# **SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

FORM 10-Q
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(Mark One)  ☑ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE ACT OF 1934	E SECURITIES EXCHANGE
For the quarterly period ended March 31, 2013	
OR	
☐ TRANSITION REPORT UNDER SECTION 13 OF 15(d) OF THE EXCHA	ANGE ACT OF 1934
From the transition period from to	_•
Commission File Number 001-35366	
Delaware (State or other jurisdiction of incorporation or organization)  24 New England Executive Park Burlington, MA 01803 (Address of principal executive offices)  (781) 652-4500 (Issuer's telephone number)	20-5157386 (IRS Employer Identification No.)
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was requirements 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 corpora Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of months (or for such shorter period that the registrant was required to submit and post such files).	this chapter) during the preceding 12
Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-company. See definitions of "large accelerated filer", "accelerated filer" and "smaller reporting comfact:	accelerated filer, or a smaller reporting apany" in Rule 12b-2 of the Exchange
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 Ex	xchange Act). Yes □ No 区
As of May 6, 2013, there were 28,048,269 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)

	March 31, 2013	December 31, 2012
ASSETS		
Current Assets:		
Cash and cash equivalents	\$ 44,052	\$ 40,199
Prepaid and other current assets	1,010	393
Total current assets	45,062	40,592
Property and equipment, net	50	51
Other assets	344	349
Total Assets	\$ 45,456	\$ 40,992
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities:		
Accounts payable	\$ 676	\$ 1,029
Interest payable	119	119
Accrued expenses	2,183	2,185
Current portion of note payable	3,190	1,799
Total current liabilities	6,168	5,132
Note payable	11,086	12,386
Other long-term liabilities	1,474	1,441
Total Liabilities	18,728	18,959
Commitments and Contingencies		
Stockholders' Equity:		
Convertible Preferred stock, \$.001 par value, 457,053 and 584,390 Series C shares authorized, 0 shares issued and outstanding as of March 31, 2013 and December 31, 2012, respectively	_	_
Common Stock, \$.001 par value, 50,000,000 shares authorized, 26,167,760 and 24,400,754 shares issued		
and outstanding as of March 31, 2013 and December 31, 2012, respectively	26	24
Additional paid-in capital	119,744	106,193
Deficit accumulated during development stage	(93,042)	(84,184)
Total Stockholders' Equity	26,728	22,033
Total Liabilities and Stockholders' Equity	\$ 45,456	\$ 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 March 31,					Period from June 28, 2006 (date of inception) to	
		2013		2012		rch 31, 2013	
Operating expenses:							
Research and development	\$	5,974	\$	4,581	\$	47,983	
General and administrative		2,484		2,000		18,763	
In-process research and development					-	21,749	
Loss from operations		(8,458)		(6,581)		(88,495)	
Interest income		76		44		556	
Interest expense		(476)		(19)		(4,429)	
Other income		_		_		733	
Warrant expense						(1,407)	
Net loss	\$	(8,858)	\$	(6,556)	\$	(93,042)	
Common Stock dividend to Series A Convertible Preferred							
Stockholders						(5,861)	
Net loss attributed to Common Stock	\$	(8,858)	\$	(6,556)	\$	(98,903)	
Basic and diluted net loss per common share	\$	(0.35)	\$	(0.35)			
Weighted average common shares outstanding—basic and diluted	25	,182,369	18	,604,245			

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 Three Months Ended March 31,		Ended Inception	
	2013	2012	2013		
Cash flows from operating activities: Net loss	¢ (0 050)	¢ (6 556)	\$ (93,042)		
	\$ (8,858)	\$ (6,556)	\$ (93,042)		
Adjustments to reconcile net loss to net cash used in operating activities:  Stock-based compensation expense	1,523	874	9,035		
Acquired in-process research and development	1,323	- 0/4 	21,749		
Noncash interest expense	129	_	2,027		
Noncash interest expense—related parties	129		2,027		
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			47		
Changes in operating assets and liabilities:	3	_	4/		
Prepaid and other assets	66	(93)	(387)		
Interest payable		(73)	119		
Accounts payable and accrued expenses	(355)	350	2,859		
Net cash used in operating activities	(7,492)	(5,425)	(54,584)		
Cash flows from investing activities:					
Purchase of office equipment	(2)		(97)		
Deposit for leasehold improvements	_	_	(225)		
Purchase of in-process research and development			(3,843)		
Net cash used in investing activities	(2)		(4,165)		
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)		
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	11,690	_	40,743		
Payment of costs related to the issuance of Common Stock	(343)	_	(2,648)		
Proceeds from issuance of Hercules Note			15,000		
Payment of debt issue costs associated with Hercules Note			(288)		
Net cash provided by financing activities	_11,347		102,801		
Increase/(decrease) in cash and cash equivalents	3,853	(5,425)	44,052		
Cash and cash equivalents—beginning of period	40,199	23,160			
Cash and cash equivalents—end of period	\$44,052	\$17,735	\$ 44,052		
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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 Three Months Ended March 31, 2013 2012			Ju	riod from ne 28, 2006 (Date of ception) to March 31, 2013	
Supplemental disclosure of cash flow information:						
Cash paid for interest	\$	347	\$	18	\$	909
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

#### Coronado Biosciences, Inc. and Subsidiary

(A development stage enterprise)

#### Notes to the Consolidated Financial Statements

# 1. Organization and Description of Business

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

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

The Company is a development-stage enterprise. Activities to date include development of key compounds, establishing 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 \$93.0 million as of March 31, 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 three months ended March 31, 2013, the Company issued 1,565,101 shares of Common Stock for total net proceeds of \$11.8 million of which \$11.1 million was received as of March 31, 2013, under the Company's At Market Issuance Sales Agreement (the "ATM") with MLV & Co. LLC ("MLV") and \$0.7 million was received on April 1, 2013. The Company has fully utilized its \$30 million ATM facility. On April 29, 2013, the Company entered into a new \$45 million At Market Issuance Sales Agreement (the "2013 ATM") with MLV whereby up to \$45 million of shares of Common Stock may be issued by the Company pursuant to its Form S-3 filed in September 2012. From January 1, 2013 through May 7, 2013, the Company issued 3.4 million shares of Common Stock for total net proceeds of \$29.9 million under its ATM facilities.

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, 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 the opinion of management, the unaudited interim consolidated financial statements reflect all adjustments, which include only normal recurring adjustments necessary for the fair statement of our balances and results for the periods presented. Certain information and footnote disclosures normally included in the Company's annual financial statements prepared in accordance with GAAP have been condensed or omitted. These consolidated financial statement results are not necessarily indicative of results to be expected for the full fiscal year or any future period.

The consolidated balance sheet at December 31, 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, as amended, 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 March 31, 2013 the Company recorded deferred financing costs of \$58,000 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. Holders of restricted Common Stock were entitled to all cash dividends, when and if declared, and such dividends are non-forfeitable. The participating securities do not have a contractual obligation to share in any losses of the Company. As a result, net losses are not allocated to the participating securities for any periods presented.

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

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

		months ended ch 31,
(\$ in thousands except share and per share amounts)	2013	2012
Historical net loss per share:		
Numerator:		
Net loss attributed to Common Stockholders	\$ (8,858)	\$ (6,556)
Denominator:		
Weighted-average common shares outstanding—Denominator		
for basic and diluted net loss per share	25,182,369	18,604,245
Basic and diluted net loss per common share attributed to	<u> </u>	
common stockholders	\$ (0.35)	\$ (0.35)

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

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

	For the three month	For the three months ended March 31,		
	2013	2012		
Warrants to purchase Common Stock	1,188,147	1,068,797		
Options to purchase Common Stock	3,984,184	1,999,015		
	5,172,331	3,067,812		

#### 4. Debt and Interest

Interest expense of \$476,000 for the three months ended March 31, 2013 principally related to the \$15 million term loan with Hercules Technology Growth Capital ("Hercules Note"), and included \$347,000 in cash interest and \$91,000 related to accretion of the debt discount. At March 31, 2013, the current portion of the Hercules Note was \$3.2 million and noncurrent portion was \$11.1 million, net of the debt discount of \$724,000.

In 2012, we acquired from Ovamed manufacturing rights for TSO in 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 \$32,500 for the three months ended March 31, 2013 and recorded as interest expense.

# 5. Property and Equipment

Property and equipment consisted of the following:

	Useful Life	As of I	March 31,		s of nber 31,
(\$ in thousands)	(Years)	2	.013	2	012
Computer equipment	3	\$	10	\$	10
Furniture & fixtures	5		40		38
Leasehold improvements	5		6		6
Total property and equipment			56		54
Less: Accumulated depreciation			(6)		(3)
Property and equipment, net		\$	50	\$	51

# 6. Accrued Liabilities and Other Long-Term Liabilities

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

	As of March 31, 2013		As of December 3 2012	
Accrued expenses:	,			,
Salaries, bonuses and related benefits	\$	575	\$	1,064
Severance		262		354
Professional fees		298		320
Research and development expenses		939		403
Other		109		44
Total accrued expenses	\$	2,183	\$	2,185
Other long-term liabilities:				
Hercules Note end of term		398		398
Ovamed manufacturing rights		1,076		1,043
Total other long-term liabilities	\$	1,474	\$	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 \$843,000 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 day's notice or due to FU Berlin's bankruptcy. As of March 31, 2013, the Company incurred sponsored research expense of \$22,000 recorded 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 March 31, 2013 computed using the effective interest rate method, is \$14.8 million. The effective interest rate considers the fair value of the warrant issued in connection with the loan, loan issuance costs and the deferred charge. The fair value measurement utilizes inputs that are categorized as Level 3.

