

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended March 31, 2012

OR

TRANSITION REPORT UNDER SECTION 13 OF 15(d) OF THE EXCHANGE ACT OF 1934

From the transition period from _____ to _____.

Commission File Number 001-35366

CORONADO BIOSCIENCES, INC.

(Exact name of small business issuer as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)

20-5157386
(IRS Employer
Identification No.)

15 New England Executive Park
Burlington, MA 01803
(Address of principal executive offices)

(781) 238-6621
(Issuer's telephone number)

(Former name, former address and former fiscal year, if changed since last report)

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

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

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

Large accelerated filer

Accelerated filer

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

Smaller reporting company

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

As of May 15, 2012, there were 18,625,749 shares of common stock of the issuer outstanding.

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PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

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>
ASSETS		
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>
LIABILITIES AND STOCKHOLDERS' EQUITY		
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, 461,263 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.

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

	Three Months Ended March 31,		Period from June 28, 2006 (Date of Inception) to March 31,
	2012	2011	2012
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	\$ (6,556)	\$ (22,543)	\$ (68,991)
Basic and diluted net loss per common share	\$ (0.35)	\$ (4.71)	
Weighted average common shares outstanding—basic and diluted	18,604,245	4,791,102	

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

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Coronado Biosciences, Inc. and Subsidiary
(A development stage enterprise)
Consolidated Statements of 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
Cash flows from operating activities:			
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	<u>(5,425)</u>	<u>(1,784)</u>	<u>(29,323)</u>
Cash flows from investing activities:			
Purchase of computer equipment	—	—	(41)
Purchase of in-process research and development	—	(3,809)	(3,843)
Net cash used in investing activities	<u>—</u>	<u>(3,809)</u>	<u>(3,884)</u>
Cash flows from financing activities:			
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	<u>—</u>	<u>—</u>	<u>50,942</u>
(Decrease) Increase in cash and cash equivalents	(5,425)	(5,593)	17,735
Cash and cash equivalents—beginning of period	23,160	14,862	—
Cash and cash equivalents—end of period	<u>\$ 17,735</u>	<u>\$ 9,269</u>	<u>\$ 17,735</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 18	\$ —	\$ 159

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	For the Three Months Ended		Period from
	March 31,		June 28, 2006
	2012	2011	(Date of Inception) to March 31, 2012
Supplemental disclosure of non-cash financing and investing activities:			
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.

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, Inmune Limited. All intercompany balances and transactions have been eliminated.

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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 Corporation ("BioReliance") and Progenitor Cell Therapy LLC ("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 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.

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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 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:

	For the three months ended March 31,	
	2012	2011
<i>(\$ in thousands except share and per share amounts)</i>		
Historical net loss per share:		
<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:

	For the three months ended March 31,	
	2012	2011
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
	3,067,815	8,349,966

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4. Accrued Liabilities

Accrued expenses consisted of the following:

<i>(\$ in thousands)</i>	As of March 31, 2012	As of December 31, 2011
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.

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:

<i>(\$ in thousands)</i>	
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
Total asset acquisition cost	<u>\$20,706</u>

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.

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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.

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:

<i>(\$ in thousands)</i>	For the three months ended		Period from
	2012	2011	June 28, 2006 (Date of Inception) to March 31, 2012
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>

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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 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.

<i>(\$ in thousands)</i>	For the three months ended		Period from
	2012	2011	June 28, 2006 (Date of Inception) to March 31, 2012
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:

	Outstanding Options			Weighted Average Remaining Contractual Life (in years)
	Number of Shares	Weighted Average Exercise Price	Total Weighted Average Intrinsic Value	
<i>(\$ in thousands except per share amounts)</i>				
At December 31, 2011	1,814,070	\$ 2.17	\$ 7,852	9.2
Options granted	390,000	6.64		
Options exercised	—			
Options cancelled	—			
At March 31, 2012	2,204,070	\$ 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.

