# UNITED STATES 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 June 30, 2013

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 registrant 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)

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  $\boxtimes$  No  $\square$ 

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  $\square$  No  $\square$ 

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
 Image: Accelerated file

As of August 2, 2013, there were 31,901,334 shares of Common Stock of the issuer outstanding.

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# PART I. FINANCIAL INFORMATION

Item 1. Unaudited Consolidated Financial Statements

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

#### Consolidated Balance Sheets (\$ in thousands except for per share amounts) (Unaudited)

	June 30, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 67,886	\$ 40,199
Prepaid and other current assets	243	393
Total current assets	68,129	40,592
Property and equipment, net	535	51
Other assets	114	349
Total Assets	\$ 68,778	\$ 40,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 1,429	\$ 1,029
Interest payable	116	119
Accrued expenses	2,797	2,185
Current portion of note payable	4,611	1,799
Total current liabilities	8,953	5,132
Note payable	9,760	12,386
Other long-term liabilities	1,507	1,441
Total Liabilities	20,220	18,959
Commitments and Contingencies		
Stockholders' Equity:		
Convertible Preferred Stock, \$.001 par value, 452,923 and 584,390 Series C shares authorized, 0 shares		
issued and outstanding as of June 30, 2013 and December 31, 2012, respectively	—	—
Common Stock, \$.001 par value, 50,000,000 shares authorized, 29,605,524 and 24,400,754 shares issued		
and outstanding as of June 30, 2013 and December 31, 2012, respectively	30	24
Additional paid-in capital	152,240	106,193
Deficit accumulated during development stage	(103,712)	(84,184)
Total Stockholders' Equity	48,558	22,033
Total Liabilities and Stockholders' Equity	\$ 68,778	\$ 40,992

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

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

#### Consolidated Statements of Operations (\$ in thousands except for share and per share amounts) (Unaudited)

		For the three months ended June 30,			For the six months ended June 30,				Period from June 28, 2006 (date of inception) to	
		2013		2012		2013		2012		June 30, 2013
Operating expenses:										
Research and development	\$	7,795	\$	4,525	\$	13,769	\$	9,116	\$	55,778
General and administrative		2,499		1,940		4,983		3,930		21,262
In-process research and development					_				_	21,749
Loss from operations		(10,294)		(6,465)		(18,752)		(13,046)		(98,789)
Interest income		109		29		185		73		665
Interest expense		(485)		(19)		(961)		(38)		(4,914)
Other income		—		_		_		—		733
Warrant expense			_		_		_			(1,407)
Net loss	\$	(10,670)	\$	(6,455)	\$	(19,528)	\$	(13,011)	\$	(103,712)
Common Stock dividend to Series A Convertible Preferred Stockholders										(5,861)
					-				-	<u> </u>
Net loss attributed to Common Stock	\$	(10,670)	\$	(6,455)	\$	(19,528)	\$	(13,011)	\$	(109,573)
Basic and diluted net loss per common share	\$	(0.38)	\$	(0.34)	\$	(0.73)	\$	(0.69)		
Weighted average common shares outstanding—basic and diluted	2	8,095,522	1	9,194,053	-	26,646,993	1	8,899,149		

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

# Coronado Biosciences, Inc. and Subsidiary (A development stage enterprise)

### Consolidated Statements of Cash Flows (\$ in thousands) (Unaudited)

	Enc	For the Six Months Ended June 30,		
	2013	2012	2013	
Cash flows from operating activities:	¢(10,500)	<b>(12 011</b> )	¢ (102 710)	
Net loss	\$(19,528)	\$(13,011)	\$ (103,712)	
Adjustments to reconcile net loss to net cash used in operating activities:	2,806	1 210	10,318	
Stock-based compensation expense Acquired in-process research and development	2,800	1,218	21,749	
Noncash interest expense	262		21,749	
Noncash interest expense—related parties	202		2,100	
Contribution of services by stockholder	_	_	130	
Issuance of Common Stock to non-employee for services			121	
Change in fair value of Common Stock warrant liability			234	
Change in fair value of embedded conversion feature			831	
Change in fair value of preferred stock warrant liability		_	1,407	
Depreciation expense	7		51	
Changes in operating assets and liabilities:				
Prepaid and other current assets	150	(71)	(303)	
Interest payable	(3)		116	
Accounts payable and accrued expenses	1,012	433	4,226	
Net cash used in operating activities	(15,294)	(11,431)	(62,386)	
Cash flows from investing activities:	· · · · · · · · · · · · · · · · · · ·		^	
Purchase of property and equipment	(266)	_	(586)	
Purchase of in-process research and development			(3,843)	
Net cash used in investing activities	(266)		(4,429)	
Cash flows from financing activities:	<u>    (                                </u>			
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)	
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 C Convertible Preferred Stock	_		(2,291)	
Proceeds from issuance of Convertible Preferred Stock Series C			25,784	
Payment of costs related to the issuance of Convertible Preferred Stock Series C	—	_	(2,884)	
Proceeds from borrowings under line of credit	—		80	
Payment of line of credit	—	—	(80)	
Proceeds from Senior Convertible Notes	_	_	7,570	
Payment of debt issue costs	—	—	(737)	
Payment of notes payable—related parties	—	—	(600)	
Proceeds from issuance of Common Stock	44,240	28,750	73,293	
Payment of costs related to the issuance of Common Stock	(993)	(2,272)	(3,298)	
Proceeds from issuance of Hercules Note			15,000	
Payment of debt issue costs associated with Hercules Note			(288)	
Net cash provided by financing activities	43,247	26,478	134,701	
Increase in cash and cash equivalents	27,687	15,047	67,886	
Cash and cash equivalents—beginning of period	40,199	23,160		
Cash and cash equivalents-end of period	\$ 67,886	\$ 38,207	\$ 67,886	