#### 9. Common Stock

At Market Issuance Sales Agreement

Pursuant to the Company's October 2012 ATM with MLV the Company issued 1,565,101 shares of Common Stock in the three month period ended March 31, 2013 for total net proceeds of \$11.8 million of which \$11.1 million was received as of March 31, 2013, and \$0.7 million was received on April 1, 2013. The \$0.7 million received on April 1, 2013 was included in other current assets at March 31, 2013. The Company has fully utilized its \$30 million ATM facility. On April 29, 2013, the Company entered into the 2013 ATM with MLV whereby up to \$45.0 million of shares may be issued by the Company pursuant to its Form S-3 filed in September 2012. Since March 31, 2013, the Company issued an additional 1.8 million shares of Common Stock for net proceeds of \$18.1 million under its ATM facilities.

# Stock-based Compensation Plans

As of March 31, 2013, the Company had two equity compensation plans, the Coronado Biosciences, Inc. 2007 Stock Incentive Plan, for employees, non-employees and outside directors and the Coronado Biosciences, Inc. 2012 Employee Stock Purchase Plan (the "ESPP").

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 three months ended March 31, 2013 and 2012, and from the period June 28, 2006 (date of inception) to date.

Dariad from

	For the three months ended March 31,			June (ince	28, 2006 date of eption) to arch 31,
(\$ in thousands)	2013		012		2013
Employee awards	\$ 972	\$	313	\$	4,178
Non-employee awards	434		445		3,847
Non-employee warrants	117		116		1,010
Total stock-based compensation expense	\$ 1,523	\$	874	\$	9,035

The following table summarizes stock option activity:

	Outstanding Options			Weighted
		Weighted Average	Total Weighted Average	Average Remaining Contractual
	Number of	Exercise	Intrinsic	Life (in
(\$ in thousands except per share amounts)	Shares	Price	Value	years)
At December 31, 2012	2,519,070	\$ 3.37	\$ 2,860	8.5
Options granted	1,771,590	5.66		
Options exercised	(193,490)	1.37		
Options cancelled				
At March 31, 2013	4,097,170	\$ 4.46	\$21,564	8.97
Options vested and expected to vest	4,097,170	\$ 4.46	\$21,564	8.97
Options vested and exercisable	857,053	\$ 2.75	\$ 5,976	8.05

As of March 31, 2013 the Company had unrecognized stock-based compensation expense related to unvested stock options to employees and non-employees of \$10.7 million, which is expected to be recognized over the remaining weighted-average vesting period of 1.9 years.

# Warrants to Purchase Common Stock

For the three months ended March 31, 2013, the Company issued 8,415 shares of Common Stock pursuant to the cashless exercise of 18,724 warrants at a weighted average exercise price of \$4.97.

#### 10. Executive Officer Agreement

On January 7, 2013, the Company entered into an employment agreement with Dr. Harlan F. Weisman, the Company's chairman and chief executive officer. Pursuant to the employment agreement, the Company will pay Dr. Weisman an annual base salary of \$600,000. At the discretion of the board of directors, he will also be eligible for an annual cash bonus based on the attainment of financial, clinical development and/or business milestones to be established by the board. Pursuant to the employment agreement, the Company also granted Dr. Weisman an option to purchase 1,686,590 shares of Common Stock, which was equal to 6% of the Company's fully-diluted capitalization as of the date of grant. The option has an exercise price of \$5.57 per share. One-third of the shares underlying the option will vest on December 28, 2013 and two anniversaries thereafter, subject to Dr. Weisman's continued employment with the Company.

# 11. Subsequent Events

#### Market Capitalization Bonuses

Pursuant to the employment agreements with three 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. On April 15, 2013, upon attainment of a \$250 million market capitalization and a 30-day trading share volume in excess of 100,000 shares per day, the second market capitalization bonus totaling \$312,500 was earned and paid to these executives.

# Executive Officer Resignation

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 will record a severance liability of approximately \$445,000 for these obligations in the three-month period ending June 30, 2013.

#### 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 approximate \$366,000. The Company expects to take 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 U.S. 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," 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.

#### 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*. 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 \$843,000 in research fees. 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, the Company filed a shelf registration statement on Form S-3 pursuant to which the Company may sell up to \$75 million of Common Stock over the next three years. In October 2012, the Company entered into an At Market Issuance Sales Agreement, or ATM, with MLV & Co. LLC, or MLV, to issue and sell up to \$30 million of Common Stock. Under the terms of the ATM we paid directly to MLV fees equal to 3% of the gross proceeds for the first \$10 million of gross proceeds and 2% of the gross proceeds thereafter. From January 1, 2013 to March 31, 2013, the Company issued 1,565,101 shares of Common Stock for total net proceeds of \$11.8 million of which \$11.1 million was received as of March 31, 2013 and \$0.7 million was received on April 1, 2013. The Company has fully utilized its \$30 million ATM facility. On April 29, 2013, the Company entered into a new \$45 million At Market Issuance Sales Agreement (the "2013 ATM") with MLV whereby up to \$45 million of shares may be issued by the Company pursuant to its Form S-3 filed in September 2012. Since March 31, 2013, the Company issued an additional 1.8 million shares of Common Stock for net proceeds of \$18.1 million.

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

Our significant accounting policies are described in more detail in the notes to our consolidated financial statements appearing in our Form 10-K for the fiscal year ended December 31, 2012. We believe the following accounting policies to be most critical to the judgments and estimates used in the preparation of our consolidated financial statements.

#### Research and Development Expenses

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued research and development expenses. This process involves reviewing open contracts and purchase orders, reviewing the terms of our license agreements, communicating with our applicable personnel to identify services that have been performed on our behalf and estimating the level of service performed and the associated cost incurred for the service when we have not yet been invoiced or otherwise notified of actual cost. The majority of our service providers invoice us monthly in arrears for services performed. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on facts and circumstances known to us at that time. We periodically confirm the accuracy of our estimates with the service providers and make adjustments if necessary. Examples of estimated accrued research and development expenses as of March 31, 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 Coronado's 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 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 ending March 31, 2013 and 2012, stock-based compensation expense was \$1.5 million, and \$0.9 million, respectively and \$9.0 million from inception through March 31, 2013. As of March 31, 2013, we had approximately \$10.9 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 1.9 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 March 31, 2013 we had an accumulated deficit of \$93.0 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 \$69.7 million for the period from inception (June 28, 2006) to March 31, 2013. Noncash, stock-based compensation expense included in research and development in for the three months ended March 31, 2013 and 2012, was \$0.8 million and \$0.5 million, respectively, and \$5.5 million from inception to March 31, 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, patent filings and regulatory filings.

We expect to continue to incur substantial expenses related to our research and development activities for the foreseeable future as we continue product development. Since product candidates in later stages of clinical development generally have higher development costs than those in earlier stages of clinical development, primarily due to the increased size and duration of later stage clinical trials, we expect that our research and development expenses will increase in the future. In addition, if our product development efforts are successful, we expect to incur substantial costs to prepare for potential commercialization of any late-stage product candidates and, in the event one or more of these product candidates receive regulatory approval, to fund the launch of the product. From inception through March 31, 2013, direct, external development costs incurred for our TSO product development program were \$17.0 million, excluding \$21.7 million of inprocess research and development costs related to our acquisition of the asset in 2011 and the manufacturing rights in 2012. From inception through March 31, 2013, direct, external development costs incurred for our CNDO-109 product development program were \$6.6 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 \$18.8 million from inception through March 31, 2013. Noncash, stock-based compensation expense included in general and administrative expenses for the three months ended March 31, 2013 and 2012, was \$0.7 million and \$0.4 million, respectively, and \$3.5 million from inception through March 31, 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 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 March 31, 2013 and 2012

	For the three months ended March 31,			
				Change
(\$ in thousands)	2013	2012	\$	%
Operating expenses:				
Research and development	\$ 5,974	\$ 4,581	\$1,393	30%
General and administrative	2,484	2,000	484	24%
Loss from operations	(8,458)	(6,581)	1,877	29%
Interest income	76	44	32	73%
Interest expense	(476)	(19)	457	NM
Net loss	\$ (8,858)	\$ (6,556)	\$2,302	35%

