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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 September 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	**20-5157386**
(State or other jurisdiction of incorporation or organization)	**(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 ☒ No ☐

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

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

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

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

As of October 30, 2013, there were 35,611,883 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)

	September 30, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	$ 106,267	$ 40,199
Prepaid and other current assets	279	393
Total current assets	106,546	40,592
Property and equipment, net	452	51
Other assets	109	349
Total Assets	$ 107,107	$ 40,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	$ 1,114	$ 1,029
Interest payable	116	119
Accrued expenses	2,352	2,185
Current portion of note payable	6,062	1,799
Total current liabilities	9,644	5,132
Note payable	8,408	12,386
Other long-term liabilities	1,541	1,441
Total Liabilities	19,593	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 September 30, 2013 and December 31, 2012, respectively	—	—
Common Stock, $.001 par value, 100,000,000 and 50,000,000 shares authorized as of September 30, 2013 and December 31, 2012, respectively, 35,255,680 and 24,400,754 shares issued and outstanding as of September 30, 2013 and December 31, 2012, respectively	35	24
Additional paid-in capital	199,023	106,193
Deficit accumulated during development stage	(111,544)	(84,184)
Total Stockholders' Equity	87,514	22,033
Total Liabilities and Stockholders' Equity	$ 107,107	$ 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 September 30,		For the nine months ended September 30,		Period from June 28, 2006 (date of inception) to September 30, 2013
	2013	2012	2013	2012	
Operating expenses:					
Research and development	$ 5,361	$ 3,777	$ 19,130	$ 12,893	$ 61,139
General and administrative	2,143	2,054	7,126	5,984	23,405
In-process research and development	—	—	—	—	21,749
Loss from operations	(7,504)	(5,831)	(26,256)	(18,877)	(106,293)
Interest income	165	79	350	152	830
Interest expense	(493)	(183)	(1,454)	(220)	(5,407)
Other income	—	—	—	—	733
Warrant expense	—	—	—	—	(1,407)
Net loss	(7,832)	(5,935)	(27,360)	(18,945)	(111,544)
Common Stock dividend to Series A Convertible Preferred Stockholders	—	—	—	—	(5,861)
Net loss attributed to Common Stock	$ (7,832)	$ (5,935)	$ (27,360)	$ (18,945)	$ (117,405)
Basic and diluted net loss per common share	$ (0.24)	$ (0.24)	$ (0.95)	$ (0.91)	
Weighted average common shares outstanding—basic and diluted	32,634,683	24,375,749	28,664,822	20,738,007	

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

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

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

	For the Nine Months Ended September 30,		Period from June 28, 2006 (Date of Inception) to September 30,
	2013	2012	2013
Cash flows from operating activities:			
Net loss	$ (27,360)	$ (18,945)	$ (111,544)
Adjustments to reconcile net loss to net cash used in operating activities:			
Stock-based compensation expense	4,072	2,173	11,584
Acquired in-process research and development	—	—	21,749
Noncash interest expense	400	35	2,298
Noncash interest expense—related parties	—	—	286
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	11	—	55
Changes in operating assets and liabilities:			
Prepaid and other current assets	114	(324)	(339)
Interest payable	(3)	97	116
Accounts payable and accrued expenses	252	875	3,466
Net cash used in operating activities	(22,514)	(16,089)	(69,606)
Cash flows from investing activities:			
Purchase of property and equipment	(187)	—	(507)
Purchase of in-process research and development	—	—	(3,843)
Net cash used in investing activities	(187)	—	(4,350)
Cash flows from financing activities:			
Proceeds from PCP notes payable—related party	—	—	570
Payment of PCP notes payable—related party	—	—	(570)
Payment of PCP notes payable—Asphelia asset purchase	—	(750)	(750)
Proceeds from notes payable—related parties	—	—	2,221
Proceeds from issuance of Series A Convertible Preferred Stock	—	—	21,681
Payment of costs related to the issuance of Series 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	90,629	28,750	119,682
Payment of costs related to the issuance of Common Stock	(1,860)	(2,305)	(4,165)
Proceeds from issuance of Hercules Note	—	15,000	15,000
Payment of debt issue costs associated with Hercules Note	—	(288)	(288)
Net cash provided by financing activities	88,769	40,407	180,223
Increase in cash and cash equivalents	66,068	24,318	106,267
Cash and cash equivalents—beginning of period	40,199	23,160	—
Cash and cash equivalents—end of period	$ 106,267	$ 47,478	$ 106,267

