

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 September 30, 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.)

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

(781) 652-4500
(Issuer's telephone number)

(Former address, 15 New England Executive Park Burlington, MA 01803)

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 November 13, 2012, there were 24,379,110 shares of common stock of the issuer outstanding.

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(A development stage enterprise)

Consolidated Balance Sheets

(\$ in thousands except for per share amounts)

(Unaudited)

	September 30, 2012	December 31, 2011
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 47,478	\$ 23,160
Prepaid and other current assets	517	215
Total current assets	47,995	23,375
Other assets	90	—
Total Assets	<u>\$ 48,085</u>	<u>\$ 23,375</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 840	\$ 575
Interest payable	116	—
PCP interest payable—related party	—	19
Accrued expenses	3,509	2,899
Total current liabilities	4,465	3,493
PCP notes payable—related party	—	750
Note payable	14,094	—
Other	398	—
Total Liabilities	<u>18,957</u>	<u>4,243</u>
Commitments and Contingencies		
Stockholders' Equity:		
Convertible Preferred Stock, \$.001 par value, 584,390 and 587,376 Series C shares authorized, 0 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	—	—
Common Stock, \$.001 par value, 50,000,000 shares authorized, 24,375,749 and 18,604,245 shares issued and outstanding as of September 30, 2012 and December 31, 2011, respectively	24	19
Additional paid-in capital	104,623	75,687
Deficit accumulated during development stage	(75,519)	(56,574)
Total Stockholders' Equity	29,128	19,132
Total Liabilities and Stockholders' Equity	<u>\$ 48,085</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)

	For the three months ended		For the nine months ended		Period from June 28, 2006 (date of inception) to September 30, 2012
	September 30,		September 30,		
	2012	2011	2012	2011	
Operating expenses:					
Research and development	\$ 3,777	\$ 1,753	\$ 12,893	\$ 5,141	\$ 37,424
General and administrative	2,054	1,778	5,984	3,965	13,608
In-process research and development	—	—	—	20,706	20,706
Loss from operations	(5,831)	(3,531)	(18,877)	(29,812)	(71,738)
Interest income	79	70	152	111	396
Interest expense	(183)	(19)	(220)	(55)	(3,504)
Other income	—	—	—	—	733
Warrant expense	—	115	—	115	(1,407)
Net loss	\$ (5,935)	\$ (3,365)	\$ (18,945)	(29,641)	\$ (75,520)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	—	—	(5,861)	(5,861)
Net loss attributed to Common Stock	\$ (\$5,935)	\$ (3,365)	\$ (18,945)	\$ (35,502)	\$ (81,381)
Basic and diluted net loss per common share	\$ (0.24)	\$ (0.48)	\$ (0.91)	\$ (6.02)	
Weighted average common shares outstanding—basic and diluted	<u>24,375,749</u>	<u>7,028,059</u>	<u>20,738,007</u>	<u>5,897,462</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 Cash Flows
(\$ in thousands)
(Unaudited)

	<u>For the nine months ended</u> <u>September 30,</u>		<u>Period from</u> <u>June 28, 2006</u> <u>(date of</u> <u>inception) to</u> <u>September 30,</u> <u>2012</u>
	<u>2012</u>	<u>2011</u>	
Cash flows from operating activities:			
Net loss	\$ (18,945)	\$ (29,641)	\$ (75,520)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	2,173	787	6,048
Acquired in-process research and development	—	20,706	20,706
Noncash interest	—	—	1,031
Noncash interest—related parties	—	—	286
Contribution of services by stockholder	—	30	130
Issuance of Common Stock to non-employee for services	—	—	120
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	—	(115)	1,407
Amortization of deferred financing costs	35	—	772
Depreciation expense	—	22	41
Changes in operating assets and liabilities:			
Prepaid and other assets	(324)	(43)	(540)
Interest payable—related parties	(19)	19	—
Interest payable	116	—	116
Accounts payable and accrued expenses	875	944	4,351
Net cash used in operating activities	<u>(16,089)</u>	<u>(7,291)</u>	<u>(39,987)</u>
Cash flows from investing activities:			
Purchase of computer equipment	—	—	(41)
Purchase of in-process research and development	—	(3,843)	(3,843)
Net cash used in investing activities	<u>—</u>	<u>(3,843)</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)
Payment of PCP notes payable—Asphelia asset purchase	(750)	—	(750)
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	25,784
Payment of costs related to the issuance of Series C Convertible Preferred Stock	—	(2,884)	(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 the issuance of Common Stock	28,750	80	28,948
Payment of costs related to the issuance of Common Stock	(2,305)	—	(2,305)
Proceeds from issuance of Hercules Note	15,000	—	15,000
Payment of debt issue costs associated with Hercules Note	(288)	—	(288)
Net cash provided by financing activities	<u>40,407</u>	<u>22,980</u>	<u>91,349</u>