Item 2. Management’s Discussion and Analysis of Financial Condition and Results of Operations.

References in this report to “we,” “us,” “our,” “the Company” and “Coronado” refer to Coronado Biosciences, Inc. and its subsidiary. References to the “SEC” refer to the United States Securities and Exchange Commission.

Forward-Looking Statements

You should read the following discussion and analysis of our financial condition and results of operations in conjunction with our consolidated financial statements and the related notes included elsewhere in this interim report. Our consolidated financial statements have been prepared in accordance with U.S. GAAP. Our consolidated financial statements and the financial data included in this interim report. The following discussion and analysis contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 and Section 21E of the Securities Exchange Act of 1934 (the “Exchange Act”), including, without limitation, statements regarding our expectations, beliefs, intentions or future strategies that are signified by the words “expect,” “anticipate,” “intend,” “believe,” or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading “Risk Factors” in our Form 10-K for the year ended December 31, 2011. Readers are cautioned not to place undue reliance on these forward-looking statements.

The following discussion of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and the related notes thereto and other financial information appearing in our Form 10-K for the year ended December 31, 2011.

Overview

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

- TSO (or CNDO-201), the microscopic eggs of the porcine whipworm *Trichuris suis*, for the treatment of autoimmune diseases, such as Crohn’s, Ulcerative Colitis and Multiple Sclerosis; and
- CNDO-109, a compound that activates Natural Killer cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia.

In February 2012, we announced positive results from our Phase 1 clinical trial of TSO in patients with Crohn’s disease. The study showed that TSO is safe and well tolerated. 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 disease 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.

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Overall, TSO was found to be safe and well tolerated across all three dose levels tested. There were only two adverse events (metallic taste and sour taste) that were considered to be study drug related as assessed by the investigators, one which was reported in the 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 disease. Under the Collaboration Agreement, Falk granted us exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in Crohn's disease, 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 disease for use in Europe. Under the agreement, we agreed to pay Falk (i) a total of €5 million (approximately \$6.5 million) after receipt of certain pre-clinical and clinical data, €2.5 million (approximately \$3.3 million) of which 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 disease, under which we and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's disease 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 disease. 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 disease. 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.

In February 2012, we filed an IND for CNDO-109. We currently plan to initiate our Phase 1/2 trial with CNDO-109 in the second half of 2012. The IND filing triggered a \$250,000 milestone payment to UCLB, which we accrued in the quarter ended March 31, 2012 and paid in April 2012.

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 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.

We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

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Research and Development (“R&D”) Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued R&D expenses. This process involves reviewing open contracts and purchase orders, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued R&D expenses as of March 31, 2012 include fees to:

- contract research organizations (“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. Milestone obligations are recognized and accrued upon achievement of each milestone event.

Stock-Based Compensation

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

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

- Fair Value of our Common Stock. When our stock was not publicly traded, we estimated the fair value of Common Stock as discussed in “Common Stock Valuations” below. Since November 17, 2011, we have utilized the public trading price of our Common Stock.
- Expected Term. Due to the limited exercise history of our own stock options, we determined the expected term based on the stratification of employee groups and the expected effect of events that have indications on future exercise activity.
- Volatility. As we have a very limited trading history for our Common Stock, the expected stock price volatility for our Common Stock was estimated by taking the average historic price volatility for industry peers based on daily price observations over a period equivalent to the expected term of the stock option grants. Industry peers consist of several public companies in the biopharmaceutical industry similar in size, stage of life cycle and financial leverage. We did not rely on implied volatilities of traded options in our industry peers’ common stock because the volume of activity was relatively low. We intend to continue to consistently apply this process using the same or similar public companies until a sufficient amount of historical information regarding the volatility of our own Common Stock share price becomes available, or unless circumstances change such that the identified companies are no longer similar to us, in which case, more suitable companies whose share prices are publicly available would be utilized in the calculation.