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

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

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

	For the Nine Months Ended September 30,		Period from June 28, 2006 (Date of Inception) to September 30,
	2013	2012	2013
Supplemental disclosure of cash flow information:			
Cash paid for interest	$ 1,052	$ 36	$ 1,609
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 pre-commercial relationships, hiring qualified personnel and raising capital to fund operations. The Company continues to report as a development stage enterprise since planned principal operations have not yet commenced. Since inception, no revenue has been recognized.

On October 14, 2013 the Company reported that the TRUST-I study, its phase 2 randomized, double-blind, placebo-controlled, U.S. multi-centered study to evaluate the safety and efficacy of TSO in Crohn's disease, did not meet its primary endpoint of improving response, defined as a 100-point decrease in the Crohn's Disease Activity Index (CDAI), nor the key secondary endpoint of remission, defined as achieving CDAI $\leq$ 150 points. In the overall patient population, response rate of patients on TSO did not separate from that of placebo.

The Company's development partner for TSO in Crohn's disease, Dr. Falk Pharma GmbH, is conducting TRUST-II, a phase 2, double-blind, randomized, placebo-controlled, multi-center study in Europe to evaluate the efficacy and safety of three different dosages of TSO in active Crohn's disease. The results from a second interim analysis are expected in the fourth quarter of 2013.

The Company has incurred losses and experienced negative operating cash flows since inception and has an accumulated deficit of $111.5 million as of September 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 nine months ended September 30, 2013, the Company issued 10,352,219 shares of Common Stock for total net proceeds of $88.0 million under the Company's 2012 and 2013 ATMs (See Note 9). Since September 30, 2013 through October 2, 2013, the Company sold an additional 206,203 shares of Common Stock for net proceeds of $1.4 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. The Company is continuing to evaluate the data from the TRUST-I trial and other current data on TSO and is awaiting the results of the TRUST-II trial to determine the future development plan for TSO. Until it has completed that process and made a determination regarding the future development for TSO, it does not expect its current level of expenditures to increase in the next 12 months. However, the Company believes that cash and cash equivalents on hand are sufficient to sustain operations at least for the next 12 months. The Company would require additional financing to fully 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 would need to seek funds through public or private equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding may not be available to the Company on acceptable terms or at all. The Company's failure to raise capital as and when needed would have a negative impact on its financial condition and its ability to pursue its business strategies. If adequate funds are not available to the Company, the Company will be required to delay, reduce or eliminate research and development programs, and pursue merger or acquisition strategies, if possible.

Operations of the Company are subject to other 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 of product candidates, failures of product candidates to successfully meet clinical-trial goals or delays in 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 September 30, 2013 the Company has deferred financing costs of $48,000 recorded in other assets in the accompanying balance sheet. (See Note 4)

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 September 30,		For the nine months ended September 30,	
($ in thousands except share and per share amounts)	2013	2012	2013	2012
Historical net loss per share:				
Numerator:				
Net loss attributed to common stockholders	$ (7,832)	$ (5,935)	$ (27,360)	$ (18,945)
Denominator:				
Weighted-average common shares outstanding—denominator for basic and diluted net loss per share	32,634,683	24,375,749	28,664,822	20,738,007
Basic and diluted net loss per common share attributed to common stockholders	$ (0.24)	$ (0.24)	$ (0.95)	$ (0.91)

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 months ended September 30,		For the nine months ended September 30,	
	2013	2012	2013	2012
Warrants to purchase Common Stock	1,040,921	1,090,294	1,097,869	1,067,187
Options to purchase Common Stock	4,285,503	2,369,342	4,130,936	2,231,425
	5,326,424	3,459,636	5,228,805	3,298,612

4. Debt and Interest

Interest expense of $493,000 and $1,453,000 for the three and nine months ended September 30, 2013, respectively, principally related to the $15 million term loan with Hercules Technology Growth Capital ("Hercules Note"), and include $355,000 and $1,052,000 in cash interest for the three and nine months ended September 30, 2013, respectively, and $99,000 and $286,000 related to accretion of the debt discount for the three and nine months ended September 30, 2013, respectively. At September 30, 2013, the current portion of the Hercules Note was $6.1 million and noncurrent portion was $8.9 million, net of the debt discount of $530,000. The Company made its first principal payment of $446,000 on October 1, 2013.