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	<u>For the nine months ended</u> <u>September 30,</u>		<u>Period from</u> <u>June 28, 2006</u> <u>(date of</u> <u>inception) to</u> <u>September 30,</u> <u>2012</u>
	<u>2012</u>	<u>2011</u>	
Increase in cash and cash equivalents	24,318	11,846	47,478
Cash and cash equivalents—beginning of period	23,160	14,862	—
Cash and cash equivalents—end of period	<u>\$ 47,478</u>	<u>\$ 26,708</u>	<u>\$ 47,478</u>
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 70	\$ 35	\$ 211
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	\$ 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
Issuance of Warrant related to Hercules Note	\$ 323	\$ —	\$ —

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 biotechnology company. 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 biotechnology company 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 \$75.5 million as of September 30, 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. On June 27, 2012, the Company completed a public offering of 5,750,000 shares of Common Stock resulting in net proceeds of \$26.4 million and on August 28, 2012, the Company received net proceeds of \$14.7 million from a \$15 million term loan with Hercules Technology Growth Capital.

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 first quarter of 2014 based on its existing business plan. 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. 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, as amended, which was initially 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, Innune 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.

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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, compensation expenses related to Common Stock, warrants and 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 exclusively on OvaMed GmbH ("OvaMed") to supply it with its requirements of *Trichuris suis ova* ("TSO"). OvaMed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it is also producing product for third parties, including Dr. Falk Pharma GmbH ("Falk"). OvaMed also relies on certain other suppliers for materials and services. Similarly, the Company currently relies on BioReliance Corporation and Progenitor Cell Therapy LLC 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.

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 Company’s adoption of this guidance during the nine months ended September 30, 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’s adoption of this guidance during the nine months ended September 30, 2012 did not have an impact on the Company’s consolidated financial statements.

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

In December 2011, the FASB issued Accounting Standard Update No. 2011-11, *Disclosures about Offsetting Assets and Liabilities*. The amendments in this update require an entity to disclose information about offsetting and related arrangements to enable users of its financial statements to understand the effect of those arrangements on its financial position. An entity is required to apply the amendments for annual reporting periods beginning on or after January 1, 2013, and interim periods within those annual periods. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. Although the Company is still evaluating the impact of this standard, the Company does not expect this adoption to have a material impact on its financial position or results of operations.

3. Net Loss Per Common Share

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

Basic net loss per share is calculated by dividing the net loss attributable to common stockholders by the weighted-average number of shares of Common Stock outstanding during the period, without consideration for Common Stock equivalents. Diluted net loss per share is computed by dividing the net loss attributable to common stockholders by the weighted-average number of Common Stock and Common Stock equivalents outstanding for the period. For purposes of this calculation, Common Stock equivalents are not included in the calculation of diluted net loss per share.

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

	For the three months ended		For the nine months ended	
	September 30,	September 30,	September 30,	September 30,
	2012	2011	2012	2011
<i>(\$ in thousands except share and per share amounts)</i>				
Historical net loss per share:				
<i>Numerator:</i>				
Net loss	\$ (5,935)	\$ (3,365)	\$(18,945)	\$(29,641)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	—	—	(5,861)

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(\$ in thousands except share and per share amounts)	For the three months ended		For the nine months ended	
	September 30,		September 30,	
	2012	2011	2012	2011
Net loss attributed to Common Stock	\$ (5,935)	\$ (3,365)	\$ (18,945)	\$ (35,502)
<i>Denominator:</i>				
Weighted average common shares outstanding—basic and diluted	24,375,749	7,028,059	20,738,007	5,897,462
Basic and diluted net loss per common share	\$ (0.24)	\$ (0.48)	\$ (0.91)	\$ (6.02)

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 shares 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 September 30,		For the nine months ended September 30,	
	2012	2011	2012	2011
Series A Convertible Preferred Stock	—	4,357,885	—	4,357,885
Series B Convertible Preferred Stock	—	2,525,677	—	2,470,168
Series C Convertible Preferred Stock	—	4,612,624	—	1,869,061
Warrants to purchase Common Stock	1,090,296	1,001,300	1,067,189	717,483
Options to purchase Common Stock	2,369,342	1,473,798	2,231,424	1,368,743
	3,459,638	13,971,284	3,298,613	10,783,340

