with like effect as if such person had originally been a party to this Agreement with respect to such Shares.

9. Miscellaneous. The respective agreements, representations, warranties, indemnities and other statements of the Company and the several Underwriters, as set forth in this Agreement or made by or on behalf of them pursuant to this Agreement, shall remain in full force and effect, regardless of any investigation (or any statement as to the results thereof) made by or on behalf of any Underwriter or the Company or the or any of their respective officers, directors or controlling persons referred to in Sections 5 and 6 hereof, and shall survive delivery of and payment for the Shares. In addition, the provisions of Sections 4(b), 5, 6 and 7 shall survive the termination or cancellation of this Agreement.

This Agreement has been and is made for the benefit of the Underwriters, the Company and their respective successors and assigns, and, to the extent expressed herein, for the benefit of persons controlling any of the Underwriters, or the Company, and directors and officers of the Company, and their respective successors and assigns, and no other person shall acquire or have any right under or by virtue of this Agreement. The term "successors and assigns" shall not include any purchaser of Shares from any Underwriter merely because of such purchase.

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All notices and communications hereunder shall be in writing and mailed or delivered or by telephone or telegraph if subsequently confirmed in writing, (a) if to the Representatives, c/o Oppenheimer & Co. Inc., 85 Broad Street, New York, New York 10004, Attention: Equity Capital Markets, with a copy to Oppenheimer & Co. Inc., 85 Broad Street, New York, New York 10004, Attention: General Counsel, to Roth Capital Partners, LLC, 888 San Clemente Drive, Newport Beach, California 92660, Attention: Managing Director, and to Lowenstein Sandler PC, 65 Livingston Avenue, Roseland, New Jersey 07068, Attention: John D. Hogoboom, and (b) if to the Company, to its agent for service as such agent's address appears on the cover page of the Registration Statement with a copy to Loeb & Loeb LLP, 345 Park Avenue, New York, New York 10154.

**This Agreement shall be governed by and construed in accordance with the laws of the State of New York** . Each of the parties hereto hereby submits to the non-exclusive jurisdiction of the Federal and state courts in the Borough of Manhattan in The City of New York in any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby. Each of the parties irrevocably and unconditionally waives any objection to the laying of venue of any suit or proceeding arising out of or relating to this Agreement or the transactions contemplated hereby in Federal and state courts in the Borough of Manhattan in The City of New York and irrevocably and unconditionally waives and agrees not to plead or claim in any such court that any such suit or proceeding in any such court has been brought in an inconvenient forum.

This Agreement may be signed in any number of counterparts, each of which shall be an original, with the same effect as if the signatures thereto and hereto were upon the same instrument.

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Please confirm that the foregoing correctly sets forth the agreement among us.

Very truly yours,

CORONADO BIOSCIENCES, INC.

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

Confirmed:

OPPENHEIMER & CO. INC.  
ROTH CAPITAL PARTNERS, LLC

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Each acting severally on behalf of itself and as  
representative of the several  
Underwriters named in Schedule I annexed hereto.

By OPPENHEIMER & CO. INC.

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

By ROTH CAPITAL PARTNERS, LLC

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



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SCHEDULE I

<u>Name</u>	<u>Number of Firm Shares to Be Purchased</u>
Oppenheimer & Co. Inc.	
Roth Capital Partners, LLC	
National Securities Corporation	
Total	

Sch I - 1

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SCHEDULE II

Lock-up Signatories

Glenn L. Cooper, M.D.  
Bobby W. Sandage, Jr., Ph.D.  
Noah D. Beerman  
Lucy Lu, M.D.  
Karin M. Hehenberger, M.D., Ph.D.  
Dale Ritter  
Eric K. Rowinsky, M.D.  
David J. Barrett  
Jimmie Harvey, Jr., M.D.  
J. Jay Lobell  
Michael W. Rogers  
Lindsay A. Rosenwald, M.D.  
Hillel Gross

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SCHEDULE III

Issuer Free Writing Prospectuses

[None]

Sch III - 1

**FORM OF LOCK-UP AGREEMENT**

June [ ], 2012

Oppenheimer & Co. Inc.  
Roth Capital Partners, LLC  
As Representatives of the Several Underwriters  
c/o Oppenheimer & Co. Inc.  
300 Madison Avenue  
New York, New York 10017

Re: Public Offering of Coronado Biosciences, Inc.