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

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

	For the 9	Six Months Ended June 30, 2012	Period from June 28, 2006 (Date of Inception) to June 30, 2013
Supplemental disclosure of cash flow information:			
Cash paid for interest	\$ 698	\$ 36	\$ 1,260
Supplemental disclosure of non-cash financing and investing activities:			
Issuance of Convertible Preferred Stock Series B for purchase of assets	\$ —	\$ —	\$ 16,114
Assumption of PCP Note related to Asphelia Asset Purchase	\$ —	\$ —	\$ 750
Issuance of Convertible Preferred Stock Series C warrants	\$ —	\$ —	\$ 1,286
Issuance of Common Stock warrants related to the Convertible Preferred Stock Series A			
financing	\$ —	\$ —	\$ 621
Conversion of Senior Convertible Notes into Convertible Preferred Stock Series A	\$ —	\$ —	\$ 8,601
Conversion of notes payable—related parties into Convertible Preferred Stock Series A	\$ —	\$ —	\$ 1,907
Issuance of Common Stock for Convertible Preferred Stock Series A, B and C	\$ —	\$ —	\$ 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 Unaudited Consolidated Financial Statements

#### 1. Organization and Description of Business

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

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

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

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit of \$103.7 million as of June 30, 2013. The Company anticipates incurring additional losses until such time, if ever, that it can generate significant sales from its product candidates. To date, the Company's operations have been funded primarily by issuing equity and debt securities. For the six months ended June 30, 2013, the Company issued 4,864,757 shares of Common Stock for total net proceeds of \$42.8 million under the Company's 2012 and 2013 ATMs (as defined in Note 9). From June 30, 2013 through August 2, 2013, the Company sold an additional 2.2 million shares of Common Stock for net proceeds of \$18.4 million under its 2013 ATM. (See Note 9.)

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 at least for the next twelve months 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, establish manufacturing, and, if deemed appropriate, sales and marketing capabilities. The Company expects that it will seek funds through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to the Company on acceptable terms or at all. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company will be required to delay, reduce or eliminate research and development programs, and pursue merger or acquisition strategies.

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

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

#### 2. Summary of Significant Accounting Policies

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

The 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 management's opinion, 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, 2012 has been derived from the audited consolidated financial statements at that date. The consolidated financial statements and related disclosures have been prepared with the presumption that users of the consolidated financial statements have read or have access to the audited consolidated financial statements for the preceding fiscal year. Accordingly, these consolidated financial statements should be read in conjunction with the Company's Form 10-K which was initially filed with the United States Securities and Exchange Commission, or SEC, on March 18, 2013.

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

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

#### Use of Estimates

The Company's consolidated financial statements include certain amounts that are based on management's best estimates and judgments. The Company's significant estimates include, but are not limited to, useful lives assigned to long-lived assets, 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 currently 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 others, including Dr. Falk Pharma GmbH ("Falk"). Ovamed also relies on certain other suppliers for materials and services. Also, the Company currently relies on BioReliance Corporation, Progenitor Cell Therapy LLC and other third parties 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.

#### **Deferred Financing Costs**

Financing costs incurred in connection with the Hercules Technology Growth Capital, Inc. ("Hercules") note payable were deferred and are being amortized over the appropriate expected life based on the term of the note using the effective interest rate method. As of June 30, 2013 the Company has deferred financing costs of \$53,000 recorded in other assets in the accompanying balance sheet.

#### **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.

#### 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. 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.

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

	For the three months ended June 30,		For the six more June 3					
(\$ in thousands except share and per share amounts)		2013		2012		2013		2012
Historical net loss per share:								
Numerator:								
Net loss attributed to common stockholders	\$	(10,670)	\$	(6,455)	\$	(19,528)	\$	(13,011)
Denominator:								
Weighted-average common shares outstanding—denominator for basic and diluted net loss per share	28	3,095,522	19	9,194,053	2	6,646,993	1	8,899,149
Basic and diluted net loss per common share attributed to common stockholders	\$	(0.38)	\$	(0.34)	\$	(0.73)	\$	(0.69)

The Company's potential dilutive securities which include stock options and warrants have been excluded from the computation of diluted net loss per share as the effect would be to reduce the net loss per share. Therefore, the weighted-average Common Stock outstanding used to calculate both basic and diluted net loss per share are the same.

The following shares of potentially dilutive securities have been excluded from the computations of diluted weighted average shares outstanding, as the effect of including such securities would be antidilutive:

	For the three mont	hs ended June 30,	For the six month	s ended June 30,
	2013	2012	2013	2012
Warrants to purchase Common Stock	1,066,156	1,042,216	1,126,815	1,055,509
Options to purchase Common Stock	4,119,808	2,324,400	4,052,371	2,161,707
	5,185,964	3,366,616	5,179,186	3,217,216

#### 4. Debt and Interest

Interest expense of \$485,000 and \$961,000 for the three and six months ended June 30, 2013, respectively, principally related to the \$15 million term loan with Hercules Technology Growth Capital ("Hercules Note"), and include \$351,000 and \$698,000 in cash interest for the three and six months ended June 30, 2013, respectively, and \$95,000 and \$186,000 related to accretion of the debt discount for the three and six months ended June 30, 2013, respectively. At June 30, 2013, the current portion of the Hercules Note was \$4.6 million and noncurrent portion was \$9.8 million, net of the debt discount of \$629,000.

In 2012, we acquired from Ovamed manufacturing rights for TSO in North and South America and Japan, the Coronado Territory, and agreed to pay Ovamed \$1.5 million in three equal installments of \$500,000 commencing in December 2014 and ending in December 2016. The Company recorded this obligation at December 31, 2012 as an other long-term liability at its estimated net present value of \$1.0 million, using an effective interest rate of 12.33%, and is accreting the carrying amount up to the \$1.5 million obligation. Accretion of the obligation was \$33,500 and \$66,000 for the three and six months ended June 30, 2013, respectively and recorded as interest expense.

# 5. Property and Equipment

Property and equipment consisted of the following:

				F	As of
	Useful Life	As c	of June 30,	Dece	mber 31,
(\$ in thousands)	(Years)		2013	2	2012
Construction in progress	N/A	\$	451	\$	
Computer equipment	3		12		10
Furniture and fixtures	5		70		38
Leasehold improvements	5		12		6
Total property and equipment			545		54
Less: Accumulated depreciation			(10)		(3)
Property and equipment, net		\$	535	\$	51

Construction in progress relates to payments made in connection with the buildout of our Woburn, Massachusetts manufacturing facility.