4. Debt

Hercules Debt Agreement

In August 2012, the Company entered into a Loan and Security (the "Loan Agreement") with Hercules Technology Growth Capital, Inc. ("Hercules") pursuant to which the Company issued a \$15 million note and received net proceeds of \$14.7 million. The loan bears interest at a rate per annum equal to the greater of (i) 9.25% or (ii) 9.25% plus the sum of the prevailing prime rate minus 3.25%. The loan matures on March 1, 2016. The loan requires interest-only payments for the initial 12 months and thereafter requires repayment of the principal balance with interest in 30 monthly installments. The Company may extend the interest-only period for an additional six months, contingent upon the Company's achievement of certain clinical development milestones. In connection with the Loan Agreement, the Company granted first priority liens and the loan is collateralized by substantially all of the Company's assets (exclusive of intellectual property). The Loan Agreement also contains representations and warranties by the Company and Hercules and indemnification provisions in favor of Hercules and customary covenants (including limitations on other indebtedness, liens, acquisitions, investments and dividends, but no financial covenants), and events of default (including payment defaults, breaches of covenants following any applicable cure period, a material impairment in the perfection or priority of Hercules' security interest or in the collateral, and events relating to bankruptcy or insolvency). Pursuant to the Loan Agreement, Hercules has the right to participate, in an amount of up to \$2,000,000, in subsequent private placements of our equity securities at the same terms and conditions, including price, as purchases by other investors. In connection with the Loan Agreement, the Company issued to Hercules a fully-vested, seven-year warrant (the "Warrant") to purchase 73,009 shares of our common stock at an exercise price of \$5.65 per share and granted to Hercules certain "piggyback" registration rights with respect to the shares of common stock underlying the Warrant.

The fair value of the warrant was calculated using the Black-Scholes option-pricing model with the following assumptions: volatility of 87.2%, an expected term equal to the contractual seven-year life of the Warrant, a risk-free interest rate of 1.1% and no dividend yield. The Company recorded the fair value of the Warrant of approximately \$323,000 as equity and as a discount to the carrying value of the loan. Also, upon full repayment or maturity of the loan, Hercules is due a payment of 2.65% of the loan, or \$398,000, which is recorded as a discount to the loan and as a long-term liability. Additionally, the Company incurred fees related to the loan agreement and reimbursed Hercules for costs incurred by them related to the loan aggregating \$218,000 and which is reflected as a discount to the carrying

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value of the loan. The Company will amortize these loan discounts totaling \$939,000 to interest expense over the term of the loan using the effective interest method, which approximates 12.3%. For the three and nine month periods ended September 30, 2012, interest expense related to the Hercules loan was \$164,000.

Paramount Capital Partners Note – Related Party

On September 24, 2012, the Company repaid the principal amount of \$750,000 plus accrued interest on its note to Paramount Capital Partners, a related party, which had a maturity date of December 31, 2013. The payment of \$767,500 included interest of \$17,500 for the quarter through the payment date.

5. Accrued Liabilities

Accrued expenses consisted of the following:

<i>(\$ in thousands)</i>	As of September 30, 2012	As of December 31, 2011
Salaries, bonuses and related benefits	\$ 756	\$ 493
Professional fees	261	215
Research and development expenses	936	653
Accrued milestones	1,500	1,500
Other	56	38
Total accrued expenses	<u>\$ 3,509</u>	<u>\$ 2,899</u>

Accrued milestones at September 30, 2012 and December 31, 2011 include \$1.5 million due to OvaMed which is required to be paid in November 2012.

6. TSO

Asphelia Asset Purchase

On January 7, 2011, the Company entered into an asset purchase agreement (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 shares of 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 shares of 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 the 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

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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 Investigational New Drug Application (“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.

In September 2012, the Company prepaid the \$750,000 PCP Note plus accrued interest of \$17,500.

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 the Company’s planned clinical trials of TSO in Crohn’s disease for use in Europe.

The Company agreed to pay Falk a total of €5 million (approximately \$6.5 million) after receipt of certain preclinical and clinical data, and a royalty equal to 1% of net sales of TSO in North America, South America and Japan. In March 2012, the Company paid Falk €1 million (approximately \$1.4 million) upon receipt of Falk’s pre-clinical data package and recorded this payment as a TSO milestone expense. In April 2012, the Company paid and expensed an additional €1.5 million (approximately \$2.0 million) upon receipt from Falk of the recommendation from the independent data monitoring committee that conducted an interim analysis of the Falk Phase 2 trial. The Company currently expects to expense and pay the remaining €2.5 million (approximately \$3.3 million) in the first half of 2014 upon achievement of the related milestones.

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

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

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.

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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, determined using Level 2 inputs, which include current interest rates on similar borrowings.

The fair value of the Hercules loan payable at September 30, 2012, computed using the effective interest rate method under the loan is \$14.8 million. The effective interest rate considers the fair value of the warrant issued in connection with the loan, loan issuance costs and the deferred charge. The fair value measurement utilizes inputs that are categorized as Level 3.

8. Common Stock

Underwritten Offering

On June 27, 2012, the Company completed an underwritten public offering of 5,750,000 shares of our Common Stock, including 750,000 shares subject to an over-allotment option exercised by the underwriters, at a price of \$5.00 per share for proceeds, net of underwriting commissions and other offering expenses, of approximately \$26.4 million.

Stock-based Compensation Plans

As of September 30, 2012, the Company had two equity compensation plans, the Coronado Biosciences, Inc. 2007 Stock Incentive Plan, for employees, non-employees and outside directors and the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (the "ESPP"). The ESPP was approved by stockholders at the Company's Annual Meeting on August 16, 2012. Eligible employees began to participate in the ESPP effective February 1, 2012.