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 $34,500 and $100,500 for the three and nine months ended September 30, 2013, respectively and recorded as interest expense.

5. Property and Equipment

Property and equipment consisted of the following:

($ in thousands)	Useful Life (Years)	As of September 30, 2013	As of December 31, 2012
Construction in progress	N/A	$ 372	$ —
Computer equipment	3	12	10
Furniture and fixtures	5	70	38
Leasehold improvements	5	12	6
Total property and equipment		466	54
Less: Accumulated depreciation		(14)	(3)
Property and equipment, net		$ 452	$ 51

Construction in progress relates to payments made in connection with the build-out 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 September 30, 2013	As of December 31, 2012
Accrued expenses:		
Salaries, bonuses and related benefits	$ 582	$ 1,064
Severance	352	354
Professional fees	399	320
Research and development expenses	851	403
State franchise taxes	56	—
Other	112	44
Total accrued expenses	$ 2,352	$ 2,185
Other long-term liabilities:		
Hercules Note, end of term obligation	$ 398	$ 398
Ovamed manufacturing rights	1,143	1,043
Total other long-term liabilities	$ 1,541	$ 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 nine months ended September 30, 2013, the Company incurred sponsored research expense of $52,500 and $127,400, 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 €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 September 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, in April 2013, 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 July 2013, the Company filed a shelf registration statement on Form S-3 (the "2013 Form S-3"), which was declared effective on August 19, 2013.The Company may sell up to a total of $200.0 million of its equity securities under the 2013 Form S-3. In connection with the 2013 Form S-3, the Company amended its 2013 ATM 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 ATM's with MLV, the Company will pay directly to MLV fees of up to 3% of the gross proceeds of the ATM then in effect. In the nine months ended September 30, 2013, the Company sold 10,352,219 shares of Common Stock under the ATMs and received net proceeds of $88.0 million. Since September 30, 2013 and through October 2, 2013, the Company sold an additional 206,203 shares of Common Stock for net proceeds of $1.4 million under the Amended 2013 ATM.

Authorized Shares

On September 30, 2013, the Company held a Special Meeting of Stockholders. At the meeting the Company's Stockholders' approved an amended and restated certificate of incorporation, to increase the number of authorized shares of capital stock from 65,000,000 shares to 115,000,000 shares and to increase the number of authorized shares of Common Stock from 50,000,000 to 100,000,000.

Stockholders' Equity

The following table summarizes stockholders' equity activity for the nine months ended September 30, 2013 ($000's):

	Common Shares		Additional Paid-in Capital	Deficit accumulated during development stage	Total Stockholders' equity
	Shares	Amount			
Balance at December 31, 2012	24,400,754	$ 24	$106,193	$ (84,184)	$ 22,033
Exercise of Common Stock options	400,157	1	679	—	680
Exercise of Common Stock warrants	81,045	—	—	—	—
Sale of Common Stock under ATM programs	10,352,219	10	87,996	—	88,006
Issuance of Common Stock related to the ESPP	21,505	—	83	—	83
Stock-based compensation expense	—	—	4,072	—	4,072
Net loss	—	—	—	(27,360)	(27,360)
Balance at September 30, 2013	35,255,680	$ 35	$199,023	$ (111,544)	$ 87,514

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

($ in thousands)	For the nine months ended September 30, 2013	2012	Period from June 28, 2006 (date of inception) to September 30, 2013
Employee awards	$ 3,174	$ 1,336	$ 6,380
Non-employee awards	758	412	4,171
Non-employee warrants	140	425	1,033
Total stock-based compensation expense	$ 4,072	$ 2,173	$ 11,584

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

($ in thousands except per share amounts)	Outstanding Options: Number of Shares	Outstanding Options: Weighted Average Exercise Price	Outstanding Options: Total Weighted Average Intrinsic Value	Weighted Average Remaining Contractual Life (in years)
At December 31, 2012	2,519,070	$ 3.37	$ 2,860	8.5
Options granted	2,031,590	6.07		
Options exercised	(400,157)	1.70		
Options cancelled	(20,000)	1.93		
At September 30, 2013	4,130,503	$ 4.87	$ 8,830	8.6
Options vested and expected to vest	4,130,503	$ 4.87	$ 8,830	8.6
Options vested and exercisable	1,080,899	$ 3.95	$ 4,269	7.7

Total weighted average intrinsic value for all computations as of September 30, 2013 is based on the closing price of the Company's common stock on September 30, 2013 of $7.01 per share.