#### NM-Not meaningful

Research and development expenses increased \$1.4 million, or 30%, from the three months ended March 31, 2012 to the three months ended March 31, 2013. This increase was primarily due to higher costs of \$2.7 million related to the Phase 2 study of TSO and \$0.3 million related to the site preparation of our manufacturing facility partially offset by the \$1.4 million dollar payment to Dr. Falk Pharma GmbH ("Falk") in connection with the Collaboration Agreement, the accrual of a contractual obligation of \$200,000 to Ovamed, \$0.5 million for product received from Ovamed, and \$0.3 million of costs related to the Phase 1 for TSO in the three months ended March 31, 2012. Additionally, external development costs related to CNDO—109 decreased \$0.2 million in the first quarter of 2013, reflecting a \$250,000 contractual payment made to UCLB in the three months ended March 31, 2012. Additionally, personnel-related costs increased \$0.5 million in the first quarter of 2013 compared to the first quarter of 2012 due in part to the research and development portion of the first market capitalization bonus of \$0.1 million to three of our executive officers for achievement of specified trading volume and market capitalization of Coronado and an increase in staffing. Stock-based compensation increased \$0.3 million due to an option granted to our new chief executive officer in the three months ended March 31, 2013. 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 \$0.5 million, or 24%, from the three months ended March 31, 2012 to the three months ended March 31, 2013, due to a \$0.2 million increase in personnel costs, due in part to the general and administrative portion of the first market capitalization bonus of \$0.1 million to three of our executive officers for achievement of specified trading volume and market capitalization of Coronado. Stock-based compensation increased \$0.4 million due to options grant to new our chief executive officer and the independent members of our board of directors in the three months ended March 31, 2013

Interest expense in 2013 relates to interest on the Hercules Note. The increase in interest income in 2013 compared to the same period last year was primarily due to higher cash balances.

# **Liquidity and Capital Resources**

To date, we have funded our operations through the sale of debt and equity securities, aggregating \$104.7 million of net proceeds. At March 31, 2013, we had cash and cash equivalents of \$44.1 million. Pursuant to the ATM with MLV, the Company issued 1,565,101 shares of Common Stock in the quarter ended March 31, 2013 for total net proceeds of \$11.8 million of which \$11.1 million

was received as of March 31, 2013, and \$0.7 million was received on April 1, 2013. The Company has fully utilized its \$30 million ATM facility. On April 29, 2013, the Company entered into a new 2013 ATM with MLV whereby up to \$45 million of shares of Common Stock may be issued by the Company pursuant to its Form S-3 filed in September 2012. Since March 31, 2013, we issued 1.8 million shares for net proceeds of \$18.1 million.

We expect to incur substantial expenditures in the foreseeable future for the development of our product candidates. We will require additional financing to develop, prepare regulatory filings and obtain regulatory approvals for our product candidates, fund operating losses, and, if deemed appropriate, establish manufacturing, sales and marketing capabilities. We have funded our operations to date primarily through the sale of equity and debt. We believe that our current cash and cash equivalents are sufficient to fund operations 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 Three Months Ended March 31, 2013 and 2012

	For the Three Months Ended				
		March 31,		Change	
(\$ in thousands)		2013		2012	
Statement of Cash Flows Data:	' <u></u>				
Total cash provided by (used in):					
Operating activities	\$	(7,492)	\$	(5,425)	\$ 2,067
Investing activities		(2)		_	2
Financing activities		11,347			11,347
Decrease in cash and cash equivalents	\$	3,853	\$	(5,425)	\$ 9,278

#### **Operating Activities**

Net cash used in operating activities increased \$2.1 million from the three months ended March 31, 2012 to the three months ended March 31, 2013 primarily reflecting increased net loss.

#### **Investing Activities**

Net cash used in investing activities in 2013 relates to the purchase of equipment for the Company's office in Burlington, Massachusetts.

#### **Financing Activities**

Net cash provided by financing activities of \$11.3 million for the three months ended March 31, 2013, reflects \$11.0 million of net proceeds from the sale of stock under the ATM plus \$0.3 from the exercise of stock options.

# **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

None.

#### Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

Under the supervision and with the participation of our management, including our principal executive officer and principal financial officer, we conducted an evaluation of the effectiveness, as of March 31, 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

None

#### PART II. OTHER INFORMATION

Item 1. Legal Proceedings

None.

Item 1A. Risk Factors

None.

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

None.

Item 3. Defaults Upon Senior Securities

None.

Item 4. Mine Safety Disclosures

None.

Item 5. Other Information

None.

# Item 6. Exhibits.

(b) Exhibits

Exhibit No.	<b>Description</b>
10.47†	Research Agreement, dated February 22, 2013, by and between Coronado Biosciences, Inc. and Freie Universitat Berlin.
10.48 <sup>†</sup>	License and Sublicense Agreement, dated February 22, 2013, by and between Coronado Biosciences, Inc. and Ovamed GmbH.
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
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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

 $<sup>\</sup>dagger$  Confidential treatment has been requested for portions of this exhibit.

<sup>\*</sup> 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.

CORONADO BIOSCIENCES, INC.

Date: May 9, 2013 By: /s/ Harlan F. Weisman

Harlan F. Weisman, Chief Executive Officer (Principal

Executive Officer)

Date: May 9, 2013 By: /s/ Lucy Lu, M.D.

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

Officer (Principal Financial Officer)

Date: May 9, 2013 By:  $\frac{\text{/s/}}{\text{Dale Ritter}}$ 

Dale Ritter, Senior Vice President, Finance and Chief Accounting Officer (Principal Accounting Officer)

# **EXHIBIT INDEX**

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Portions of this document marked [\*] are requested to be treated confidentially.

#### **EXECUTION COPY**

# RESEARCH AGREEMENT

between Coronado Biosciences, Inc.

24 New England Executive Park

Burlington, MA 01803

Project Leader: Dr. Karin Hehenberger, Dr. Bobby Sandage

(hereinafter referred to as "Coronado")

and Freie Universität Berlin

represented by Peter Lange,

Director of Administration and Finance

Kaiserswerther Straße 16-18

14195 Berlin

on behalf of the executing

Department of Veterinary Medicine

Institute of Immunology

Prof. Dr. Susanne Hartmann (Principal Scientist)

(hereinafter referred to as "FU Berlin")

Coronado and FU Berlin are hereinafter also referred to individually as "Party" and collectively as "Parties".

This Agreement is entered into by and between the Parties as of the Effective Date (each as defined herein).

# **PREAMBLE**

WHEREAS FU Berlin possesses valuable expertise within Immune modulation by helminths, proteomics, and auto-immune animal

models, certain of which is included in the FU Berlin Background Know-How (as defined herein); and

WHEREAS FU Berlin has used Material (Trichuris suis ova ("TSO")) delivered by Ovamed GmbH ("Ovamed") on the basis of the

Ovamed MTA; and

WHEREAS FU Berlin will supply expertise and knowledge on immune modulation by *Trichuris suis* larval excretory/secretory

products to Coronado; and



WHEREAS Coronado owns or controls Coronado Intellectual Property (as defined herein) and is engaged in an ongoing research

and development program with respect to TSO; and

WHEREAS Coronado will supply support for evaluation of T. suis larval excretory/secretory components; and

WHEREAS The research project contemplated in this Agreement is of mutual interest and benefit to FU Berlin and Coronado and

may potentially further research objectives of FU Berlin and Coronado; and

WHEREAS The Parties have on the Effective Date entered into a License Agreement (as defined herein) relating to the Project.

NOW THEREFORE, in consideration of the premises and the mutual covenants set forth herein, the Parties hereto agree to the following:

#### **ARTICLE 1 - DEFINITIONS**

1.1. In this Agreement, the following capitalized terms will have the meaning set forth in this Article 1.1, unless otherwise defined.

- 1.1.1. "Affiliate(s)" means any corporation, company, partnership, joint venture or other entity which Controls, is controlled by, or is under common Control with a Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of a Party.
- 1.1.2. "Agreement" means this Research Agreement including its appendices.
- 1.1.3. "Coronado Confidential Information" is defined in Article 9.1.
- 1.1.4. "Coronado Intellectual Property" is defined in Article 8.1.
- 1.1.5. "Effective Date" means the date of the last signature of this Agreement.
- 1.1.6. "FU Berlin Background Know-How" means the Know-How that has been created by, is owned or controlled by or has been reduced to practice by FU Berlin or FU Berlin Personnel related to the project "Functional characterization of T. suis larval products in mice" prior to the Effective Date, whether or not patentable, and as summarized on **Appendix A** attached hereto.
- 1.1.7. "FU Berlin Intellectual Property" means any intellectual property, including Patents and Know-How that (a) is included in or covers FU Berlin Background Know-How, or (b) becomes during the Term owned or controlled by FU Berlin or its Affiliates and relates to the Project, this Agreement, or a Licensed Product (as defined in the License Agreement), including FU Berlin's right, title and interest in any Project Results and/or Joint Patents.