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, compensation expense for the ESPP and warrants to non-employees for the nine months ended September 30, 2012 and 2011, and from the period June 28, 2006 (date of inception) to date.

(\$ in thousands)	For the nine months ended		Period from
	September 30, 2012	September 30, 2011	June 28, 2006 (date of inception) to September 30, 2012
Employee awards	\$ 1,336	\$ 359	\$ 2,071
Non-employee awards	412	192	3,225
Non-employee warrants	425	231	752
Total stock-based compensation expense	\$ 2,173	\$ 782	\$ 6,048

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	
At December 31, 2011	1,814,070	\$ 2.17	\$ 7,852	9.2
Options granted	620,000	6.86		
Options exercised	—			
Options cancelled	25,000			
At September 30, 2012	2,409,070	\$ 3.28	\$ 4,573	8.7

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	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>				
Options vested and expected to vest	2,409,070	\$ 3.28	\$ 4,573	8.7
Options vested and exercisable	578,023	\$ 1.96	\$ 1,873	8.4

As of September 30, 2012, the Company had unrecognized stock-based compensation expense related to unvested stock options and warrants granted to employees and non-employees of \$5.2 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.6 years.

Warrants to Purchase Common Stock

On August 16, 2012, the Company issued a fully vested warrant to purchase 25,000 shares of Common Stock at a purchase price of \$5.72 as compensation for consulting services provided by a non-employee. The warrant expires on the fifth anniversary of its issuance date. The fair value of the warrant was calculated using a Black-Scholes option-pricing model with the following assumptions: five-year contractual term; 110.33% volatility; 0% dividend rate; and a risk-free interest rate of 0.83%. The fair value of the warrants was determined to be \$112,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of general and administrative expense in the consolidated statements of operations.

On August 16, 2012, the Company issued a fully vested warrant to purchase 20,000 shares of Common Stock at a purchase price of \$5.72 as compensation for consulting services provided by a non-employee. The warrant expires on the sixth anniversary of its issuance date. The fair value of the warrants was calculated using a Black-Scholes option-pricing model with the following assumptions: six-year contractual term; 104.51% volatility; 0% dividend rate; and a risk-free interest rate of 1.06%. The fair value of the warrant was determined to be \$92,000 and was recorded as additional paid-in capital in the consolidated balance sheets and as a component of general and administrative expense in the consolidated statements of operations.

On August 28, 2012, the Company issued a fully vested warrant to purchase 73,009 shares of Common Stock at a purchase price of \$5.65 per share to Hercules in connection with the Loan Agreement. (See Note 4.)

2011 Special Dividend Declaration

In May 2011, the Company's Board of Directors declared a dividend for an aggregate of 2,178,917 shares of Common Stock to the holders of Series A Convertible Preferred Stock ("Series A Shares") in satisfaction of the Special Dividend that would have been due April 26, 2012. In connection with such issuance, the Company (i) eliminated the provision for a Series A Special Dividend on April 26, 2012 and (ii) amended the event 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.

Warrants to Purchase Series C Shares

In connection with the Company's Series C Share offering, the Company (i) paid to National Securities Corporation ("NSC"), a related party, as consideration for its services as the placement agent, a fee equal to 10% of the gross proceeds of the issuance, or \$2.6 million, and (ii) issued warrants to NSC to purchase an aggregate of 461,263 shares of the Company's Series C Shares at an exercise price of \$5.59 per share. The warrants are fully vested and exercisable for five years commencing May 31, 2011.

The fair value of the warrants was \$1.3 million 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 are marked-to-market each reporting period, which resulted in \$115,000 decrease in the warrant liability at September 30, 2011 from the balance at June 30, 2011. The estimated fair value of \$1,170,000 at September 30, 2011 was determined using an option pricing model assuming 90.9% volatility, a 1.76% risk-free rate of interest, a term of five years and an estimated fair value of the Company's Series C Shares of \$5.59 per share.

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.

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9. Lease

In July 2012, the Company entered into a five-year lease for approximately 3,200 square feet of office space in Burlington, Massachusetts at an average annual rent of approximately \$94,000. Total rent expense for the term of this lease will approximate \$470,000. The Company took occupancy of this space in October 2012.

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.

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 Form 10-Q. 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 this Form 10-Q.

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 biologic agents for the treatment of autoimmune diseases and cancer. Our two principal pharmaceutical product candidates in clinical development are:

- TSO, or CNDO-201, the microscopic eggs of the porcine whipworm, for the treatment of autoimmune diseases, such as Crohn's disease, Ulcerative Colitis 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.

In June 2012, we completed an underwritten public offering of 5,750,000 shares of our Common Stock, including 750,000 shares subject to an over-allotment option exercised by the underwriters, at a price of \$5.00 per share for proceeds, net of underwriting commissions and other offering expenses, of approximately \$26.4 million. On August 28, 2012, we received net proceeds of \$14.7 million from a \$15 million term loan with Hercules.