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- 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 three months ended March 31, 2012 and 2011, stock-based compensation expense was \$874,000 and \$210,000, 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.

Common Stock Valuations prior to becoming a publicly-traded company

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

- arm's length private transactions involving our preferred stock, including the sale of our Series A Convertible Preferred Stock ("Series A Shares") at \$8.39 per share in 2010 and our shares of Series C Convertible Preferred Stock 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

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the AICPA Guidelines, an option pricing method was used to value the shares using a contingent claims analysis, which applies a series of call options whose inputs reflect the liquidation preferences and conversion behavior of the different classes of equity. The value of the Common Stock was then derived by analyzing the fair value of these options. After the equity value of the business enterprise was determined, the total equity value of any equity instruments such as preferred stock, stock options, restricted stock and warrants outstanding and the concluded common stock value on a converted basis is allocated. Next, the option pricing method was used to allocate the residual equity value (inclusive of any infusion of cash from in-the-money options and warrants) to our Common Stock. Since our shares were not publicly traded, a discount for lack of marketability was applied. This lack of marketability discount was estimated to be 10% prior to becoming a publicly-traded company, 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 R&D expenses, purchase of in-process research and development and general and administrative (“G&A”) expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant or any revenues.

R&D Expenses

Conducting research and development is central to our business and aggregated \$29.1 million for the period from inception (June 28, 2006) to March 31, 2012. R&D expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;
- license fees and milestone payments related to in-licensed products and 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 and regulatory filings.

We expect to continue to incur substantial expenses related to our R&D activities for the foreseeable future as we continue product development. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our R&D expenses will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product. From inception through March 31, 2012, direct, external development costs incurred for our CNDO-109 product development program were \$5.0 million. 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. We also intend to fund, generally by providing product supply and/or grants, certain investigator-initiated studies evaluating TSO in a range of autoimmune disorders.

G&A Expenses

G&A expenses consist principally of personnel-related costs, professional fees for legal, consulting, audit and tax services, rent and other general operating expenses not otherwise included in R&D and such expenses were \$9.6 million from inception through March 31, 2012. We anticipate G&A expenses will increase in future periods, reflecting continued and increasing costs associated with:

- support of our expanded research and development activities;
- an expanding infrastructure and increased professional fees and other costs associated with the Exchange Act, the Sarbanes-Oxley Act of 2002 (“SOX”) and NASDAQ regulatory requirements and compliance; and
- increased business development activity.

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Comparison of three months ended March 31, 2012 and 2011

(\$ in thousands)	For the three months ended		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>	<u>(71%)</u>

NM—Not meaningful

R&D 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 R&D expenses to increase in future quarters as we continue clinical development of our product candidates and provide 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.

G&A 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 G&A 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 shares of Series B Convertible Preferred Stock 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 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.

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 for our product candidates, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt. We believe that our current cash and cash equivalents are sufficient to fund operations into the fourth quarter of 2012 based on our current business plan. Our current financial condition raises substantial doubt about our ability to continue as a going concern. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. We will seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to us on acceptable terms or at all. If adequate funds are not available to us, we will be required to delay, curtail or eliminate one or more of our research and development programs.

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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
Statement of Cash Flows Data:		
Total cash provided by (used in):		
Operating activities	\$ (5,425)	\$ (1,784)
Investing activities	—	(3,809)
Decrease 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 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.

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 sublicense fees (1)	10,950	4,200	4,250	500	2,000
Purchase and other obligations	<u>4,281</u>	<u>1,799</u>	<u>2,482</u>	<u>—</u>	<u>—</u>
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 disease. 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 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, 2011 and March 31, 2012. Our existing debt is at a fixed rate and we currently do not have exposure to foreign currency fluctuations.