Ladies and Gentlemen:

The undersigned, a holder of common stock, par value \$0.001 ("Common Stock"), or rights to acquire Common Stock, of Coronado Biosciences, Inc. (the "Company") understands that you, as Representatives (the "Representatives") of the several Underwriters, propose to enter into an Underwriting Agreement (the "Underwriting Agreement") with the Company, providing for the public offering (the "Public Offering") by the several Underwriters named in Schedule I to the Underwriting Agreement (the "Underwriters"), of shares of Common Stock of the Company (the "Securities"). Capitalized terms used herein and not otherwise defined shall have the meanings set forth in the Underwriting Agreement.

In consideration of the Underwriters' agreement to enter into the Underwriting Agreement and to proceed with the Public Offering of the Securities, and for other good and valuable consideration receipt of which is hereby acknowledged, the undersigned hereby agrees for the benefit of the Company, you and the other Underwriters that, without the prior written consent of the Representatives on behalf of the Underwriters, the undersigned will not, during the period ending 90 days (the "Lock-Up Period") after the date of the prospectus relating to the Public Offering (the "Prospectus"), directly or indirectly (1) offer, pledge, assign, encumber, announce the intention to sell, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, any shares of Common Stock, or any securities convertible into or exercisable or exchangeable for Common Stock owned either of record or beneficially (as defined in the Securities Exchange Act of 1934, as amended) by the undersigned on the date hereof or hereafter acquired or (2) enter into any swap or other agreement that transfers, in whole or in part, any of the economic consequences of ownership of the Common Stock, whether any such transaction described in clause (1) or (2) above is to be settled by delivery of Common Stock or such other securities, in cash or otherwise, or publicly announce an intention to do any of the foregoing. In addition, the undersigned agrees that, without the prior written consent of the Representatives on behalf of the Underwriters, it will not, during the period ending 90 days

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after the date of the Prospectus, make any demand for or exercise any right with respect to, the registration of any shares of Common Stock or any security convertible into or exercisable or exchangeable for Common Stock. The foregoing shall not apply to (a) Common Stock to be transferred as a gift or gifts, (b) sales under any 10b-5 plan, (c) transfers to any trust for the direct or indirect benefit of the undersigned or the immediate family of the undersigned, (d) transfers by will or under the laws of descent and (e) transfers to affiliates (within the meaning set forth in Rule 405 as promulgated by the SEC under the Securities Act of 1933, as amended), limited partners, general partners, limited liability company members, or stockholders of the undersigned to the extent that the undersigned is a partnership, limited liability company, or corporation, provided, however, that in the case of (a), (c), (d) and (e) above, it shall be a condition to the transfer that the donee, trustee, legatee, heir, distributee or other transferee, as the case may be, agree to be bound in writing by the terms hereof.

Notwithstanding the foregoing, if (x) during the last 17 days of the Lock-Up Period the Company issues an earnings release or material news or a material event relating to the Company occurs; or (y) prior to the expiration of the Lock-Up Period, the Company announces that it will release earnings results during the 16-day period beginning on the last day of the 90 day period; the restrictions imposed in this Letter Agreement shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event; provided, however, that this sentence shall not apply if the research published or distributed on the Company is compliant under Rule 139 of the Securities Act and the Company's securities are actively traded as defined in Rule 101(c)(1) of Regulation M of the Exchange Act.

In furtherance of the foregoing, the Company, and any duly appointed transfer agent for the registration or transfer of the securities described herein, are hereby authorized to decline to make any transfer of securities if such transfer would constitute a violation or breach of this Letter Agreement.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Letter Agreement. All authority herein conferred or agreed to be conferred and any obligations of the undersigned shall be binding upon the successors, assigns, heirs or personal representatives of the undersigned.

The undersigned understands that, if the Underwriting Agreement does not become effective, or if the Underwriting Agreement (other than the provisions thereof which survive termination) shall terminate or be terminated prior to payment for and delivery of the Common Stock to be sold thereunder, the undersigned shall be released from all obligations under this Letter Agreement.

The undersigned, whether or not participating in the Offering, understands that the Underwriters are entering into the Underwriting Agreement and proceeding with the Public Offering in reliance upon this Letter Agreement.

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This lock-up agreement shall be governed by and construed in accordance with the laws of the State of New York, without regard to the conflict of laws principles thereof.

Very truly yours,

**[STOCKHOLDER]**

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

Name:

Title:

A-3

**[Form of Waiver of Lock-up]**

**[Representative Letterhead]**

Coronado Biosciences, Inc.  
Public Offering of Common Stock

[ ], 20[ ]

[Name and Address of  
Officer or Director  
Requesting Waiver]

Dear Mr./Ms. [Name]:

This letter is being delivered to you in connection with the offering by Coronado Biosciences, Inc. (the "Company") of [ ] shares of common stock, \$0.001 par value (the "Common Stock"), of the Company and the lock-up agreement dated June [ ], 2012 (the "Lock-up Agreement"), executed by you in connection with such offering, and your request for a [waiver] [release] dated [ ], 20[ ], with respect to [ ] shares of Common Stock (the "Shares").