#### 6. Accrued Expenses and Other Long-Term Liabilities

Accrued expenses and other long-term liabilities consisted of the following:

	As of June 30, 2013	As of December 31, 2012
Accrued expenses:		
Salaries, bonuses and related benefits	\$ 739	\$ 1,064
Severance	554	354
Professional fees	328	320
Research and development expenses	1,038	403
Other	138	44
Total accrued expenses	\$ 2,797	\$ 2,185
Other long-term liabilities:		
Hercules Note, end of term obligation	398	398
Ovamed manufacturing rights	1,109	1,043
Total other long-term liabilities	\$ 1,507	\$ 1,441

#### 7. TSO

#### **Research Agreement**

On February 22, 2013, the Company and Freie Universität Berlin ("FU Berlin") entered into a Research Agreement (the "Research Agreement") to, among other things, identify and evaluate secretory proteins from TSO (the "Project"). The duration of the Project is expected to be four years, during which the Company will pay FU Berlin a total maximum amount of approximately €648,000, or approximately \$853,000 in research fees and FU Berlin will periodically produce written progress reports on the Project. The Research Agreement terminates on the later of the date that the last payment or report is due, subject to early termination by either party upon three months written notice for cause or without cause. If the Company terminates the Research Agreement, the Company must pay FU Berlin a termination fee comprised primarily of unpaid research fees due on the first payment date after which termination occurred (subject to adjustment), except where termination is due to a breach by FU Berlin which it fails to cure within 60 days notice or due to FU Berlin's bankruptcy. For the three and six months ended June 30, 2013, the Company incurred sponsored research expense of \$52,700 and \$75,000, respectively, which was reflected in research and development expense.

On February 22, 2013, the Company and FU Berlin also entered into a Joint Ownership and Exclusive License Agreement (the "JOELA"), pursuant to which the Company agreed to jointly own all intellectual property arising from the Project (the "Joint Intellectual Property"). FU Berlin also granted the Company (a) an exclusive worldwide license (including the right to sublicense) to its interest in the Joint Intellectual Property and its know-how related to the Project (the "Licensed IP"), and (b) the right to commercialize products that, without the licenses granted under the JOELA, would infringe the Licensed IP (the "Licensed Products"). FU Berlin retains the non-exclusive and non-transferable right to use the Licensed IP for its own internal, academic purposes. Pursuant to the JOELA, the Company will pay FU Berlin a total maximum amount of €3,830,000, or approximately \$4,982,000 in potential milestone payments, based primarily on the achievement of clinical development and regulatory milestones, and royalties on potential net sales of products ranging from 1.0% to 2.5%. The JOELA continues until the last-to-expire patent in any country, subject to early termination by either party without penalty if the other party breaches

the JOELA and the breach is not cured within 60 days after receiving notice of the breach or if a party is in bankruptcy. The Company also has the right to terminate the JOELA after giving FU Berlin 60 days written notice of a regulatory action that affects the safety, efficacy or marketability of the Licensed Products or if the Company cannot obtain sufficient materials to conduct trials, or upon 180 days written notice for any reason.

In connection with the Research Agreement and JOELA, the Company entered into a License and Sublicense Agreement (the "LSA") with Ovamed GmbH ("Ovamed") on February 22, 2013, pursuant to which the Company licensed is rights to the Joint Intellectual Property and sublicensed its rights to the Licensed IP to Ovamed in all countries outside North America, South America and Japan (the "Ovamed Territory"). Pursuant to the LSA, Ovamed would pay the Company a total maximum amount of  $\notin$ 1,025,000, or approximately \$1,333,000, based primarily on the achievement of regulatory milestones, and royalties on potential net sales of products ranging from 1.0% to 2.5%, subject to adjustment, in each case equal to the comparable payments due under the JOELA. The LSA continues until the last-to-expire patent in any country in the Ovamed Territory, subject to early termination by either party upon the same terms as in the JOELA.

On February 22, 2013, Coronado, Ovamed and FU Berlin entered into a Letter Agreement (the "Letter Agreement") to amend a Material Transfer Agreement dated May 14, 2012 by and between Ovamed and FU Berlin. The Letter Agreement provides that Ovamed will retain a 10% interest in FU Berlin's rights to the Joint Intellectual Property in the Ovamed Territory. It also grants Ovamed certain rights if FU Berlin terminates the JOELA due to the Company's breach, including the right to have the JOELA survive and the Company's rights and obligations thereunder assigned to Ovamed.

#### 8. Fair Value Measurement

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

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

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

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

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

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

Certain of the Company's financial instruments are not measured at fair value on a recurring basis but are recorded at amounts that approximate their fair value due to their liquid or short-term nature, such as cash and cash equivalents, accounts payable, accrued expenses and other current liabilities. The carrying value of the accrued Ovamed manufacturing rights license included in long-term liabilities has been recorded at its net present value, which approximates its fair value.

The estimated fair value of the Hercules Note at June 30, 2013 computed using the effective interest rate method is \$14.9 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.

#### 9. Common Stock

#### At Market Issuance Programs

In September 2012, the Company filed a shelf registration statement on Form S-3 (the "2012 Form S-3") pursuant to which it could sell up to a total of \$75.0 million of its equity securities and, in October 2012, entered into an At Market Issuance Sales Agreement with MLV & Co LLC ("MLV") to issue and sell up to \$30.0 million of shares of Common Stock under the 2012 Form S-3 (the "2012 ATM"). Upon completion of the 2012 ATM, the Company entered into a new At Market Issuance Sales Agreement with MLV whereby it could issue and sell up to \$45.0 million of shares of Common Stock under the 2012 Form S-3 (the "2013 ATM"). In the six months ended June 30, 2013, the Company sold 4,864,757 shares of Common Stock under the 2012 and 2013 ATMs and received net proceeds of \$42.8 million. Since June 30, 2013 and through August 2, 2013, the Company issued an additional 2.2 million shares of Common Stock for net proceeds of \$18.4 million under the 2013 ATM.

In July 2013, the Company filed a shelf registration statement on Form S-3 (the "2013 Form S-3"). Upon effectiveness of the 2013 Form S-3, the Company may sell up to a total of \$200.0 million of its equity securities. In connection with the 2013 Form S-3, the Company, amended its At Market Sales Issuance Agreement with MLV such that it may offer and sell additional shares of Common Stock having an aggregate offering price of up to \$70.0 million from time to time under the 2013 Form S-3 (the "Amended 2013 ATM"). Pursuant to the terms of the At Market Sales Issuance Agreements with MLV, the Company will pay directly to MLV fees of up to 3% of the gross proceeds of the ATM then in effect.