- 1.1.8. "Know-How" means results, data, ideas, concepts, discoveries, Inventions (whether patentable or not) developments, methods, processes and trade secrets, techniques, methodologies, modifications, innovations, improvements, enhancements, design and design concepts, formulations, biological samples, tissues, animals, organisms, compounds, intermediates, and all other tangible and intangible materials and information.
- 1.1.9. "Joint Patent" means any and all Patents that embody, disclose or claim an invention or discovery (an "Invention") first made, conceived, created and/or reduced to practice (a) by one or more employees and/or agents (including professors, students and/or any other Project staff) of FU Berlin ("FU Berlin Personnel") or (b) jointly by FU Berlin Personnel and one or more employees of Coronado, in either case in the course of or in furtherance of conducting or performing the Project or pursuant to this Agreement.
- 1.1.10. "License Agreement" means the Joint Ownership and Exclusive License Agreement entered into by the Parties as of the Effective Date, as it may be amended in accordance with the terms thereof, attached hereto as **Appendix C**.
- 1.1.11. "Ovamed MTA" means the Material Transfer Agreement, by and between FU Berlin and Ovamed, as amended as of the Effective Date by and together with the Letter Agreement among FU Berlin, Ovamed and Coronado.
- 1.1.12. "Patent(s)" means any patents, patent applications (including provisional applications), certificates of invention, or applications for certificates of invention and any supplementary protection certificates, together with any extensions, registrations, confirmations, patents of addition, reissues, substitutions, divisions, continuations or continuations-in-part, reexaminations or renewals thereof or thereto.
- 1.1.13. "Performance Period" means the period for performing the Project, which shall commence on the Effective Date and expire, unless earlier terminated as set forth herein, four (4) years thereafter.
- 1.1.14. "Project" means the research project as described on **Appendix B** attached hereto entitled "Functional characterization of secretory T. suis larval products in mice".
- 1.1.15. "Project Director for FU Berlin" is Prof. Dr. Susanne Hartmann.
- 1.1.16. "Project Directors for Coronado" are Dr. Karin Hehenberger and Dr. Bobby Sandage or any duly qualified substitute who replaces a Project Director for Coronado.
- 1.1.17. "Project Results" means any and all Know-How in any form that is (a) conceived, developed or otherwise generated by or on behalf



of either Party in the course of performing the Project or pursuant to this Agreement; or (b) generated within (6) months after the expiration of the Performance Period from an analysis of the data generated in the performance of the Project.

1.1.18. "Research Fees" is defined in Article 5.

#### **ARTICLE 2 - RESEARCH WORK**

- 2.1 The Parties will commence the performance of the Project promptly after the Effective Date of this Agreement and will perform the Project during the Performance Period in accordance with the terms and conditions of this Agreement. FU Berlin will not make any changes to the Project without the prior written consent of Coronado, such consent to be given or denied at Coronado's sole discretion. Notwithstanding anything in this Agreement to the contrary, Coronado and FU Berlin may at any time amend the Project in accordance with Article 13.1 hereof.
- 2.2 FU Berlin will select and supervise staff for the Project as set out in the Project or, if not specified in the Project, as required for the timely performance of the Project. Notwithstanding the foregoing, the Project will be supervised by Prof. Dr. Susanne Hartmann and, if for any reason Prof. Dr. Susanne Hartmann is unable to continue to serve as Project Director for FU Berlin, Coronado shall have the right to terminate this Agreement. In such event, the provisions of Article 14.4 shall be applicable.
- 2.3 Unless otherwise provided herein or in the License Agreement (including as set forth in Article 5 thereof), or as agreed by the Parties in writing, FU Berlin will not during the Term of this Agreement or the License Agreement cooperate, work with, or enter into any agreement or arrangement with any third party relating to TSO or granting any intellectual property rights relating to the foregoing.
- 2.4 Except as otherwise provided herein or in the License Agreement, nothing in this Agreement will be construed as granting to either Party any license with respect to the other Party's proprietary rights or Confidential Information.
- 2.5 Each Party covenants towards the other Party that its performance under the Agreement and the Project will be in accordance with all applicable laws and regulations.

#### ARTICLE 3 - INDEPENDENT CONTRACTOR

- 3.1 In the performance of this Agreement
  - FU Berlin will be deemed to be and will be performing its work hereunder solely as an independent contractor and, as such, none
    of FU Berlin, Project Director for FU Berlin nor any FU Berlin Personnel will be entitled to any benefits applicable to employees
    of Coronado.



ii) The relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party, its employees or its Project Director(s) will be authorised or empowered to act as an agent or intermediary for the other Party for any purpose, nor to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party.

#### **ARTICLE 4 - REPORTING**

- 4.1 FU Berlin will disclose to Coronado in written progress reports in mutually-agreed upon form any and all Project Results as follows: (a) every six (6) months, in a short summary form; and (b) a full progress report once each calendar year, or within thirty (30) days of the termination of the Performance Period or early termination of this Agreement, whichever occurs first, describing the progress made and Project Results. In addition, Coronado shall be advised via regular communication via telephone conferencing as reasonably requested by Coronado. Any report prepared by FU Berlin hereunder referencing and/or containing Project Results (Invention Disclosure) is considered Confidential Information until publication of such Project Results in accordance with Article 7 hereof and shall be subject to the terms of the License Agreement.
- 4.2 During the Performance Period, representatives of FU Berlin will meet with representatives of Coronado at least once a year at times and places mutually agreed upon to discuss progress and Project Results, as well as plans for the Project performed hereunder. Meetings will take the form of a presentation from the FU Berlin (Hartmann lab) with updates on the current state of research and roundtable discussion. The meetings will be held either at Coronado's facilities in the United States or at FU Berlin's facilities in Berlin, at Coronado's choice. In the event that such meetings are held at Coronado's premises, Coronado will reimburse FU Berlin for preapproved reasonable travel expenses on economy class and reasonable hotel expenses, upon submission of appropriate documentation evidencing such expenses. FU Berlin will provide to Coronado a summary progress report at least two (2) weeks prior to the above meetings.

#### **ARTICLE 5 - RESEARCH FEES**

- 5.1 In consideration of FU Berlin's performance of the Project, Coronado will pay FU BERLIN the fees (the "Research Fees") as set forth in and subject to the terms and conditions of this Article 5.
- 5.2 During the Performance Period, Coronado will pay the specified Research Fees (which, for clarification, include 20 % overhead costs for FU Berlin) on the dates (the "Payment Dates") set forth in this Article 5.2 (provided that if any specified Payment Date is not a business day, the payment will be made on the next following business day):
  - within ten (10) business days after the Effective Date, an amount equal to €81,000 pro rated for the period of time commencing on the Effective Date and terminating on June 30, 2013 based on the €81,000 representing 180 days;



- €81,000 on July 1, 2013;
- €81,000 on January 2, 2014;
- €81,000 on July 1, 2014;
- €81,000 on January 2, 2015;
- €81,000 on July 1, 2015;
- €81,000 on January 2, 2016;
- €81,000 on July 1, 2016; and
- on January 2, 2017, an amount equal to €81,000 less the amount paid for the period of time commencing on the Effective Date and terminating on June 30, 2013.
- 5.3 For clarification, (a) the aggregate Research Fees shall not exceed the sum EUR 648,000 during the Performance Period, (b) all bank fees related to receipt of interbank transfers must be borne by Coronado, and (c) the Research Fees do not include any payments mentioned under the License Agreement. Any payment payable by Coronado under this Agreement is subject to receipt by Coronado of an invoice allowing forty five (45) days from receipt by Coronado of such invoice until settlement.
- 5.4 The Research Fees made by Coronado under this Agreement impose no obligation, express or implied, for FU Berlin or Project Director for FU Berlin to prescribe, provide favourable formulary status for, or otherwise support Coronado's products or services.
- 5.5 If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article 5, FU Berlin shall provide Coronado, prior to any such payment, annually or more frequently if required, with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to Form W-8BEN or any successor forms) and Coronado shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this Article 5. Coronado will reasonably cooperate with FU Berlin to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries.

#### **ARTICLE 6 - PUBLICITY**

- 6.1 Except as may be required by applicable law or as provided in this Agreement or the License Agreement, the Parties will not use the name of the other Party, nor of any employee or member of the other Party's Project staff, in any advertising or promotional activities without the prior written approval of the other Party, which approval shall not be unreasonably withheld and which shall only apply for the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar information that has previously been disclosed unless there have been material developments since the date of the previous disclosure.
- 6.2 Notwithstanding the foregoing, it is understood and agreed by FU Berlin that Coronado may make disclosure of this Agreement and the License Agreement and the terms hereof and thereof (a) in any filings required by



the Securities and Exchange Commission ("SEC"), other governmental authority or securities exchange, and may file this Agreement and the License Agreement as exhibits to any filing with the SEC, other governmental authority or securities exchange, and (b) in press releases or other public announcements as required by applicable laws. Coronado shall provide FU Berlin with notice of the initial such press release disclosure. Except as required by law, FU Berlin shall not make any public announcement or other disclosure to a third party concerning the existence of or terms of this Agreement or the License Agreement or with respect to the Project or Licensed Product without the prior written consent of Coronado.