As of September 30, 2013 the Company had unrecognized stock-based compensation expense related to unvested stock options to employees and non-employees of $9.1 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.5 years.

On May 31, 2013, the Company issued 21,505 shares of Common Stock under Company's Employee Stock Purchase Plan ("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 nine months ended September 30, 2013, the Company issued 80,705 shares of Common Stock pursuant to the cashless exercise of 158,429 warrants at a weighted average exercise price of $5.02, and 340 shares of Common Stock for cash proceeds of $1,098.

10. Market Capitalization Bonuses and Executive Officer Resignations and Agreements

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 June 30, 2013 upon 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 September 30, 2013, the Company paid $107,000 of the severance obligation to Dr. Sandage and $94,900 to Dr. Glenn Cooper in connection with his severance arrangement recorded in 2012. For the nine months ended September 30, 2013 a total of $446,200 was paid to Drs. Sandage and 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 commenced occupancy of this space in May 2013.

12. Subsequent Events

TRUST-I Data

On October 14, 2013, the Company reported that the TRUST-I study, its phase 2 randomized, double-blind, placebo-controlled, U.S. multi-centered study to evaluate the safety and efficacy of TSO in Crohn's disease, did not meet its primary endpoint of improving response, defined as a 100-point decrease in the Crohn's Disease Activity Index (CDAI), nor the key secondary endpoint of remission, defined as achieving CDAI $\leq$ 150 points. In the overall patient population, response rate of patients on TSO did not separate from that of placebo.

The Company's development partner for TSO in Crohn's disease, Dr. Falk Pharma GmbH, is conducting TRUST-II, a phase 2, double-blind, randomized, placebo-controlled, multi-center study in Europe to evaluate the efficacy and safety of three different dosages of TSO in active Crohn's disease. The results from a second interim analysis are expected in the fourth quarter of 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, in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013 and below, in Item 1A. 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 October 14, 2013 the Company announced that its TRUST-I study did not meet its primary endpoint of improving response, defined as a 100-point decrease in the Crohn's Disease Activity Index (CDAI), nor the key secondary endpoint of remission, defined as achieving CDAI $\leq$ 150 points. In the overall patient population, response rate of patients on TSO did not separate from that of placebo. The randomization was stratified by disease activity as measured by CDAI. In the corresponding pre-defined subset analysis, TSO showed a non-significant improved response in patients with CDAI>290. The lack of overall response was driven by higher-than-expected placebo response rate in patients with CDAI<290.TSO was safe and well-tolerated, and adverse events were balanced between the TSO and the placebo group. The most common adverse event reported was abdominal pain and occurred in 11% of both TSO and placebo groups.

Coronado's development partner for TSO in Crohn's disease, Dr. Falk Pharma GmbH, or Falk, is conducting TRUST-II, a phase 2, double-blind, randomized, placebo-controlled, multi-center study in Europe to evaluate the efficacy and safety of three different dosages of TSO in active Crohn's disease. The results from a second interim analysis are expected in the fourth quarter of 2013.

We are continuing to evaluate the data from TRUST-I. We will use this analysis, along with the results of TRUST-II, other current data on TSO and other factors to determine our future development plans for TSO.

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 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 & 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, in April 2013, 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 "2013 ATM"). In July 2013, we filed a shelf registration statement on Form S-3 (the "2013 Form S-3"), which was declared effective on August 19, 2013. We may sell up to $200.0 million of our equity securities under the 2013 Form S-3. In connection with the 2013 Form S-3, we amended our 2013 ATM 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 ATM's with MLV, we will pay directly to MLV fees of up to 3% of the gross proceeds of the ATMs then in effect. In the nine months ended September 30, 2013, we sold 10,352,219 shares of Common Stock under the ATMs and received net proceeds of $88.0 million. Since September 30, 2013 and through October 2, 2013, we sold an additional 206,203 shares of Common Stock for net proceeds of $1.4 million under the Amended 2013 ATM.