We acquired our exclusive rights to TSO in January 2011 from Asphelia for an aggregate purchase price of \$20.7 million, consisting of 2,525,677 shares of our Series B Convertible Preferred Stock, or Series B Shares, valued at \$6.38 per share, the assumption of promissory notes due to PCP, in the amount of \$750,000, which was prepaid in September 2012 and the assumption of Asphelia's obligation to reimburse OvaMed for certain development costs. Of this purchase price, \$3.8 million 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 payments totaling up to \$5.4 million contingent upon the achievement of various milestones related to regulatory events for the first product, and make additional milestone payments contingent 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 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

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€5 million (approximately \$6.5 million) after receipt of certain pre-clinical and clinical data, of which €2.5 million (approximately \$3.4 million) has been paid and the remaining €2.5 million is expected to be paid in the first half of 2014, and (ii) a royalty of 1% of net sales of TSO in North America, South America and Japan. A steering committee comprised of our representatives and representatives of Falk and OvaMed is overseeing the clinical development program for Crohn's 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.

We acquired an exclusive worldwide license to CNDO-109 in November 2007 from University College of London Business PLC ("UCLB"). In consideration for the license, we paid UCLB initial license fees totaling \$0.1 million and are required to make milestone payments totaling up to \$22 million upon the achievement of various milestones related to regulatory events for the first three indications. In March 2012 we recognized our \$250,000 milestone obligation to UCLB related to our IND filed in February 2012 and in April 2012 we paid UCLB for this milestone. In June 2012, we were notified by the FDA that CNDO-109 was granted orphan drug designation and in September 2012, the U.S. Patent and Trademark Office issued the first U.S. patent covering CNDO-109. If CNDO-109 is commercialized, we will be obligated to pay to UCLB annual royalties based upon net sales of the product or a portion of sublicensing revenues.

Critical Accounting Policies and Use of Estimates

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

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing elsewhere in this Form 10-Q. 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 September 30, 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 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.

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Stock-Based Compensation

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

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

- **Fair Value of our Common Stock.** When our stock was not publicly traded, we estimated the fair value of Common Stock as discussed in “Common Stock Valuations Prior to Becoming a Publicly Traded Company” below. Since November 17, 2011, we have utilized the public trading price of our Common Stock.
- **Expected Term.** Due to the limited exercise history of our own stock options, we determined the expected term based on the stratification of 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.

Stock-based compensation expense for the three months ended September 30, 2012 and 2011 was \$0.9 million and \$0.3 million, respectively, and stock-based compensation expense for the nine months ended September 30, 2012 and 2011 was \$2.2 million and \$0.8 million, respectively. As of September 30, 2012, we had approximately \$5.2 million of unrecognized compensation expense related to employee options and non-employee options and warrants, net of related forfeiture estimates, which we expect to recognize over a weighted-average period of approximately 1.6 years.

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

Common Stock Valuations Prior to Becoming a Publicly Traded Company

Prior to our becoming a publicly-traded company on November 17, 2011, the fair value of the Common Stock underlying our stock options, Common Stock warrants and restricted stock was determined by our board of directors, which intended all options granted to be exercisable at a price per share not less than the per share fair value of our Common Stock underlying those options on the date of grant. However, certain options granted on October 5, 2010 were granted with an exercise price that was below the fair value of our Common Stock as subsequently determined by an independent valuation as of that date. All other options previously granted or to be granted in the future are granted at the determined grant date fair value. The

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valuations of our Common Stock were determined in accordance with the guidelines outlined in the American Institute of Certified Public Accountants, or AICPA, Practice Aid, Valuation of Privately-Held-Company Equity Securities Issued as Compensation, or the Guidelines. The assumptions we use in the valuation model are based on future expectations combined with management judgment. In the absence of a public trading market, our board of directors, with input from management, exercised significant judgment and considered numerous objective and subjective factors to determine the fair value of our Common Stock as of the date of each option, restricted stock and warrant grant, including the following factors:

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

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

As our business and programs evolved, beginning in 2010, we migrated away from the cost approach to a market approach to incorporate the indication of value established through our development efforts and reflected in our Series A Share issuances during 2010. Under this approach, the business enterprise value was established based on the contemporaneous equity offerings. Pursuant to the AICPA Guidelines, an option pricing method was used to value the shares using a contingent claims analysis, which applies a series of call options whose inputs reflect the liquidation preferences and conversion behavior of the different classes of equity. The value of our Common Stock was then derived by analyzing the fair value of these options. After the equity value of the business enterprise was determined, the total equity value of any equity instruments such as preferred stock, stock options, restricted stock and warrants outstanding and the concluded common stock value on a converted basis is allocated. Next, the option pricing method was used to allocate the residual equity value (inclusive of any infusion of cash from in-the-money options and warrants) to our Common Stock. Since our shares were not publicly traded, a discount for lack of marketability was applied. This lack of marketability discount was estimated to be 10% prior to becoming a publicly-traded company. A theoretical put option model was used to capture the cost to ensure stock could be sold at the price prevailing at the valuation date after the time required to finding a market, or the time until an expected liquidity event. The put option model considers the expected time to a liquidity event, estimated volatility based on peer company data, risk free interest rates and management judgment. The ultimate fair values of our Common Stock were used as an input in determining the fair value of the warrants, restricted stock and stock options at various periods of time.