Internal Control Over Financial Reporting

Pursuant to Section 404 of SOX, in our Annual Report on Form 10-K required to be filed with the SEC for the fiscal year ending December 31, 2012, our management will be required to report on, and our independent registered public accounting firm to attest to, the effectiveness of our internal control over financial reporting. The rules governing the standards that must be met for management to assess our internal control over financial reporting are complex and require significant documentation, testing and possible remediation. We have documented, improved and instituted internal controls over financial reporting for compliance with Section 404 of SOX. If material weaknesses or deficiencies in our internal controls exist and go undetected, our financial statements could contain material misstatements that, when discovered in the future could cause us to fail to meet our future reporting obligations and cause the price of our Common Stock to decline.

Net Operating Loss Tax Carryforwards

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 March 31, 2012 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.

Item 3. Quantitative and Qualitative Disclosures about Market Risks

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of March 31, 2012, of the design and operation of our disclosure controls and procedures, as such term is defined in Exchange Act Rules 13a-15(e) and 15d-15(e). Based on this evaluation, our principal executive officer and principal financial officer have concluded that, as of such date, our disclosure controls and procedures are effective to ensure that information required to be disclosed by us in our Exchange Act reports is recorded, processed, summarized, and reported within the time periods specified in the SEC's rules and forms, and that such information is accumulated and communicated to our management, including our principal executive officer and principal financial officer, as appropriate to allow timely decisions regarding required disclosure.

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Changes in Internal Control over Financial Reporting

In February 2012, we hired Lucy Lu, M.D., as Chief Financial Officer.

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

In addition to the other information set forth in this report, you should carefully consider the risk factors discussed in Part I, “Item 1A. Risk Factors” in our Form 10-K for the year ended December 31, 2011, all of which could materially affect our business, financial condition or future results. The risks referred to therein or herein are not the only risks facing our company. Additional risks and uncertainties not currently known to us or that we currently deem to be immaterial also may materially adversely affect our business, financial condition and/or operating results.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

Item 6. Exhibits.

(b) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive Data Files

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SIGNATURES

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

CORONADO BIOSCIENCES, INC.

Date: May 15, 2012

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

Date: May 15, 2012

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

Date: May 15, 2012

By: /s/ Dale Ritter
Dale Ritter, Senior Vice President, Finance and Chief
Accounting Officer (Principal Accounting Officer)

EXHIBIT INDEX

<u>Exhibit No.</u>	<u>Description</u>
31.1	Certification of Chief Executive Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer, pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer and Chief Financial Officer, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101	Interactive Data Files

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

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

(1) I have reviewed this Quarterly Report on Form 10-Q of Coronado Biosciences, Inc. (the “Registrant”);

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

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

(4) The registrant’s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. evaluated the effectiveness of Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s first fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and

(5) The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal controls over financial reporting.

By: /s/ Bobby W. Sandage, Jr.

Bobby W. Sandage, Jr., Ph.D.

Chief Executive Officer

(Principal Executive Officer)

May 15, 2012

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

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

(1) I have reviewed this Quarterly Report on Form 10-Q of Coronado Biosciences, Inc. (the “Registrant”);

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

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

(4) The registrant’s other certifying officers and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) for the registrant and have:

a. designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the Registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b. evaluated the effectiveness of Registrant’s disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

c. disclosed in this report any change in the Registrant’s internal control over financial reporting that occurred during the Registrant’s first fiscal quarter that has materially affected, or is reasonably likely to materially affect, the Registrant’s internal control over financial reporting; and

(5) The Registrant’s other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the Registrant’s auditors and the audit committee of the registrant’s board of directors (or persons performing the equivalent functions):

(a) all significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the Registrant’s ability to record, process, summarize and report financial information; and

(b) any fraud, whether or not material, that involves management or other employees who have a significant role in the Registrant’s internal controls over financial reporting.

By: /s/ Lucy Lu

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

May 15, 2012

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

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

In connection with the Quarterly Report of Coronado Biosciences, Inc. on Form 10-Q for the quarterly period March 31, 2012, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), each of the undersigned does hereby certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that, to the best of his or her knowledge and belief:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of the operation of the company.

May 15, 2012

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

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