In April 2013, Dr. Bobby W. Sandage, Jr. resigned from his position as president of our company and as a member of the Board of Directors. (See Note 10 of Notes to Unaudited 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 September 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 September 30, 2013 and 2012, stock-based compensation expense was $1.3 million and $1.0 million, respectively, for the nine months ended September 30, 2013 and 2012, stock-based compensation expense was $4.1 million and $2.2 million, respectively, and from inception through September 30, 2013 stock-based compensation expense was $11.6 million. As of September 30, 2013, we had approximately $9.1 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 1.5 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 September 30, 2013 we had an accumulated deficit of $111.5 million primarily as a result of research and development expenses, purchase of in-process research and development and general and administrative expenses. While we may in the future generate revenue from a variety of sources, including license fees, milestone payments, research and development payments in connection with strategic partnerships and/or product sales, our product candidates are at an early stage of development and may never be successfully developed or commercialized. Accordingly, we expect to continue to incur substantial losses from operations for the foreseeable future and there can be no assurance that we will ever generate significant or any revenues.

We are continuing to evaluate the data from the TRUST-I trial and other current data on TSO and are awaiting the results of the TRUST-II trial to determine the future development plan for TSO. Until we have completed that process and made a determination regarding the future development for TSO, we do not expect our current level of expenditures to increase in the next 12 months.

Research and Development Expenses

Conducting research and development is central to our business and aggregated $61.1 million for the period from inception (June 28, 2006) to September 30, 2013. Included in research and development expense is noncash, stock-based compensation expense of $0.6 million and $0.3 million for the three months ended September 30, 2013 and 2012, respectively, $2.1 million and $0.8 million for the nine months ended September 30, 2013 and 2012, respectively, and $6.7 million from inception to September 30, 2013. Research 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. 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. As a result, pending our determination of the TSO development plan, our research and development expenses could 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 September 30, 2013, direct, external development costs incurred for our TSO product development program were $23.5 million, excluding $21.7 million of in-process research and development costs related to our acquisition of the asset in 2011 and the manufacturing rights in 2012. From inception through September 30, 2013, direct, external development costs incurred for our CNDO-109 product development program were $7.9 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 $23.4 million from inception through September 30, 2013. Included in general and administrative expense is noncash, stock-based compensation expense of $0.6 million and $0.6 million for the three months ended September 30, 2013 and 2012, respectively, $2.0 million and $1.4 million for the nine months ended September 30, 2013 and 2012, respectively, and $4.8 million from inception to September 30, 2013. General administrative expenses relate primarily to:

- 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 September 30, 2013 and 2012

($ in thousands)	For the three months ended September 30, 2013	2012	Change $	%
Operating expenses:				
Research and development	$ 5,361	$ 3,777	$1,584	42%
General and administrative	2,143	2,054	89	4%
Loss from operations	(7,504)	(5,831)	1,673	29%
Interest income	165	79	(86)	109%
Interest expense	(493)	(183)	310	NM
Net loss	$ (7,832)	$ (5,935)	$1,897	32%

NM–Not meaningful

Research and development expenses increased $1.6 million, or 42%, from $3.8 million in the three months ended September 30, 2012 to $5.4 million in the three months ended September 30, 2013. This increase was primarily due to increases of $0.8 million related to establishing our TSO manufacturing facility, $0.3 million related to stock compensation, $0.2 related to TSO development and $0.2 million related to our phase 1/2 trial for CNDO-109. Partially offsetting these increases was a $0.1 million decrease in net compensation-related expense.

General and administrative expenses remained essentially unchanged at $2.1 million in the three months ended September 30, 2012 and 2013.

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 and 2012 relates primarily to the Hercules Note.