#### **ARTICLE 7 - PUBLICATION**

- 7.1 Coronado agrees that FU Berlin will be permitted to (a) present at symposia and at international or regional professional meetings, and (b) publish in scientific journals, theses, or dissertations the Project Results, always provided that Coronado is furnished with copies of any proposed presentation or publication at least thirty (30) calendar days in advance of the submission of such proposed presentation or publication. Within this thirty (30) day period, Coronado has the right to comment on and object to such proposed presentation or proposed publication either because there may be patentable subject matter or if Coronado Confidential Information is contained in the proposed publication or presentation. In the event that Coronado puts forward comments to the proposed presentation or publication, FU Berlin undertakes to take into due consideration any such comments. In the event that Coronado makes an objection to the proposed presentation or publication including because there may be patentable subject matter, FU Berlin must refrain from making such publication or presentation for ninety (90) days from the date of receipt by FU Berlin of such objection in order for Coronado to file patent application(s) with the patent office(s) directed to the patentable subject matter contained in the proposed publication or presentation. Except with the express written consent of Coronado, to be decided at Coronado's sole discretion, FU Berlin will under no circumstances publish or disclose any Coronado Confidential Information or Coronado Intellectual Property.
- 7.2 The Parties agree that any publication of the Project Results will support current, internationally accepted requirements for biomedical publication including ethical principles and recommendations applying to authorship and contributorship.

#### **ARTICLE 8 - INTELLECTUAL PROPERTY**

8.1 FU Berlin understands and acknowledges that Coronado is engaged in an ongoing research and pre-clinical and clinical development program with respect to TSO and owns and controls and may obtain during the Term additional ownership or control of Patents, Know-how, trade secrets, and other intellectual property relating to TSO ("Coronado Intellectual Property") and shall retain all such ownership and control during and after the Project. Coronado grants to FU Berlin during the Performance Period a



- non-exclusive non-transferable license to Coronado Intellectual Property solely to the extent necessary for FU Berlin's own internal use for the sole purpose of conducting the Project in accordance with the terms of this Agreement.
- 8.2 FU Berlin retains at all time its ownership of the FU Berlin Intellectual Property, subject to the exclusive rights and licenses thereto granted to Coronado under the License Agreement.

#### License to Project Results and Joint Patents

- 8.3 FU Berlin will disclose to Coronado any and all Project Results in accordance with Article 4 and will promptly disclose to Coronado in writing any Inventions. Any and all Project Results and Joint Patents, including all rights, title and interest thereon and any Inventions relating thereto or claimed therein, will be jointly owned by the Parties as provided for and in accordance with the terms and conditions of the License Agreement.
- 8.4 FU Berlin and Prof. Dr. Susanne Hartmann (a) shall ensure that all FU Berlin Personnel who will have responsibilities and/or will engage in activities relating to the Project has entered or will enter into upon recruitment an employment agreement or other agreement that provides for disclosure and assignment to FU Berlin of any Inventions made by such FU Berlin Personnel (including assignment of any of such individual's right, title and interest in and to any such Inventions and intellectual property relating to any such Inventions), during the course of his or her employment, performance of the Project and conduct of the activities contemplated under this Agreement, and is familiar with and abides by the terms of this Article 8.3, and (b) agree specifically that Prof. Dr. Susanne Hartmann has entered into such contractual agreement and assignment with FU Berlin.
- 8.5 The License Agreement sets out, *amongst others*, the exclusive rights and licenses to Coronado to use and exploit FU Berlin Intellectual Property, Project Results and Joint Patents.

#### **ARTICLE 9 - CONFIDENTIALITY**

9.1 FU Berlin undertakes from the date of disclosure during the Term and for a period ending on the later of (a) seven (7) years after the expiration of the Term, or (b) expiry or termination of the License Agreement, to treat all Coronado Intellectual Property as well as any other confidential or proprietary information of Coronado, including, technical, financial or business information disclosed by Coronado which is clearly marked "confidential", "proprietary" or by other appropriate legend indicative of its confidential nature (collectively, "Coronado Confidential Information"), as strictly confidential (provided, that if Confidential Information is not marked or otherwise identified as such, it shall be treated as confidential in accordance with the terms of this Agreement if a reasonable person knowledgeable in the field of research or medical practice would conclude that such information was the confidential, proprietary information of Coronado) and not to disclose any of the foregoing to any third party and to use it only for the performance of the Project in accordance with the terms of this Agreement.



- 9.2 The obligations set forth in this Article 9 will also apply to Project Results and reports referencing and/or containing Project Results prepared by FU Berlin hereunder (together with Coronado Confidential Information, "Confidential Information") until (and only to the extent) released for publication in accordance with Article 7 of this Agreement.
- 9.3 The obligations set forth in Articles 9.1-9.2 above will not apply to Confidential Information that:
  - i) is or becomes known to the public through no fault of the receiving Party;
  - ii) is already known to the receiving Party prior to its receipt from the disclosing Party as shown by the written records of the receiving Party;
  - iii) becomes known to the receiving Party by disclosure from a third party who has lawful right to disclose the information;
  - iv) is independently developed by or for the receiving Party as shown by the receiving Party's written records; or
  - v) is required to be disclosed by law or by legal, administrative or judicial process.
  - Confidential Information disclosed hereunder shall not be deemed to be within the foregoing exceptions (i-v) merely because such information is embraced by more general knowledge in the public domain or is in possession of the receiving Party solely as a result of the disclosing Party's activities under this Agreement.
- 9.4 FU Berlin may disclose Confidential Information only to employees who need to know in order to perform FU Berlin's obligations under this Agreement, and provided that such employees are bound by obligations of confidentiality and non-use to FU Berlin which are at least as restrictive as those contained in this Agreement. FU Berlin will at all times ensure that such employees are fully aware of FU Berlin's obligations of this Agreement and will at all times be responsible for any breach by its employees of the provisions herein.
- 9.5 FU Berlin will promptly notify Coronado if FU Berlin becomes aware of any potential breach of the obligations of confidentiality and non-use by any individual to whom FU Berlin has disclosed any Confidential Information. FU Berlin will give Coronado all reasonable assistance in connection with any action, demand, claim or proceeding that Coronado may institute against any such individual in respect of such potential breach.
- 9.6 FU Berlin undertakes to destroy or, upon request of Coronado, to return to Coronado promptly upon completion of the Project or early termination of



this Agreement any and all Confidential Information (and all copies thereof), apart from one copy to be retained in the legal files of FU Berlin for the sole purpose of determining the scope of obligations incurred under this Agreement or as otherwise required by law (which shall remain subject to the confidentiality restrictions contained herein). FU Berlin will no later than one (1) month after completion of the Project or termination of this Agreement provide written confirmation that the obligation in this Article 9.6 has been fulfilled.

# ARTICLE 10 - INSURANCE AND INDEMNIFICATION

- 10.1 FU Berlin represents and warrants that FU Berlin has adequate liability insurance, such protection being applicable to FU Berlin Personnel to the extent permitted by law.
- 10.2 Each Party hereby assumes any and all risks of personal injury and property damage attributable to the intentional or negligent acts or omissions of that Party and its officers, employees, staff and agents.
- 10.3 FU Berlin hereby agrees to hold harmless and indemnify Coronado, including, but not limited to, Coronado's attorneys' fees, by reason of breach of this Agreement by FU Berlin or FU Berlin Personnel.
- 10.4 In respect of any information or materials supplied by FU Berlin under the Project, no warranty or representation of any kind is made, given or implied as to the sufficiency or fitness for purpose nor as to the absence of any infringement of any proprietary rights of third parties. FU Berlin shall not be responsible for punitive damages, indirect or consequential loss or similar damage such as, but not limited to, loss of profit, loss of revenue or loss of contracts, provided such damages was not caused by a willful act or by breach of confidentiality.

#### **ARTICLE 11 - ASSIGNMENT**

11.1 Neither Party may assign this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld, except that without such consent of FU Berlin, Coronado may assign or transfer this Agreement to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets related to TSO or Licensed Product or in the event of a merger, consolidation, change in control or similar corporate transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement. In connection with the foregoing, Coronado acknowledges the "Guiding Principles" of FU Berlin and shall provide notice to FU Berlin of any such assignment.