Results of Operations

General

To date, we have not generated any revenues from operations and, at September 30, 2012, we had an accumulated deficit of \$75.5 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.

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Research and Development Expenses

Conducting research and development is central to our business. Research and development expenses for the period from inception (June 28, 2006) to September 30, 2012 were \$37.4 million, including \$3.8 million and \$1.8 million for the three month periods ended September 30, 2012 and 2011, respectively, and \$12.9 million and \$5.1 million for the nine month periods ended September 30, 2012 and 2011, respectively. These 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 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 September 30, 2012, direct, external development costs incurred for our TSO product development program were \$11.3 million (excluding \$20.7 million of in-process research and development costs related to our acquisition of the asset in 2011), including \$2.2 million and \$0.5 million for the three month periods ended September 30, 2012 and 2011, respectively, and \$8.4 million and \$0.7 million for the nine month periods ended September 30, 2012 and 2011, respectively. From inception through September 30, 2012, direct, external development costs incurred for our CNDO-109 product development program were \$5.9 million, including \$0.4 million and \$0.4 million for the three month periods ended September 30, 2012 and 2011, respectively, and \$1.5 million and \$1.3 million for the nine month periods ended September 30, 2012 and 2011, respectively.

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. General and administrative expenses for the period from inception (June 28, 2006) to September 30, 2012 were \$13.6 million, including \$2.1 million and \$1.8 million for the three month periods ended September 30, 2012 and 2011, respectively, and \$6.0 million and \$4.0 million for the nine month periods ended September 30, 2012 and 2011, respectively. General and administrative expenses may increase in future periods due to costs associated with:

- support of our expanded research and development activities;
- an expanding infrastructure and increased professional fees and other costs associated with the regulatory requirements and increased compliance associated with being a public reporting company.

Comparison of Three Months Ended September 30, 2012 and 2011

(\$ in thousands)	For the three months ended September 30,		Variance	
	2012	2011	\$	%
Operating expenses:				
Research and development	\$ 3,777	\$ 1,753	\$2,024	115%
General and administrative	2,054	1,778	276	16%
Loss from operations	(5,831)	(3,531)	2,300	65%
Interest income	79	70	9	13%
Interest expense	(183)	(19)	164	863%
Warrant expense	—	115	(115)	(100%)
Net loss	\$ (5,935)	\$ (3,365)	\$2,570	76%

NM—Not meaningful

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Research and development expenses increased \$2.0 million, or 115%, from the three months ended September 30, 2011 to the three months ended September 30, 2012. External development costs related to TSO increased \$1.7 million reflecting costs related to the commencement during the 2012 period of our Phase 2 trial evaluating TSO in Crohn's disease. Personnel costs increased \$0.4 million due to increased staffing while consulting expenses decreased \$0.2 million. We expect our research and development expenses to increase in future quarters as our Phase 2 trial with TSO continues, our Phase 1/2 trial with CNDO-109 is initiated and we provide clinical supplies or grants for investigator-initiated studies or conduct other proof-of-concept clinical trials evaluating TSO in various autoimmune disorders.

General and administrative expenses increased \$0.3 million, or 16%, from the three months ended September 30, 2011 to the three months ended September 30, 2012, reflecting an increase of \$0.2 million in personnel costs related to the addition of our Chief Financial and Operating Officers, an increase of \$0.2 million relating to non-employee stock compensation expense and an increase of \$0.1 million related to an enhanced insurance program. Offsetting these increases are decreased accounting fees and legal fees of \$0.3 million due to costs incurred in 2011 related to becoming a public company.

Interest expense in the three month and nine month periods ended September 30, 2012 included \$164,000 related to the Hercules note. Interest expense in future quarters related to the Hercules note is expected to be approximately \$450,000.

Comparison of Nine Months Ended September 30, 2012 and 2011

(\$ in thousands)	For the nine months ended September 30,		Variance	
	2012	2011	\$	%
Operating expenses:				
Research and development	\$ 12,893	\$ 5,141	\$ 7,752	151%
General and administrative	5,984	3,965	2,019	51%
In-process research and development	—	20,706	(20,706)	NM
Loss from operations	(18,877)	(29,812)	(10,935)	(37%)
Interest income	152	111	41	37%
Interest expense	(220)	(55)	165	300%
Warrant expense	—	115	(115)	NM
Net loss	(18,945)	(29,641)	(10,696)	(36%)
Common Stock dividend to Series A Preferred Stockholders	—	(5,861)	(5,861)	NM
Net loss	<u>\$ (18,945)</u>	<u>\$ (35,502)</u>	<u>\$(16,557)</u>	<u>(47%)</u>