#### Stock-based Compensation Plans

The Company has three equity compensation plans, the Coronado Biosciences, Inc. 2007 Stock Incentive Plan, the Coronado Biosciences, Inc. 2013 Stock Incentive Plan, (the "2013 Plan") and the 2012 Employee Stock Purchase Plan (the "ESPP"). At the Company's Annual Meeting of Stockholders held on June 19, 2013, the stockholders approved the 2013 Plan, authorizing the Company to grant up to 2,300,000 shares of Common Stock to eligible employees, directors and consultants in the form of stock options, stock appreciation rights, restricted stock awards, and restricted stock unit awards. The Board of Directors determines the amount, terms and exercisability provisions of grants under the 2013 Plan.

*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 six months ended June 30, 2013 and 2012, and from the period June 28, 2006 (date of inception) to date.

	For the six m June		Period from June 28, 2006 (date of inception) to June 30,
(\$ in thousands)	2013	2012	2013
Employee awards	\$ 2,016	\$ 812	\$ 5,222
Non-employee awards	652	242	4,065
Non-employee warrants	138	164	1,031
Total stock-based compensation expense	\$ 2,806	\$ 1,218	\$ 10,318

The following table summarizes stock option activity since December 31, 2012:

	Ou	tstanding Options		Weighted
(\$ in thousands except per share amounts)	Number of	Weighted Average Exercise	Total Weighted Average Intrinsic	Average Remaining Contractual Life (in
At December 31, 2012	Shares 2,519,070	Price \$ 3.37	Value \$ 2,860	years) 8.5
Options granted	2,031,590	6.07	\$ 2,000	0.5
Options exercised	(245,157)	1.56		
Options cancelled	(20,000)	1.93		
At June 30, 2013	4,285,503	\$ 4.77	\$16,434	8.9
Options vested and expected to vest	4,285,503	\$ 4.77	\$16,434	8.9
Options vested and exercisable	1,047,053	\$ 2.84	\$ 6,031	7.9

As of June, 2013 the Company had unrecognized stock-based compensation expense related to unvested stock options to employees and non-employees of \$10.6 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.7 years.

On May 31, 2013, the Company issued 21,505 shares of Common Stock in connection with the ESPP. Common Stock was issued at \$3.88 per share, which represents 85% of the closing price of \$4.56 of the Common Stock on December 3, 2012.

#### Warrants to Purchase Common Stock

For the six months ended June 30, 2013, the Company issued 73,011 shares of Common Stock pursuant to the cashless exercise of 143,429 warrants at a weighted average exercise price of \$5.18, and 340 shares of Common Stock for cash proceeds of \$1,098.

#### 10. Market Capitalization Bonuses and Executive Officer Resignations

#### Market Capitalization Bonuses

Pursuant to the employment agreements with certain executive officers, the Company is obligated to pay certain bonuses to these executive officers upon attainment of specified market capitalizations and trading volumes. The first market capitalization bonus of \$231,250 was earned and paid in the three months ended March 31, 2013 upon attainment of a \$125 million market capitalization and a 30-day trading share volume in excess of 50,000 shares per day. The second market capitalization bonus of \$312,500 was earned and paid in the three months ended Jupon attainment of a \$250 million market capitalization and a 30-day trading share volume in excess of 100,000 shares per day. Expense related to these bonuses were reflected in the periods in which they were earned.

#### Executive Officer Resignations

On April 22, 2013, Dr. Bobby W. Sandage, Jr. resigned as president and director of the Company. In accordance with Dr. Sandage's employment agreement, as amended, Dr. Sandage is entitled to receive his salary and COBRA benefits for twelve months from the date of his resignation. The Company recorded a severance liability of \$445,000 for these obligations in the three-month period ended June 30, 2013. For the three months ended June 30, 2013, the Company paid \$71,000 of the severance obligation to Dr. Sandage and \$81,009 to Dr. Glenn Cooper in connection with his severance arrangement recorded in 2012. For the six months ended June 30, 2013 a total of \$244,000 was paid to Dr. Sandage and Dr. Cooper.

#### 11. Lease

#### New York City Office Lease

In April 2013, the Company entered into a three-year lease for approximately 1,500 square feet of office space in New York City, New York at an average annual rent of approximately \$122,000. Total rent expense for the term of this lease will be approximately \$366,000. The Company took occupancy of this space in May 2013.

#### 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 accounting principles generally accepted in the United States, or GAAP. 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," "may," "will," or similar language. All forward-looking statements included in this document are based on information available to us on the date hereof, and we assume no obligation to update any such forward-looking statements. Our business and financial performance are subject to substantial risks and uncertainties. Actual results could differ materially from those projected in the forward-looking statements. In evaluating our business, you should carefully consider the information set forth under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2012 and below, in Item 1.A. Risk Factors.

#### Overview

We are a clinical stage 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, multiple sclerosis, autism, psoriasis, type 1 diabetes and rheumatoid arthritis; and
- CNDO-109, a biologic that activates natural killer, or NK, cells of the immune system to seek and destroy cancer cells, for the treatment of acute myeloid leukemia.

On February 22, 2013, we and Freie Universität Berlin ("FU Berlin") entered into a Research Agreement to, among other things identify and evaluate secretory proteins from *Trichuris suis ova* ("*TSO*"). The duration of the project is expected to be four years, during which time the Company will pay FU Berlin a total maximum amount of approximately \$853,000 in research fees, commencing February 2013 and ending January 2017. We also entered into several license agreements regarding intellectual property that may result from this research. (See Note 7 of Notes to Consolidated Financial Statements.)

In July 2013, we completed enrollment of TRUST-I, our phase 2 clinical trial with TSO, in 250 Crohn's Disease patients. We expect to have initial study results of this trial in the fourth quarter of 2013.

In September 2012, we filed a shelf registration statement on Form S-3 (the "2012 Form S-3") pursuant to which we could sell up to a total of \$75.0 million of our equity securities and, in October 2012, entered into an At Market Issuance Sales Agreement with MLV to issue and sell up to \$30.0 million of shares of Common Stock under the 2012 Form S-3 (the "2012 ATM"). Upon completion of the 2012 ATM, we entered into a new \$45 million At Market Issuance Sales Agreement with MLV whereby we could issue and sell up to \$45.0 million of shares of Common Stock under the 2012 Form S-3 (the "2012 ATM"). In the six months ended June 30, 2013, we sold 4,864,757 shares of Common Stock under the 2012 and 2013 ATMs and received net proceeds of \$42.8 million. Since June 30, 2013 and through August 2, 2013, we issued an additional 2.2 million shares of Common Stock for net proceeds of \$18.4 million under the 2013 ATM.