# **ARTICLE 12 - NOTICES**

12.1 Specifically excepting any invoice or payment payable hereunder for which reference is made to Article 5 hereof, any notice, report, request, approval, consent or other communication required or permitted to be given under this Agreement will be in writing and will for all purposes be deemed to have been fully given and received if delivered in person or



sent by registered or electronic mail, by recognized international courier service, or by fax transmission (with an appropriate transmission receipt) to the respective Parties at the following addresses:

If to Coronado: 24 New England Executive Park

Burlington, MA 01803

Attn: Bobby W. Sandage, Jr., Ph.D <u>bsandage@coronadobio.com</u>

Fax:+1-781-652-4545

If to FU Berlin: Freie Universität Berlin

Fachbereich Veterinärmedizin Institut für Immunologie

Attn: Prof. Dr. Susanne Hartmann <a href="mailto:susanne.hartmann@fu-berlin.de">susanne.hartmann@fu-berlin.de</a>

Fax: +49 30 2093 6051



# **ARTICLE 13 - OTHER PROVISIONS**

- 13.1 Amendment. No amendments or additions to this Agreement (including to this Article 13.1) or to the Project will be binding on the Parties unless made in writing and signed by a duly authorised representative of each Party.
- 13.2 Counterparts. This Agreement may be executed in one or more counterparts, each of which will be deemed to be an original copy of the Agreement, and all of which, when taken together, will be deemed to constitute one and the same Agreement. Signatures to this Agreement transmitted by fax or by electronic mail in "portable document format" (".pdf") will have the same effect as physical delivery of the paper document bearing the original signatures.
- 13.3 No Third Party Beneficiaries. No provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any party other than the Parties and their respective successors and assigns.
- 13.4 Severability. If, under applicable law, any provision of this Agreement is invalid or unenforceable, the affected provision of this Agreement will be limited or eliminated only to the extent necessary, and the remainder of this Agreement will remain in full force and effect, provided that the remaining provisions are in accordance with the intention of the Parties. In the event the terms of this Agreement are materially altered as a result of the foregoing, such invalid and/or unenforceable provision shall be replaced by a valid and enforceable provision that comes closest to the invalid and/or unenforceable provision in light of the overall intent and purposes of this Agreement and the Parties will renegotiate in good faith the terms of this Agreement to resolve any other inequities.
- 13.5 Entire Agreement. This Agreement together with the License Agreement constitute the entire agreement between the Parties with respect to performance of the Project and supersedes any and all oral or written communications, understandings or term sheets relating thereto.



# **ARTICLE 14 - TERM AND TERMINATION**

- 14.1 This Agreement will become effective on the Effective Date and will continue in effect until the later of the date that the last payment or report is due hereunder (the "Term") unless sooner terminated in accordance with this Article 14. The Parties may extend the Term by amending this Agreement in accordance with Article 13.1 hereof.
- 14.2 Either Party may terminate this Agreement early, with or without cause, with a three months prior written notice.
- 14.3 Either Party shall be entitled to terminate this Agreement or suspend its obligations with immediate effect, and without any compensation becoming due, in the event of the following:
  - i) if either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this Agreement, the Non-Breaching Party may deliver notice of such breach to the Breaching Party; if the Breaching Party fails to cure such breach within the sixty (60) day period after the Breaching Party's receipt of such notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; or
  - ii) upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof
- 14.4 In the event of early termination of this Agreement by Coronado pursuant to Article 14 or Article 2.2 hereof, (a) the Performance Period shall terminate on the effective date of the termination of this Agreement, and (b) Coronado will pay FU Berlin an amount (a "Termination Fee") equal to the amount of the Research Fee that would have been payable in accordance with Article 5.2 on the first Payment Date following the effective date of termination, based on a 180-day period and *pro rated* for the actual number of days since the last Payment Date prior to the effective date of termination, subject to the following sentence. In the event FU Berlin incurs under German law non-cancellable severance or similar obligations in accordance with the Project prior to the early termination, and the amount of such obligations exceeds the Termination Fee calculated in accordance with the previous sentence, the Termination Fee shall be increased by an amount equal to the lesser of (i) the amount of such obligations or (ii) € 100.000, provided that FU Berlin will use reasonable efforts to mitigate such obligations and related costs.
- 14.5 Except as set forth in this Agreement, termination of this Agreement by



either Party for any reason will not affect the rights and obligations of the Parties accrued prior to the effective date of termination of this Agreement in accordance with the terms of this Agreement. In addition, notwithstanding any other provision of this Agreement, no termination of this Agreement, however effectuated, will (a) release the Parties from their rights and obligations under Articles 8 and 9 of this Agreement or affect the Parties' rights and obligations under the License Agreement, or (b) terminate the License Agreement, unless the License Agreement otherwise terminates in accordance with then applicable termination provisions of the License Agreement.

#### ARTICLE 15 - DISPUTE RESOLUTION AND GOVERNING LAW

- 15.1 The Parties will use commercially reasonable efforts to settle all matters in dispute amicably. The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) Business Days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of Coronado and the Director of Administration and Finance of FU Berlin. Such individuals shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) Business Days after such notice is received by the Party to whom the notice was sent. If such individuals are unable to settle the Dispute between themselves within twenty (20) Business Days, they shall so report to the parties in writing. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.
- 15.2 Any Dispute which has not been resolved by negotiation as provided in Article 15.1 within twenty (20) Business Days, shall be finally resolved under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The arbitration will take place in Berlin and will be conducted in the English language. The award of the arbitrator(s) will be final and binding on both Parties. The Parties bind themselves to carry out the awards of the arbitrator(s).
- 15.3 Notwithstanding, without resorting to prior arbitration and in addition to any other remedies provided by law, Coronado will be entitled to seek temporary and permanent injunctive relief against any threatened or actual breach of this Agreement or the continuation of any such breach in any court of competent jurisdiction.
- 15.4 This Agreement will as far as legally possible be construed and interpreted pursuant to the laws of Germany without regard to principles of conflicts of law.

#### ARTICLE 16 - REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

- 16.1 Each Party represents and warrants to the other Party that:
  - (a) it has the legal right, title, authority and power to enter into this Agreement and to perform its obligations hereunder and thereunder:



- (b) it has taken all necessary action to authorize the execution, delivery and performance of this Agreement;
- (c) the performance of its obligations under this Agreement and the License Agreement will not conflict with or result in the breach of any agreements, contracts or other arrangements to which it is a Party.

### 16.2 FU Berlin represents and warrants to Coronado that:

- (a) FU Berlin is the sole and exclusive owner of the FU Berlin Intellectual Property, free and clear of any liens, charges and encumbrances, and no other person, corporate or other entity, or governmental entity or subdivision thereof, has any claim or ownership interest in, to or under the FU Berlin Intellectual Property whatsoever, except that as set forth in the Ovamed MTA, Ovamed has a 10% interest in FU Berlin's interest in Joint Patents in the Ovamed Territory;
- (b) Without limiting the generality of the foregoing, any and all Inventions and intellectual property relating thereto that have been, are or may be made, conceived, created and/or reduced to practice by any FU Berlin Personnel, including Prof. Dr. Susanne Hartmann, those under Prof. Dr. Hartmann's supervision and control, or any other person performing services under this Agreement, have been or are contractually assigned to and are and will be owned solely by FU Berlin;
- (c) FU Berlin has not (a) assigned, transferred, conveyed or otherwise encumbered its right, title and interest in and to the FU Berlin Intellectual Property or to any Joint Intellectual Property; (b) granted any license or other rights to or under the FU Berlin Intellectual Property or to any Joint Intellectual Property except that as set forth in the Ovamed MTA, Ovamed has a 10% interest in FU Berlin's interest in Joint Patents in the Ovamed Territory; or (c) entered into any agreement with any third party which relates to the Project or is inconsistent or in conflict with the rights granted to Coronado hereunder or which would otherwise interfere with the practice of the Licensed IP (as defined in the License Agreement) by Coronado as contemplated under the License Agreement;
- (d) FU Berlin has disclosed to Coronado all information known by it that is reasonably believed by FU Berlin to be related to the FU Berlin Intellectual Property or the Project and the rights and licenses granted under the License Agreement and the activities contemplated under this Agreement; and
- (e) there are no pending or threatened actions, suits, investigations, claims, judgments, settlements or proceedings relating to the FU Berlin Intellectual Property.



16.3 <u>LIMITATION OF LIABILITY</u>. EXCEPT AS OTHERWISE SET FORTH HEREIN, NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY. This limitation of liability shall not apply to the extent that any such liability is the result of intentional acts or omissions by, or accountable to, any Party.

SIGNED BY:	
Date: February 22, 2013	Date: 22.02.2013
Coronado Biosciences, Inc.	Freie Universität Berlin
By: <u>/s/ Harlan F. Weisman, M.D.</u> Name: Harlan F. Weisman, M.D. Title: Chairman and CEO	By: /s/ Peter Lange Name: Peter Lange Title: Director of Administration and Finance
Acknowledged and read:	Acknowledged and Agreed:
Date: February 22, 2013	Date: <u>2/22/13</u>
Project Director for Coronado	Principal Scientist and Project Director for FU Berlin
/s/ Bobby Sandage Dr. Bobby Sandage, Principal Scientist	/s/ S. Hartmann Prof. Dr. Susanne Hartmann Principal Scientist / Group Leader



# Appendix A FU Berlin Background Know-How

[\*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

[\*]



Appendix B PROJECT

[\*]

[\*] Confidential treatment requested; certain information omitted and filed separately with the SEC.



# Appendix C Joint Ownership and License Agreement

### **EXECUTION COPY**

### JOINT OWNERSHIP AND EXCLUSIVE LICENSE AGREEMENT

between Coronado Biosciences, Inc.