Research and development expenses increased \$7.8 million, or 151%, from the nine months ended September 30, 2011 to the nine months ended September 30, 2012. This increase was primarily due to \$7.8 million of increased external development costs related to TSO, including milestone expenses of \$3.4 million related to the Collaboration Agreement with Falk

General and administrative expenses increased \$2.0 million, or 51%, from the nine months ended September 30, 2011 to the nine months ended September 30, 2012, reflecting the increase of our business activity that commenced during 2011 as we transitioned to being a public company. The increase in general and administrative expenses consisted primarily of a \$1.3 million increase in personnel costs related to the addition of our Chief Financial and Operating Officers and other support staff and \$0.5 million increased stock compensation expense.

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 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.

Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities aggregating \$93.3 million of net proceeds. In June 2012, we completed an underwritten public offering of 5,750,000 shares of our Common Stock, including 750,000 shares subject to an over-allotment option exercised by the underwriters, at a price of \$5.00 per share, for proceeds, net of underwriting commissions and other offering expenses, of approximately \$26.4 million. In August 2012, we received net proceeds of \$14.7 million from the \$15 million term loan from Hercules. In September 2012, we repaid the \$750,000 PCP Note which we assumed from Asphelia together with accrued interest of \$17,500. At September 30, 2012, we had cash and cash equivalents of \$47.5 million.

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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 believe that our current cash and cash equivalents are sufficient to fund operations into the first quarter of 2014 based on our current business plan. Our failure to raise capital as and when needed would have a material adverse impact on our financial condition and our ability to pursue our business strategies. 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.

Cash Flows for the Nine Months Ended September 30, 2012 and 2011

(\$ in thousands)	For the nine months ended September 30,		
	2012	2011	Variance
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	\$ (16,089)	\$ (7,291)	\$ (8,798)
Investing activities	—	(3,843)	3,843
Financing activities	40,407	22,980	17,427
Increase in cash and cash equivalents	\$ 24,318	\$ 11,846	\$ 12,472

Operating Activities. Net cash used in operating activities increased \$8.8 million from the nine months ended September 30, 2011 to the nine months ended September 30, 2012 and primarily reflects increased net loss. Cash used in operating activities of \$7.3 million in the nine months ended September 30, 2011 primarily reflects the net loss of \$29.6 million, net of the \$20.7 million of non-cash expense for in-process research and development related to the Asphelia Asset Purchase. Cash used in operating activities of \$16.1 million in the nine months ended September 30, 2012 primarily reflects the net loss of \$18.9 million offset by \$2.2 million of noncash expense stock-based compensation and an increase in accounts payable and accrued expenses of \$0.8 million.

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

Financing Activities. Net cash provided by financing activities for the nine months ended September 30, 2011 of \$23.0 million primarily consisted of \$22.9 million of net proceeds from issuance of the Series C Shares and \$80,000 from the exercise of employee stock options. Cash provided by financing activities for the nine months ended September 30, 2012 of \$40.4 million consists of net proceeds of \$26.4 from the issuance of 5,750,000 shares of Common Stock in our underwritten public offering in June 2012, net proceeds of \$14.7 from the Hercules term-loan, offset by the repayment of the PCP note related to the Asphelia transaction of \$0.8 million.

Contingent Contractual Payments. The following table summarizes our contractual obligations as of September 30, 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
Note Payable and interest (1)	\$18,707	\$ 1,984	\$16,723	\$—	\$ —
Operating leases	476	100	188	188	—
Annual license fees (2)	8,700	1,950	4,250	500	2,000
Purchase and other obligations	14,036	10,102	3,934	—	—
Total	\$41,919	\$14,136	\$25,094	\$688	\$2,000

(1) Relates to Hercules Note.

(2) Annual sublicense fees are projected through 2025 and include payments to OvaMed, Falk and UCLB.

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As of September 30, 2012, \$2.4 million of contingent contractual payments are recorded in accrued expenses.

Our purchase and other obligations are primarily associated with our clinical trials, including approximately \$11.8 million for our Phase 2 trial evaluating TSO in Crohn's disease, including \$1.3 million of product supply from Ovamed and approximately \$1.9 million for services associated with our planned Phase 1/2 CNDO-109 trial.

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

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 September 30, 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.

Changes in Internal Control over Financial Reporting

None

PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. 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 September 30, 2012, we had an accumulated deficit of approximately \$75.5 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.

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

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

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

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

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

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

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

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obtaining BLA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Our development of CNDO-109, which is an individualized immunotherapy, may in particular be affected because to date the FDA has only approved one individualized immunotherapy treatment. In addition to the significant clinical testing requirements, our ability to obtain marketing approval for these products depends on obtaining the final results of required non-clinical testing, including characterization of the manufactured components of our product candidates and validation of our manufacturing processes. The FDA may determine that our product manufacturing processes, testing procedures or facilities are insufficient to justify approval. Approval policies or regulations may change and the FDA has substantial discretion in the pharmaceutical approval process, including the ability to delay, limit or deny approval of a product candidate for many reasons. Despite the time and expense invested in clinical development of product candidates, regulatory approval is never guaranteed.