In July 2013, we filed a shelf registration statement on Form S-3 (the "2013 Form S-3"). Upon effectiveness of the 2013 Form S-3, we may sell up to \$200.0 million of our equity securities. In connection with the 2013 Form S-3, we amended our At Market Sales Issuance Agreement with MLV such that we may offer and sell additional shares of our Common Stock having an aggregate offering price of up to \$70.0 million from time to time under the 2013 Form S-3 (the "Amended 2013 ATM"). Pursuant to the terms of the At Market Sales Issuance Agreements with MLV, we will pay directly to MLV fees of up to 3% of the gross proceeds of the ATMs then in effect.

In April 2013, Dr. Bobby W. Sandage, Jr. resigned from his position as president of the Company and as a member of the Board of Directors. (See Note 10 of Notes to Consolidated Financial Statements.)

#### **Critical Accounting Policies and Use of Estimates**

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

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements in our Form 10-K for the fiscal year ended December 31, 2012. We believe the following accounting policies are the 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 June 30, 2013 include fees to:

- · Contract Research Organizations, or 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.

#### 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. 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 option holder groups. Our employee options meet the criteria for the Simplified Method under SAB 107, while the expected term for our non-employees is the remaining contractual life for both options and warrants.
- 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 incorporating the first year of our historical volatility and the average historical 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. Coronado's historical volatility is weighted with that of the peer group and that combined historical volatility is weighted 80% with a 20% weighting of our implied volatility, which is obtained from traded options of our stock. We intend to continue to consistently apply this process using the same or similar public companies until we have sufficient historical information regarding the volatility of our own Common Stock that is consistent with the expected life of our options. Should circumstances change such that the identified companies are no longer similar to us, more suitable companies whose share prices are publicly available would be utilized in the calculation.
- Risk-Free Interest 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 plan to pay cash dividends in the foreseeable future. Consequently, we used an expected dividend yield of zero.

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

For the three months ended June 30, 2013 and 2012, stock-based compensation expense was \$1.3 million and \$0.3 million, respectively, for the six months ended June 30, 2013 and 2012, stock-based compensation expense was \$2.8 million and \$1.2 million, respectively, and from inception through June 30, 2013 stock-based compensation expense was \$10.3 million. As of June 30, 2013, we had approximately \$10.6 million of total unrecognized compensation expense, related to unvested stock options and warrants granted to employees and non-employees, which we expect to recognize over a weighted-average period of approximately 1.7 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.

#### **Results of Operations**

#### General

To date, we have not generated any revenues from operations and at June 30, 2013 we had an accumulated deficit of \$103.7 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 or any revenues.

#### **Research and Development Expenses**

Conducting research and development is central to our business and aggregated \$55.8 million for the period from inception (June 28, 2006) to June 30, 2013. Included in research and development expense is noncash, stock-based compensation expense of \$0.6 million and a credit of \$44,000 for the three months ended June 30, 2013 and 2012, respectively, \$1.4 million and \$0.5 million for the six months ended June 30, 2013 and 2012, respectively, \$1.4 million and \$0.5 million for the six months ended June 30, 2013 and 2012, respectively, \$1.4 million and \$0.5 million for the six months ended June 30, 2013 and 2012, respectively, \$1.4 million and development expenses consist primarily of:

- employee-related expenses, which include salaries and benefits, and rent expense;
- noncash stock-based compensation 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, 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 receives regulatory approval, to fund the launch of the product. From inception through June 30, 2013, direct, external development costs related to our acquisition of the asset in 2011 and the manufacturing rights in 2012. From inception through June 30, 2013, direct, external development costs incurred for our CNDO-109 product development program were \$7.2 million. We also intend to fund, generally by providing product supply and/or grants, certain investigator-initiated studies evaluating TSO in a range of autoimmune disorders.

#### 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 and such expenses were \$21.3 million from inception through June 30, 2013. Included in general and administrative expense is noncash, stock-based compensation expense of \$0.7 million and \$0.4 million for the three months ended June 30, 2013 and 2012, respectively, \$1.4 million and \$0.7 million for the six months ended June 30, 2013 and 2012, respectively, and \$4.2 million from inception to June 30, 2013. We anticipate general and administrative expenses will increase in future periods, reflecting continued and increasing costs associated with:

- · support of our expanded research and development and business activities; and
- 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 June 30, 2013 and 2012

	For the three n			
	June	Change		
(\$ in thousands)	2013	2012	\$	%
Operating expenses:				
Research and development	\$ 7,795	\$ 4,525	\$ 3,270	72%
General and administrative	2,499	1,940	559	29%
Loss from operations	(10,294)	(6,465)	(3,829)	59%
Interest income	109	29	80	276%
Interest expense	(485)	(19)	(466)	NM
Net loss	\$ (10,670)	\$ (6,455)	\$(4,215)	65%

NM-Not meaningful

Research and development expenses increased \$3.3 million, or 72%, from \$4.5 million in the three months ended June 30, 2012 to \$7.8 million in the three months ended June 30, 2013. This increase was primarily due to increased costs of \$2.8 million related to our Phase 2 study of TSO in Crohn's, \$1.5 million related to compensation and benefits and \$0.8 million related to establishing our TSO manufacturing facility partially offset by the \$2.3 million milestone payment to Dr. Falk Pharma GmbH ("Falk") in 2012 in connection with the Collaboration Agreement. The \$1.5 million increase in compensation and benefits reflects \$0.8 million increased wage and benefits relating to increased staffing, including our new chief executive officer, net of the savings from the resignation of Dr. Sandage, the expense associated with the achievement of a second market capitalization bonus payment of \$0.1 million to certain of our executive officers, \$0.4 million of severance related to the resignation of Dr. Sandage (see Note 10 of Notes to Consolidated Financial Statements) and \$0.7 million of stock-based compensation primarily related to an increase in stock option grants. We expect our research and development expenses to increase in future quarters as we continue clinical development of our product candidates and provide clinical supplies or grants for investigator-initiated studies evaluating TSO in various autoimmune disorders.