24 New England Executive Park

Burlington, MA 01803

Project Leaders: Dr. Karin Hehenberger, Dr. Bobby Sandage

(hereinafter referred to as "Coronado")

and Freie Universität Berlin

represented by Peter Lange

Director of Administration and Finance

Kaiserswerther Straße 16-18

14195 Berlin

on behalf of the executing

Department of Veterinary Medicine

Institute of Immunology

(hereinafter referred to as the "FU Berlin")

Project Leader: Prof. Dr. Susanne Hartmann (Principal Scientist)

Coronado and FU Berlin are hereinafter also referred to individually as "Party" and collectively as the "Parties".

This Joint Ownership and Exclusive License Agreement ("License Agreement") is entered into by and between the Parties as of the Effective Date (as defined herein).

### **PREAMBLE**

WHEREAS The Parties have on the Effective Date entered into a Research Agreement related to the Project (as defined herein);

WHEREAS FU Berlin wishes to grant Coronado the exclusive right and license to exploit FU Berlin Intellectual Property, Project

Results and Joint Patents (each as defined herein); and

WHEREAS The Parties and Ovamed GmbH ("Ovamed") have on the Effective Date entered into a Letter Agreement which, in

part, amends the Ovamed MTA, and Coronado and Ovamed have on the Effective Date entered into a License and

Sublicense Agreement relating to Licensed Products for the Ovamed Territory;

### Licensed Products for the Ovamed Territory;

NOW THEREFORE, in consideration of the premises and the mutual covenants set forth herein, the Parties hereto agree to the following:

### 1. ARTICLE 1 - DEFINITIONS

- 1.1. In this License Agreement, the following capitalized terms will have the meaning set forth in this Article 1.1, unless otherwise defined.
  - 1.1.1. "Affiliate(s)" means any corporation, company, partnership, joint venture or other entity which Controls, is controlled by, or is under common Control with a Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of a Party.
  - 1.1.2. "Coronado Territory" means North America, South America and Japan, and such other countries or jurisdictions as may be agreed to from time to time between Coronado and Ovamed.
  - 1.1.3. "Effective Date" means the commencement date of this License Agreement which is the date of the last signature hereto.
  - 1.1.4. **"FU Berlin Background Know-How"** means the Know-How that has been created by, is owned or controlled by or has been reduced to practice by FU Berlin or FU Berlin Personnel related to the project "Functional characterization of T. suis larval products in mice" prior to the Effective Date, whether or not patentable, as summarized on **Schedule 1.1.4** attached hereto.
  - 1.1.5. **"FU Berlin Intellectual Property"** means any intellectual property, including Patents and Know-How, that (a) is included in or covers FU Berlin Background Know-How, or (b) becomes during the Term owned or controlled by FU Berlin or its Affiliates and relates to the Project, the Research Agreement or any Licensed Product, including FU Berlin's right, title and interest in any Project Results and/or Joint Patents that for any reason, do not become or remain during the Term jointly-owned by the Parties.
  - 1.1.6. **"IND"** means an Investigational New Drug Application, filed in accordance with U.S. 21 C.F.R. Part 312, under which clinical investigation of an experimental drug or biologic (in this Agreement, Licensed Product) may be performed in human subjects, or a corresponding filing in Europe.
  - 1.1.7. **"Issued Patent Claim"** means a claim of any granted Patent that has not: (i) lapsed, expired or been withdrawn, canceled, abandoned or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; (ii) been finally rejected or held invalid by a final decision of a Patent Authority from which no appeal has been or can be taken; or (iii) been held invalid or unenforceable in an unappealable decision of a court or competent body having jurisdiction (including a decision which was appealable, but which was not timely appealed).
  - 1.1.8. "Joint Intellectual Property" has the meaning set forth in Article 2.1.
  - 1.1.9. "Joint Patent" means any and all Patents that embody, disclose or claim an invention or discovery (an "Invention") first

made, conceived, created and/or reduced to practice solely or jointly by one or more employees and/or agents (including professors, students and/or any other Project staff) of FU Berlin ("FU Berlin Personnel") or jointly by FU Berlin Personnel and one or more employees of Coronado in the course of or in furtherance of conducting or performing the Project or pursuant to the Research Agreement.

- 1.1.10. **"Know-How"** means results, data, ideas, concepts, discoveries, Inventions (whether patentable or not) developments, methods, processes and trade secrets, techniques, methodologies, modifications, innovations, improvements, enhancements, design and design concepts, formulations, biological samples, tissues, animals, organisms, compounds, intermediates, and all other tangible and intangible materials and information.
- 1.1.11. "Licensed Product" means a pharmaceutical or biologic product in final form, the use or sale of which in a particular country would, in the absence of the rights and licenses granted hereunder, infringe an Issued Patent Claim of a Joint Patent or Patent included in Licensed IP in such country.
- 1.1.12. "Licensed IP" means, collectively, FU Berlin Intellectual Property and FU Berlin's interest in Joint Intellectual Property.
- 1.1.13. "Net Sales" means the actual gross amount invoiced for sales of Licensed Products by Coronado, its Affiliates or sublicensees to third parties, less the sum of the following: (a) quantity or other trade discounts; (b) sales, excise, VAT, custom or tariff duties and/or taxes; (c) amounts allowed or credited on returns or rejections (including as a result of recalls, market withdrawals or other corrective actions), and retroactive price reductions or allowances; (e) outbound transportation prepaid or allowed, packaging and freight charges and transportation insurance; (f) rebates or similar payments paid in connection with sales of Licensed Product to any governmental or regulatory authority in respect of any state or federal Medicare, Medicaid or similar programs in any country of the Territory, patient discount programs, administrative fees and chargebacks or similar price concessions, and sales commissions; and (g) allowances for bad debt. Net Sales does not include sales of Licensed Product solely for non-profit research or clinical testing or for indigent or similar public support or compassionate use programs. A Licensed Product shall be considered "sold" only when billed or invoiced.
- 1.1.14. **"Ovamed MTA"** means the Material Transfer Agreement, by and between FU Berlin and Ovamed, as amended as of the Effective Date by, and together with, the Letter Agreement among FU Berlin, Ovamed and Coronado.
- 1.1.15. "Ovamed Territory" means all countries outside the Coronado Territory.
- 1.1.16. "Patent(s)" means any patents, patent applications (including provisional applications), certificates of invention, or applications for certificates of invention and any supplementary protection certificates, together with any extensions, registrations, confirmations, patents of addition, reissues, substitutions, divisions, continuations or continuations-in-part, reexaminations or renewals thereof or thereto.

- 1.1.17. **"Performance Period"** means the period for performing the Project, which shall commence on the Effective Date and expire, unless earlier terminated as set forth in the Research Agreement, four (4) years thereafter.
- 1.1.18. **"Project"** means the research project as described in **Appendix B** attached to the Research Agreement entitled "Functional characterization of secretory T. suis larval products in mice".
- 1.1.19. **"Project Results"** means any and all Know-How in any form that is (i) conceived, developed or otherwise generated by or on behalf of either Party in the course of performing the Project or pursuant to the Research Agreement; or (ii) generated within (6) months after the expiration or termination of the Performance Period from an analysis of the data generated in the performance of the Project.
- 1.1.20. "Regulatory Approval" means all approvals (including pricing and reimbursement approvals required for marketing authorization), product and/or establishment licenses, registrations or authorizations of all regional, federal, state or local regulatory agencies, departments, bureaus or other governmental entities, necessary for the manufacture, use, storage, import, export, transport and sale of a Licensed Product in a regulatory jurisdiction.
- 1.1.21. **"Research Agreement"** means the Research Agreement entered into as of the Effective Date by and between FU Berlin and Coronado, as may be amended in accordance with the terms thereof.
- 1.1.22. "Research Proposal" has the meaning set forth in Article 5.
- 1.1.23. "Royalty Term" means, with respect to a Licensed Product in in each country in the Territory, the period commencing on the date of first commercial sale of such Licensed Product in the applicable country and expiring on the expiration or invalidation of the last Issued Patent Claim covering such Licensed Product in the applicable country in the Territory.
- 1.1.24. "Royalty Year" means (a) for the year in which the first commercial sale of Licensed Product occurs, the twelve (12) month period commencing on the first day of the calendar quarter in which such first commercial sale occurs and expiring on the last day of the twelfth (12th) month following such first day; and (b) for each subsequent year, each successive twelve (12) month period.
- 1.1.25. "Territory" means worldwide.
- 1.1.26. "TSO" means Trichuris suis ova, incorporated into any formulation or delivery system.