Comparison of nine months ended September 30, 2013 and 2012

($ in thousands)	For the nine months ended September 30, 2013	2012	Variance $	%
Operating expenses:				
Research and development	$ 19,130	$ 12,893	$6,237	48%
General and administrative	7,126	5,984	1,142	19%
Loss from operations	(26,256)	(18,877)	7,379	39%
Interest income	350	152	(198)	130%
Interest expense	(1,454)	(220)	1,234	NM
Net loss	$ (27,360)	$ (18,945)	$8,415	44%

Research and development expenses increased $6.2 million, or 48%, from $12.9 million in the nine months ended September 30, 2012 to $19.1 million in the nine months ended September 30, 2013. This increase was primarily due to increased costs of $5.2 million related to our Phase 2 study of TSO in Crohn's disease, $2.6 million related to compensation and benefits and $1.8 million related to establishing our TSO manufacturing facility, partially offset by $3.6 million of milestone payments primarily to Falk in 2012 in connection with the Collaboration Agreement. The $2.6 million increase in compensation and benefits reflects $1.3 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 Unaudited Consolidated Financial Statements) and $1.3 million of stock-based compensation primarily related to an increase in stock option grants.

General and administrative expenses increased $1.1 million, or 19%, from $6.0 million in the nine months ended September 30, 2012 to $7.1 million in the nine months ended September 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 primarily through the sale of debt and equity securities, aggregating $180.2 million of net proceeds. At September 30, 2013, we had cash and cash equivalents of $106.3 million. In the nine months ended September 30, 2013, we sold 10,352,210 shares of Common Stock pursuant to our 2012 and 2013 ATMs and received net proceeds of $88.0 million. Since September 30, 2013, we sold an additional 206,203 shares of Common Stock for net proceeds of $1.4 million under our Amended 2013 ATM.

In July 2013, we filed the 2013 Form S-3, which was declared effective on August 19, 2013. 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. While we do not currently plan to continue selling shares under the Amended 2013 ATM we may do so. As of October 30, 2013, $53.7 million remains available under the Amended 2013 ATM. On September 30, 2013, our stockholders voted to approve an amended and restated certificate of incorporation to increase the number of authorized shares of capital stock from 65,000,000 shares to 115,000,000 shares and to increase the number of authorized shares of Common Stock from 50,000,000 to 100,000,000.

We will require additional financing to fully develop, and 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 securities. We believe that our current cash and cash equivalents are sufficient to fund operations for at least the next twelve months. 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 would seek funds through equity or debt financings, collaborative or other arrangements with corporate sources, or through other sources of financing. Adequate additional funding, particularly subsequent to the negative results from our Trust-I clinical trial, may not be available to us on acceptable terms or at all. If adequate funds are not available to us when needed, we may be required to delay, curtail or eliminate one or more of our research and development programs or seek strategic alternatives.

Cash Flows for the nine months ended September 30, 2013 and 2012

	For the Nine Months Ended September 30,		Change
($ in thousands)	**2013**	**2012**	
Statement of Cash Flows Data:			
Total cash provided by (used in):			
Operating activities	$ (22,514)	$ (16,089)	$ (6,425)
Investing activities	(187)	—	(187)
Financing activities	88,769	40,407	48,362
Increase in cash and cash equivalents	$ 66,068	$ 24,318	$41,750

Operating Activities

Net cash used in operating activities increased $6.4 million from the nine months ended September 30, 2012 to the nine months ended September 30, 2013 primarily reflecting $8.4 million of increased net loss and $1.9 million of increased noncash stock-based compensation expense.

Investing Activities

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

Financing Activities

Net cash provided by financing activities of $88.8 million in the nine months ended September 30, 2013 primarily reflects $88.0 million of net proceeds from the sale of Common Stock under our 2012 and 2013 ATMs. Net cash provided by financing activities of $40.4 million in the nine months ended September 30, 2012 reflects $26.4 million of net proceeds from our June 2012 underwritten public offering of Common Stock and $14.7 million of net proceeds from the Hercules debt offset by the repayment of a $750,000 note to Paramount Capital Partners.

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 September 30, 2013 and December 31, 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 September 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 September 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

There have been no material changes to the risk factors previously disclosed in our Annual Report on Form 10-K for the year ended December 31, 2012 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2013 except as set forth below.

Risks Related to our Business and Industry

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

Our two product candidates, 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.