General and administrative expenses increased \$0.6 million, or 29%, from \$1.9 million in the three months ended June 30, 2012 to \$2.5 million in the three months ended June 30, 2013, primarily due to an increase in compensation-related expenses, due in part to the addition of our new chief executive officer, and includes \$0.3 million of noncash stock-based compensation, and the general and administrative portion of the second market capitalization bonus of \$0.1 million to certain of our executive officers for achievement of specified trading volume and market capitalization of Coronado.

The increase in interest income in 2013 compared to the same period last year was primarily due to higher cash balances.

Interest expense in 2013 relates to interest on the Hercules Note.

#### Comparison of six months ended June 30, 2013 and 2012

	For the six months ended June 30,		Variance	
(\$ in thousands)	2013	2012	\$	%
Operating expenses:				
Research and development	\$ 13,769	\$ 9,116	\$ 4,653	34%
General and administrative	4,983	3,930	1,053	21%
Loss from operations	(18,752)	(13,046)	(5,706)	30%
Interest income	185	73	112	61%
Interest expense	(961)	(38)	(923)	NM
Net loss	<u>\$(19,528)</u>	<u>\$(13,011)</u>	<u>\$(6,517)</u>	33%

Research and development expenses increased \$4.7 million, or 34%, from \$9.1 million in the six months ended June 30, 2012 to \$13.8 million in the six months ended June 30, 2013. This increase was primarily due to increased costs of \$5.5 million related to our Phase 2 study of TSO in Crohn's, \$2.3 million related to compensation and benefits and \$1.1 million related to establishing our TSO manufacturing facility partially offset by \$3.6 million of milestone payments to Falk in 2012 in connection with the Collaboration Agreement. The \$2.3 million increase in compensation and benefits reflects \$1.4 million of increased wage and benefits relating to increased staffing, including our new chief executive officer, net of the savings from the resignation of Dr. Sandage, the market capitalization bonuses of \$0.3 million to certain of our executive officers, \$0.4 million of severance related to the resignation of Dr. Sandage (see Note 10 of Notes to Consolidated Financial Statements) and \$1.0 million of stock-based compensation primarily related to an increase in stock option grants. We expect our research and development expenses to increase in future quarters as we continue clinical development of our product candidates and provide clinical supplies or grants for investigator-initiated studies evaluating TSO in various autoimmune disorders.

General and administrative expenses increased \$1.1 million, or 21%, from \$3.9 million in the six months ended June 30, 2012 to \$5.0 million in the six months ended June 30, 2013, primarily due to an increase in compensation-related expenses, due in part to the addition of our new chief executive officer, and includes \$0.6 million of noncash stock-based compensation, and the general and administrative portion of the market capitalization bonuses of \$0.2 million to certain of our executive officers for achievement of specified trading volume and market capitalization of Coronado.

# Liquidity and Capital Resources

To date, we have funded our operations through the sale of debt and equity securities, aggregating \$134.7 million of net proceeds. At June 30, 2013, we had cash and cash equivalents of \$67.9 million. In the six months ended June 30, 2013, the Company sold 4,864,757 shares of Common Stock pursuant to its 2012 and 2013 ATMs and received net proceeds of \$42.8 million. Since June 30, 2013, the Company issued an additional 2.2 million shares of Common Stock for net proceeds of \$18.4 million under its 2013 ATM.

In July 2013, we filed the 2013 Form S-3. Upon its effectiveness and under the Amended 2013 ATM established in connection therewith, we may offer and sell shares of Common Stock having an aggregate offering price of up to \$70.0 million.

We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates. We will require additional financing to develop, prepare regulatory filings and obtain regulatory approvals for our product candidates, fund operating losses, and, if deemed appropriate, establish or secure through third parties manufacturing for our potential products, sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt. We believe that our current cash and cash equivalents are sufficient to fund operations for at least the next twelve months 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 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 six months ended June 30, 2013 and 2012

	For the Six Months Ended June 30, Change		
(\$ in thousands)	2013	2012	
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	\$(15,294)	\$ (11,431)	\$(3,863)
Investing activities	(266)	_	(266)
Financing activities	43,247	26,478	16,769
Increase in cash and cash equivalents	\$ 27,687	\$ 15,047	\$12,640

#### **Operating Activities**

Net cash used in operating activities increased \$3.9 million from the six months ended June 30, 2012 to the six months ended June 30, 2013 primarily reflecting \$6.5 million of increased net loss and \$1.6 million of increased noncash stock-based compensation expense.

#### **Investing Activities**

Net cash used in investing activities in the six months ended June 30, 2013 relates primarily to payments for construction of our Woburn manufacturing facility.

#### **Financing Activities**

Net cash provided by financing activities of \$43.3 million in the six months ended June 30, 2013 reflects net proceeds primarily from the sale of Common Stock under our 2012 and 2013 ATMs of \$42.9 million as well as proceeds from the exercise of employee options and our ESPP plan. Net cash provided by financing activities of \$26.5 million in the six months ended June 30, 2012 reflects net proceeds from our June 2012 underwritten public offering of Common Stock.

#### **Contractual Obligations and Commitments**

There have been no material changes to our contractual obligations and commitments outside of the ordinary course of business from those disclosed on our annual report on Form 10-K for the year ended December 31, 2012.

#### **Off-Balance Sheet Arrangements**

None.

# Net Operating Loss Tax Carryforwards

As of December 31, 2012, we had net federal operating loss carryforwards of approximately \$53.5 million to offset future federal income taxes which expire beginning in 2026 and state operating loss carryforwards of \$16.8 million to offset future state taxes which expire beginning in 2030. Current federal and state tax laws include substantial restrictions on the utilization of net operating loss and tax credits in the event of an ownership change. Even if the carryforwards are available, they may be subject to substantial annual limitations, due to ownership change limitations provided by the Internal Revenue Code of 1986 as amended, or IRC and similar state provisions. At December 31, 2011 and 2012, we recorded a 100% valuation allowance against our deferred tax assets, as our management believes it is more likely than not that they will not be realized. If we determine in the future that we will be able to realize all or a portion of our net operating loss carryforwards, an adjustment to our net operating loss carryforwards would increase net income in the period in which we make such a determination.