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

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

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

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

- obtaining regulatory clearance to commence a clinical trial;
- identifying, recruiting and training suitable clinical investigators;
- reaching agreement on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation, may be subject to modification from time to time and may vary significantly among different CROs and trial sites;
- obtaining sufficient quantities of a product candidate for use in clinical trials;
- obtaining Investigator Review Board, or IRB, or ethics committee approval to conduct a clinical trial at a prospective site;
- identifying, recruiting and enrolling patients to participate in a clinical trial; and
- retaining patients who have initiated a clinical trial but may withdraw due to adverse events from the therapy, insufficient efficacy, fatigue with the clinical trial process or personal issues. Any delays in the commencement of our clinical trials will delay our ability to pursue regulatory approval for our product candidates. In addition, many of the factors that cause, or lead to, a delay in the commencement of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate.

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

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

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

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

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

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

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We rely completely on OvaMed, Progenitor Cell Therapy, or 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 exclusively on OvaMed to supply us with our requirements of TSO. OvaMed is the sole supplier of this product, which it is currently producing at only one facility in Germany, where it also is producing product for 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 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;
- 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;

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- 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 our product candidates. These indemnification obligations may require us to pay significant sums of money for claims that are covered by these indemnifications.

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

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

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

We will need to expand and effectively manage our managerial, operational, financial and other resources in order to successfully pursue our clinical development and commercialization efforts. As a company with a limited number of personnel, we are highly dependent on the development, regulatory, commercial and financial expertise of the members of our senior management, in particular 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.

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

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

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

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

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

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

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

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

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

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

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

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

Our success also depends upon our ability and the ability of any of our future collaborators to develop, manufacture, market and sell our product candidates without infringing the proprietary rights of third parties. Numerous United States and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

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

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- abandon an infringing product candidate or redesign our products or processes to avoid infringement;
- pay substantial damages, including 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.

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

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

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

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

We are a company in the development stage and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses in all periods since our inception in September 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 \$18.9 million in the nine months ended September 30, 2012. At September 30, 2012, we had an accumulated deficit of approximately \$75.5 million. We expect to make substantial expenditures and incur increasing operating costs in the future and our accumulated deficit will increase significantly as we expand development and clinical trial 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.

Our existing loan agreement contains affirmative and negative covenants that impose significant restrictions on our business and financing activities. If we default on our obligations, whether due to events beyond our control or otherwise, the lender would have a right to foreclose on substantially all of our assets. A default could materially and adversely affect our operating results and our financial condition.

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

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

Our operations have consumed substantial amounts of cash since inception. During the years ended December 31, 2009, 2010 and 2011 and the nine months ended September 30, 2012, we incurred research and development expenses of approximately \$2.3 million, \$8.3 million, \$8.6 million and \$12.9 million, respectively. 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 current cash will be sufficient to meet our anticipated cash requirements into the first quarter of 2014 and that we will require substantial additional funds to support our continued research and development activities, including costs of preclinical studies and clinical trials, obtaining regulatory approvals and potential commercialization and for the payment of principal and interest under our existing loan agreement. We have based this estimate, however, on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

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

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 June 30, 2012 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.

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 will 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.

Prior to 2011, 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 September 30, 2012, Lindsay A. Rosenwald, M.D., a member of our board of directors, beneficially owned approximately 14.7% 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 6.0% of our

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

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

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

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

- sales or potential sales of substantial amounts of our common stock;
- delay or failure in initiating or completing pre-clinical or clinical trials or unsatisfactory results of these trials;
- announcements about us or about our competitors, including clinical trial results, regulatory approvals or new product introductions;
- developments concerning our licensors 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.

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

Almost all of our 24.4 million outstanding shares of common stock, as well as a substantial number of shares of our common stock underlying outstanding warrants, are available for sale in the public market, either pursuant to Rule 144 under the Securities Act of 1933, as amended, or the Securities Act, or an effective registration statement. In addition, we recently filed a shelf registration statement on Form S-3 pursuant to which we may sell up to \$75 million of our equity securities over the next three years. Sales of a substantial number of shares of our common stock, or the perception that such sales may occur, may adversely impact the price of our common stock.

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

We have never paid cash dividends on any of our capital stock and we currently intend to retain future earnings, if any, to fund the development and growth of our business. In addition, the terms of existing and future debt agreements may preclude us from paying dividends. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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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.

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: November 14, 2012

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

Date: November 14, 2012

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

Date: November 14, 2012

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

EXHIBIT INDEX

Exhibit No.	Description
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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., President and 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)

November 14, 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., Executive Vice President and Chief Financial Officer (Principal 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)

November 14, 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 September 30, 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.

November 14, 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)