On October 14, 2013, we announced that our TRUST-I study did not meet its primary endpoint of improving response, defined as a 100-point decrease in the Crohn's Disease Activity Index (CDAI), nor the key secondary endpoint of remission, defined as achieving CDAI £ 150 points. In the overall patient population, response rate of patients on TSO did not separate from that of placebo. The randomization was stratified by disease activity as measured by CDAI. In the corresponding pre-defined subset analysis, TSO showed a non-significant improved response in patients with CDAI>290. The lack of overall response was driven by higher-than-expected placebo response rate in patients with CDAI<290. While we are continuing to analyze the trial data, the results of this trial negatively impact the potential for successful development of TSO.

Until we have fully analyzed the TRUST-I trial data, have received, reviewed and fully analyzed the results of the TRUST-II trial, and have determined the development path, if any, for TSO, we cannot give any assurances as to the future development of TSO, the indications for which TSO could be a treatment, or the costs and timelines for any development plans.

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 your investment in our Company.

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:

- the results of the TRUST-II trial and other announcements we make regarding our TSO program, including any impact of financial, operational, manufacturing and managerial decisions and needs related to the TSO program;
- 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 any 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. Most significantly and subsequent to the release of the results from our TRUST-I clinical trial, the price of our stock dropped $4.05, or 70%, from $5.77 at October 11, 2013 to $1.72 on October 21, 2013.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

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Item 6. Exhibits.

(b) Exhibits

Exhibit No.	Description
3.5	Second Certificate of Amendment of Amended and Restated Certificate of Incorporation, as Amended, dated October 1, 2013
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

SIGNATURES

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

CORONADO BIOSCIENCES, INC.

Date: November 1, 2013

By: /s/ Harlan F. Weisman
Harlan F. Weisman, Chief Executive Officer
(Principal Executive Officer)

Date: November 1, 2013

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

Date: November 1, 2013

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

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EXHIBIT INDEX

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Exhibit 3.5

SECOND CERTIFICATE OF AMENDMENT OF
AMENDED AND RESTATED CERTIFICATE OF INCORPORATION, AS AMENDED
OF
CORONADO BIOSCIENCES, INC.

Coronado Biosciences, Inc., a corporation organized and existing under the laws of the State of Delaware (the "***Company***"), does hereby certify as follows:

ONE: The Company's original Certificate of Incorporation was filed with the Delaware Secretary of State on June 28, 2006. An Amended and Restated Certificate of Incorporation of the Company was filed with the Delaware Secretary of State on April 21, 2010. A First Certificate of Amendment of Amended and Restated Certificate of Incorporation of the Company was filed with the Delaware Secretary of State on May 20, 2011.

TWO: Harlan F. Weisman is the duly elected Chairman of the Board of Directors of the Company and Chief Executive Officer of the Company.

THREE: This amendment of the Company's Amended and Restated Certificate of Incorporation, as amended to date was duly adopted by the Company's Board of Directors and stockholders in accordance with the applicable provisions of Sections 242 and 211 of the General Corporation Law of the State of Delaware.

FOUR: Article IV, Section A of the Company's Amended and Restated Certificate of Incorporation, as amended to date is hereby amended to read in its entirety as follows:

> "This Corporation is authorized to issue two classes of stock to be designated "Common Stock" and "Preferred Stock." The total number of shares which the Corporation is authorized to issue is 115,000,000 shares, 100,000,000 of which shall be Common Stock, par value $0.001 per share, and 15,000,000 of which shall be Preferred Stock, par value $0.001 per share."

FIVE: All other provisions of the Company's Amended and Restated Certificate of Incorporation, as amended to date shall remain in full force and effect.

SIX: This Second Certificate of Amendment will be effective upon filing.

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IN WITNESS WHEREOF, the Company has caused this Second Certificate of Amendment to be executed on its behalf by Harlan Weisman, its Chairman of the Board and Chief Executive Officer, effective as of October 1, 2013.

CORONADO BIOSCIENCES, INC.

By: /s/ Harlan Weisman
Harlan Weisman, Chairman of the Board of Directors and Chief Executive Officer

Exhibit 31.1

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 officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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)

November 1, 2013

Exhibit 31.2

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 officer 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)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) 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
Lucy Lu, M.D.
Chief Financial Officer
(Principal Financial Officer)

November 1, 2013

Exhibit 32.1

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 September 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.

November 1, 2013

By: /s/ Harlan F. Weisman
Harlan F. Weisman
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

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 September 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.

November 1, 2013

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