#### Item 3. Quantitative and Qualitative Disclosures about Market Risks

We held no marketable securities at June 30, 2013 and December 31, 2012. The Company's Loan and Security Agreement with Hercules Technology Growth Capital, Inc., or the Hercules Note, pursuant to which the Company issued a \$15 million note, 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%. To the extent the prevailing prime rate exceeds 3.25%, the Company will pay a higher rate of interest on any then-outstanding principal balance.

# 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 June 30, 2013, 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

No change in internal control over financial reporting occurred during the most recent fiscal quarter with respect to our operations, which has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

# 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 June 30, 2013, we had an accumulated deficit of approximately \$103.7 million. We have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our products. The successful commercialization of any of our products will require us to perform a variety of functions, including:

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

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

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

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

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

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

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 the 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 Biologics License Application ("BLA") to the FDA and even fewer are approved for commercialization.

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

The clinical development, manufacturing, labeling, storage, record-keeping, advertising, promotion, import, export, marketing and distribution of our product candidates, TSO and CNDO-109, are subject to extensive regulation by the FDA in the United States and by comparable health authorities in foreign markets. In the United States, we are not permitted to market our product candidates until we receive approval of a BLA from the FDA. The process of obtaining BLA approval is expensive, often takes many years and can vary substantially based upon the type, complexity and novelty of the products involved. Our development of CNDO-109, which is an individualized immunotherapy, may in particular be affected because to date the FDA has only approved one individualized immunotherapy treatment, Provenge by Dendreon Corporation. 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 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 another 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 our manufacturing processes or facilities or those 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 CNDO-109 Phase 1/2 trial is subject to a set of DLTs that could suspend or stop dose escalation by predetermined criteria, including allergic reactions, prolonged aplasia or other organ toxicities of a serious nature.

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

Delays in the commencement of our clinical trials could result in increased costs and delay our ability to pursue regulatory approval. The commencement of clinical trials can be delayed for a variety of reasons, including delays in:

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

Though we are in the process of establishing a U.S. manufacturing facility, we currently rely completely on Ovamed, and other third parties to manufacture our supplies of TSO. Our dependence on third party suppliers or our inability to successfully produce TSO could adversely impact our business.

While we are establishing a manufacturing facility in Woburn, MA for a portion of our Phase 3 clinical supplies and our potential commercial supplies of TSO, we currently rely exclusively on Ovamed to supply us with our requirements of TSO. Ovamed produces TSO at only one facility in Germany, where it also produces 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. In the event that the FDA or such other agencies determine that we, Ovamed or Ovamed's 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 or Ovamed are able to obtain appropriate replacement material. Furthermore, if Ovamed, we or any other contract manufacturer who supply Ovamed or us 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 TSO. We, Ovamed and our third-party suppliers are and will be required to maintain compliance with cGMPs and will be subject to inspections by the FDA or comparable agencies in other jurisdictions to confirm such compliance. Any delay, interruption or other issues that arise in the manufacture, packaging or storage of our products as a result of a failure of our or Ovamed's facilities or operations or of our third party suppliers to pass any regulatory agency inspection could significantly impair our ability to develop and commercialize our products.

We do and 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 TSO. We will and Ovamed does rely on a single source of ova. We do not have any control over the process or timing of the acquisition of 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 or Ovamed may not have the resources or capacity to commercially manufacture TSO, if approved, and we will likely continue to be dependent upon third party manufacturers at least until we have completed establishing our manufacturing facility in Woburn, MA and potentially even thereafter. Our current inability or 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 TSO on a timely basis or at all.

# We currently rely completely on Progenitor Cell Therapy, or PCT, and other third parties to manufacture our preclinical and clinical pharmaceutical supplies of CNDO-109 and expect to continue to rely on these third parties to produce commercial supplies of CNDO-109, and our dependence on third party suppliers could adversely impact our business.

We are completely dependent on third party manufacturers for product supply of CNDO-109. 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, 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 CNDO-109. 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 CNDO-109. 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 CNDO-109 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 CNDO-109.

We do not expect to have the resources or capacity to commercially manufacture CNDO-109, 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 CNDO-109 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 and do use CROs to conduct our planned clinical trials and will and do rely upon such CROs, as well as medical institutions, clinical investigators and consultants, to conduct our trials in accordance with our clinical protocols. Our CROs, investigators and other third parties will and do play a significant role in the conduct of these trials and the subsequent collection and analysis of data from the clinical trials.

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

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

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

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

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

- the efficacy and safety as demonstrated in clinical trials;
- the clinical indications for which the product is approved;

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

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

# We may 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 and do 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 Harlan F. Weisman, M.D., our chairman and chief executive officer. The loss of this individual or the services of any of our other senior management could delay or prevent the further development and potential commercialization of our product candidates and, if we are not successful in finding suitable replacements, could harm our business. Our success also depends on our continued ability to

attract, retain and motivate highly qualified management and scientific personnel and we may not be able to do so in the future due to the intense competition for qualified personnel among biotechnology and pharmaceutical companies, as well as universities and research organizations. If we are not able to attract and retain the necessary personnel, we may experience significant impediments to our ability to implement our business strategy.

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

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

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

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

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

Our success will depend, in large part, on obtaining and maintaining patent protection and trade secret protection for our product candidates and their formulations and uses, as well as successfully defending these patents against third-party challenges. UIRF, Falk and Ovamed are responsible for prosecuting and maintaining patent protection relating to their respective patents relating to TSO and UCLB is responsible for prosecuting and maintaining patent protection for CNDO-109, in each case at our expense for our territories. If UIRF, Falk, Ovamed and/or UCLB fail to appropriately prosecute and maintain patent protection for these product 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 U.S. government and other international governmental bodies to limit the scope of
  patent protection both inside and outside the United States for disease treatments that prove successful as a matter of public
  policy regarding worldwide health concerns; and
- countries other than the United States may have patent laws less favorable to patentees than those upheld by U.S. courts, allowing foreign competitors a better opportunity to create, develop, and market competing products.