The Representatives hereby agree to [waive] [release] the transfer restrictions set forth in the Lock-up Letter, but only with respect to the Shares, effective [ ], 20[ ][date to be 3 business days from date of letter]; provided, however, that such [waiver] [release] is conditioned on the Company announcing the impending [waiver] [release] by press release through a major news service at least two business days before effectiveness of such [waiver] [release]. This letter will serve as notice to the Company of the impending [waiver] [release].

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Except as expressly [waived] [released] hereby, the Lock-up Letter shall remain in full force and effect.

Yours very truly,  
OPPENHEIMER & CO. INC.

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

Name:

Title: ROTH CAPITAL PARTNERS, LLC

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

Name:

Title:

cc: [Company contact]



**[Form of Lock Up Waiver/Release Company Press Release]****Coronado Biosciences, Inc.****[Date]**

Coronado Biosciences, Inc. (the "Company") announced today that Oppenheimer & Co. Inc. and Roth Capital Partners, LLC, the book-running managers in the Company's recent public sale of 4,600,000 shares of common stock, is [waiving] [releasing] a lock-up restriction with respect to [ ] shares of the Company's common stock held by [ ], an [officer/director] of the Company. The [waiver] [release] will take effect on [ ], 20[ ], and the related shares may be sold on or after such date.

**This press release is not an offer for sale of the securities in the United States or in any other jurisdiction where such offer is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the United States Securities Act of 1933, as amended.**

June 21, 2012

Coronado Biosciences, Inc.  
15 New England Executive Park  
Burlington, MA 01803

Ladies and Gentlemen:

We have acted as counsel to Coronado Biosciences, Inc., a Delaware corporation (the "Company"), in connection with the Registration Statement on Form S-1 (the "Registration Statement") filed with the Securities and Exchange Commission under the Securities Act of 1933, as amended (the "Act"), for the registration for an underwritten public offering of (i) 4,600,000 shares (the "Shares") of the Company's common stock, par value \$.001 per share (the "Common Stock") and (ii) up to 690,000 shares of Common Stock (the "Over-Allotment Shares") for which the underwriters have been granted an over-allotment option.

In connection with the foregoing, we have examined originals or copies, satisfactory to us, of the (i) Registration Statement, (ii) the certificate of incorporation of the Company, as amended to date, (iii) the by-laws of the Company, and (iv) certain records of the Company's corporate proceedings. We have also reviewed such other matters of law and examined and relied upon all such corporate records, agreements, certificates and other documents as we have deemed relevant and necessary as a basis for the opinion hereinafter expressed. In such examination, we have assumed the genuineness of all signatures, the authenticity of all documents submitted to us as originals and the conformity with the original documents of all documents submitted to us as copies or facsimiles. Where factual matters relevant to such opinion were not independently established, we have relied upon certificates of officers and responsible employees and agents of the Company.

Based upon and subject to the foregoing, we are of the opinion that the Shares and the Over-Allotment Shares to be sold to the underwriters, when issued and sold in accordance with and in the manner described in the Underwriting section of the Registration Statement, will be validly issued, fully paid and non-assessable.

We are opining solely on all applicable statutory provisions of Delaware corporate law, including the rules and regulations underlying those provisions, all applicable provisions of the Delaware Constitution and all applicable judicial and regulatory determinations.

We hereby consent to the filing of this opinion as an exhibit to the Registration Statement and to the reference made to us under the caption "Legal Matters" in the prospectus constituting part of the Registration Statement. In giving this consent, we do not thereby admit that we are within the category of persons whose consent is required under Section 7 of the Act, the rules and regulations of the Securities and Exchange Commission promulgated thereunder or Item 509 of Regulation S-K promulgated under the Act.

Very truly yours,

/s/ LOEB & LOEB LLP

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the use in this Amendment No. 2 to the Registration Statement on Form S-1 of Coronado Biosciences, Inc. of our report dated March 29, 2012 relating to the financial statements of Coronado Biosciences, Inc., which appears in such Registration Statement. We also consent to the reference to us under the heading "Experts" in such Registration Statement.

/s/ PricewaterhouseCoopers LLP

PricewaterhouseCoopers LLP

Boston, Massachusetts

June 21, 2012