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

We also intend to rely on our ability to obtain and maintain a regulatory period of market exclusivity for any of our biologic product candidates that are successfully developed and approved for commercialization. Although this period in the United States is currently 12 years from the date of marketing approval, there is a risk that the U.S. Congress could amend laws to significantly shorten this exclusivity period, as proposed by President Obama. 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, U.S. 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 America Invents Act, was signed into law, and includes a number of significant changes to U.S. 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 U.S. Patent and Trademark Office implemented the America Invents Act on March 16, 2013, and it remains to be seen how the judicial system and the U.S. Patent and Trademark Office will interpret and enforce these new laws. Accordingly, it is not clear what impact, if any, the America Invents 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 on 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 U.S. and foreign issued patents and pending patent applications, which are owned by third parties, exist in the fields in which we are developing products, some of which may be directed at claims that overlap with the subject matter of our intellectual property. Because patent applications can take many years to issue, there may be currently pending applications, unknown to us, which may later result in issued patents that our product candidates or proprietary technologies may infringe. Similarly, there may be issued patents relevant to our product candidates of which we are not aware.

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

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

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

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

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

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

### 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 or any revenues or whether we will achieve or sustain profitability.

We are a development stage company and our prospects must be considered in light of the uncertainties, risks, expenses and difficulties frequently encountered by companies in their early stages of operations. We have generated operating losses in all periods since our inception in June 2006, including losses of approximately \$10.0 million, \$36.4 million and \$27.6 million for the years ended December 31, 2010, 2011 and 2012, respectively, and approximately \$19.5 million for the six months ended June 30, 2013. At June 30, 2013, we had an accumulated deficit of approximately \$103.7 million. We expect to make substantial expenditures and incur increasing operating costs and interest expense 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 or any revenues or if we will ever achieve or sustain profitability.

Our existing \$15.0 million term 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, other than our intellectual property. A default could materially and adversely affect our operating results and our financial condition. The loan agreement also contains several affirmative and negative covenants that impose significant restrictions on our business and operations. 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 satisfy 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, 2010, 2011 and 2012, we incurred research and development expenses of approximately \$8.3 million, \$8.6 million and \$17.5 million, respectively. Since our inception in 2006 to June 30, 2013, we have incurred research and development expenses of approximately \$55.8 million. We expect to continue to spend substantial amounts on product development, including conducting clinical trials for our product candidates, establishing manufacturing capabilities for TSO in the United States, and purchasing clinical trial materials from our suppliers. We believe that our current cash will be sufficient to meet our anticipated cash requirements for the next twelve months 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 estimation on assumptions that may prove to be wrong, and we could spend our available financial resources much faster than we currently expect.

Until such time, if ever, as we can generate a sufficient amount of product revenue and achieve profitability, we expect to seek to finance future cash needs through equity or debt financings or corporate collaboration or licensing arrangements. We cannot be certain that additional funding will be available on acceptable terms, or at all. If we are unable to raise additional capital, we will have to delay, curtail or eliminate one or more of our research and development programs.

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

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

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

Pursuant to Section 404 of the Sarbanes Oxley Act of 2002 and related rules, our management is required to report on, and our independent registered public accounting firm is 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. 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**

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, product manufacturers or our ability to produce TSO;
- 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 31,901,334 outstanding shares of Common Stock as of August 2, 2013, 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. We sold 3,361 shares of our Common Stock resulting in net proceeds to us of \$19,000 in 2012 and, from January 1, 2013 through to August 2, 2013, we sold 7,105,567 shares of our Common Stock resulting in net proceeds to us of \$61.2 million pursuant to the 2012 and 2013 ATMs. Upon effectiveness of the 2013 Form S-3, we may sell up to a total of \$200.0 million of our equity securities. 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.

Provisions in our certificate of incorporation, our bylaws 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 amended and restated certificate of incorporation, as amended and our amended and restated bylaws 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.

Delaware General Corporation Law generally prohibits a publicly-held Delaware corporation from engaging in a business combination with an interested stockholder for a period of three years after the date of the transaction in which the person became an interested stockholder, unless, upon consummation of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, or the business combination was 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
<b>N</b> .				

None.

Item 4.	Mine Safety Disclosures
None.	

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Item 5. Other Information
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None.

#### Item 6. Exhibits.

(b) Exhibits

Exhibit No.	Description
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, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of 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.INS*	XBRL Instance Documents
101.SCH*	XBRL Taxonomy Extension Schema Document
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Document
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document

\* Pursuant to Rule 406T of Regulation S-T, the XBRL-related information in Exhibit 101 to this Quarterly Report on Form 10-Q shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended or otherwise subject to liability of that Section, and shall not be part of any registration statement or other document filed under the Securities Act of 1933, as amended or the Securities Exchange Act of 1934, as amended, except as shall be expressly set forth by specific reference in such filing.

#### 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.

Date: August 5, 2013 By: /s/ Harlan F. Weisman Harlan F. Weisman, Chief Executive Officer (Principal Executive Officer) Date: August 5, 2013 By: /s/ Lucy Lu, M.D. Officer (Principal Financial Officer) Date: August 5, 2013 By: <u>/s/ Dale Ritt</u>er Dale Ritter, Senior Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)

CORONADO BIOSCIENCES, INC.

Lucy Lu, M.D., Executive Vice President and Chief Financial

# EXHIBIT INDEX

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#### CORONADO BIOSCIENCES, INC. CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Harlan F. Weisman, 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. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) 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/ Harlan F. Weisman

Harlan F. Weisman Chief Executive Officer (Principal Executive Officer)

August 5, 2013

#### CORONADO BIOSCIENCES, INC. CERTIFICATION PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

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. designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c. 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

d. disclosed in this report any change in the Registrant's internal control over financial reporting that occurred during the Registrant's most recent fiscal quarter (the registrant's fourth quarter in the case of an annual report) 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, M.D.

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

August 5, 2013

#### CORONADO BIOSCIENCES, INC. CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO 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 ended June 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I Harlan F. Weisman, Chief Executive Officer, 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 operations of the company, as of, and for, the periods presented in the Report.

August 5, 2013

By: /s/ Harlan F. Weisman

Harlan F. Weisman Chief Executive Officer (Principal Executive Officer)

#### CORONADO BIOSCIENCES, INC. CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350 AS ADOPTED PURSUANT TO 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 ended June 30, 2013, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I, Lucy Lu, Chief Financial Officer, 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 operations of the company, as of, and for, the periods presented in the Report.

August 5, 2013

By: /s/ Lucy Lu, M.D.

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