### 2. ARTICLE 2 - JOINT OWNERSHIP

- 2.1. All Project Results and Joint Patents, including all rights, title and interest thereon and any Inventions relating thereto or claimed therein ("Joint Intellectual Property"), will be jointly owned by the Parties, regardless of the contribution by either Party or its employees or agents towards inventorship, provided, however, that in accordance with the Ovamed MTA, FU Berlin's rights, title and interest in Joint Patents in the Ovamed Territory shall be subject to Ovamed's interest therein.
- 2.2. Each Party shall execute and cause to be executed all documents necessary to vest jointly in the Parties all rights, title and interest in the Joint Intellectual Property, including instruments of conveyance, assignments or other documents as may reasonably be deemed necessary

- and appropriate to give full and proper effect to such assignment and joint ownership and apply for and obtain Patents in accordance with the terms of this License Agreement.
- 2.3. Each Party represents and warrants that each of its employees, agents and/or consultants who will have responsibilities and/or will engage in activities relating to the Project or under the Research Agreement, (a) has entered or will enter into an employment agreement or other agreement that provides for assignment to such Party of all Inventions made by such employee, agent or consultant during the course of his or her employment or performance of the Project and conduct of the activities contemplated under the Research Agreement, and (b) is familiar with and abides by the terms of this Article 2.

### 3. ARTICLE 3 - PROSECUTION, MAINTENANCE AND ENFORCEMENT

- 3.1. Coronado or its designees will have the first right and responsibility for preparation, filing, prosecution and maintenance and protection (including handling of oppositions, re-examinations and interferences) in the Territory of any Joint Patent (in the names of both Parties) and of any Patent included in FU Berlin Intellectual Property, at Coronado's expense. If Coronado or its designees decide not to file a patent application or to discontinue prosecution or maintenance of any such Patent in a particular country or jurisdiction in the Territory, Coronado shall advise FU Berlin of such decision. FU Berlin may in that case take over the filing, prosecution and/or maintenance of such Patent in such country or jurisdiction at its own expense. FU Berlin shall promptly disclose to Coronado in writing all Inventions of which it becomes aware. Coronado will inform FU Berlin at least 90 days after Coronado receives a written notice of invention or invention disclosure if a patent application will be filed. Coronado acknowledges and agrees that in the event of any patentable Inventions it would expect to file patent applications on such patentable Invention in at least the United States and one jurisdiction in Europe.
- 3.2. Coronado will keep FU Berlin informed of material developments in the preparation, filing, prosecution, maintenance and protection of such Patents and will permit FU Berlin a reasonable opportunity to comment on any proposed material action with respect to any such Patent. The same obligations will apply with respect to FU Berlin in case FU Berlin takes over the prosecution and/or maintenance of Patents as per the above.
- 3.3. FU Berlin will cooperate with and provide assistance to Coronado including by executing or causing to be executed on a timely basis all documents, and performing all acts reasonably necessary, for Coronado to prepare, file and prosecute such patent applications and maintain, protect, defend and enforce such Patents.
- 3.4. Each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement of any Joint Patent or Patent included in FU Berlin Intellectual Property. Coronado shall have the unilateral right, but not the obligation, to take legal or other action against any third party to enforce and defend such Patents at its sole discretion and expense. Any monetary recovery from any legal or other action shall vest with Coronado.
- 3.5. FU Berlin makes no warranties, express or implied, of merchantability or fitness for a particular purpose of any subject matter defined by the claims of the Patents or Licensed IP or tangible materials related thereto.

- 3.6. If any warning letter or other notice of infringement is received by a Party, or legal action is brought against a Party, alleging infringement of third party rights in the manufacture, use or sale of any Licensed Product or use of any Joint Patents or Licensed IP, that Party shall promptly inform the other Party and the Parties shall discuss how to respond. Coronado or its designees shall, without the consent of FU Berlin, have the right but not the obligation to defend such action and shall have the right but not the obligation to settle with such third party, provided that Coronado or such designee does not concede invalidity, non-infringement or unenforceability of any of the Joint Patents without first consulting with FU Berlin.
- 3.7. If Coronado or its designee is unable to initiate, prosecute, or defend any actions referred to in this Article 3 solely in its own name, FU Berlin will join such action voluntarily and will execute on a timely basis all documents necessary for Coronado or such designee to prosecute, defend and maintain such action.
- 3.8. The Parties shall cooperate with each other in obtaining patent term extensions or restorations or supplemental protection certificates or their equivalents in any country in the Territory where applicable and where desired by Coronado. If elections with respect to obtaining such extension or supplemental protection certificates are to be made, Coronado shall have the right but not the obligation to make the election.
- 3.9. FU Berlin shall not (a) sell, transfer, assign, encumber or otherwise dispose of or grant any third party any rights or licenses in or to, any of FU Berlin's right, title and interest in or to any FU Berlin Intellectual Property or any Joint Intellectual Property, including in or to any Patents included therein, or (b) take any other action or enter into any agreement or arrangement with any third party to do any of the foregoing that is inconsistent or in conflict with the rights granted to Coronado hereunder or that would otherwise interfere with the practice of the Licensed IP by Coronado as contemplated under this Agreement.

### 4. ARTICLE 4 - EXCLUSIVE LICENSE

- 4.1. In consideration of the terms and conditions of this Agreement and the Research Agreement, FU Berlin hereby grants to Coronado a fully paid up, irrevocable, perpetual, exclusive (even as to FU Berlin), transferable right and license (including the right to grant sublicenses) in the Territory, under the Licensed IP, to develop, make, have made, use, import, export, market, offer for sale and sell Licensed Products. In the event that consent by FU Berlin is necessary for Coronado to license or sublicense any Joint Intellectual Property, FU Berlin hereby consents to Coronado's grant of one or more licenses or sublicenses under such Joint Intellectual Property to third parties and shall execute any document or do any other reasonable act deemed necessary to evidence such consent.
- 4.2. FU Berlin retains the non-exclusive and non-transferable right to use the Licensed IP solely for its own internal non-commercial, academic, research and teaching purposes, provided that FU Berlin shall not directly or indirectly, (a) grant any rights or take any other action that adversely impacts, is inconsistent with, could interfere or conflict with, or could reduce the value of, the rights and licenses granted to Coronado hereunder; or (b) distribute TSO, Licensed Product, or any other product utilizing any Licensed IP, to any third party, subject to the provisions of Article 5.

- 4.3. FU Berlin understands and acknowledges that Coronado is engaged in an ongoing research and pre-clinical and clinical development program with respect to TSO and owns or controls and may during the Term own or control Patents, Know-how, trade secrets, and other intellectual property relating to TSO ("Coronado Intellectual Property") and shall retain all such ownership, rights and licenses to and under the Coronado Intellectual Property during and after the Term.
- 4.4. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right except as expressly set forth herein.

### 5. ARTICLE 5 - RESEARCH PROPOSALS

- 5.1. If at any time during the Term FU Berlin proposes to conduct a research project on TSO in addition to the Project "Functional characterization of T. suis larval products in mice", it shall first submit to Coronado a written proposal for Coronado to sponsor such research project in accordance with this Article 5 (each, a "Research Proposal"). A Research Proposal shall include any such projects underway as of the Effective Date, including a research proposal relating to a project as summarized on Appendix 5.1. Any Research Proposal shall contain, at a minimum, information supporting the scientific rationale for such Research Proposal and a research project plan, timeline and budget associated with the Research Proposal. If after evaluating such Research Proposal, Coronado elects to sponsor such research, the Parties shall promptly negotiate in good faith a mutually acceptable research project plan and budget and a new research agreement relating thereto on reasonable and customary terms and conditions.
- 5.2. Upon execution by the Parties of such new research agreement, (a) any and all Know-How in any form that is (i) conceived, developed or otherwise generated by or on behalf of either Party in the course of performing the Research Proposal or pursuant to the new research agreement; or (ii) generated within (6) months after the expiration or termination of the performance period of the Research Proposal from an analysis of the data generated in the performance of the Research Proposal, and (b) any Patents relating thereto, including all FU Berlin's rights, title and interest thereon and any Inventions or other intellectual property relating thereto or claimed therein, shall automatically become Licensed IP and subject to the terms and conditions of this License Agreement.
- 5.3. If Coronado elects not to sponsor the research set forth in the Research Proposal, or if the Parties are unable to agree on terms and conditions of a new research agreement, then FU Berlin shall be free to present such Research Proposal to a third party. However, FU Berlin agrees not to present a Research Proposal to a third party that would include the ownership or grant of any intellectual property rights with or to a third party (a) on materially better terms than those last offered to Coronado without first offering such terms to Coronado, in which case Coronado will have a period of at least thirty (30) days in which to accept or reject the offer; (b) that conflicts or is inconsistent with any of the rights or licenses

granted to Coronado hereunder or under the Research Agreement; or (c) that could reasonably be considered to have an adverse impact on the commercialization of TSO or Licensed Product.

### 6. ARTICLE 6 - PAYMENTS

- 6.1. Patent Costs. Coronado will pay the patent costs as set forth in Article 3.
- 6.2. <u>Milestone Payments.</u> Coronado will pay FU Berlin the following non-creditable and non-refundable milestone payments, contingent upon occurrence of the specified event with respect to a Licensed Product, with each milestone payment to be made (a) for each of the first two (2) Licensed Products, (b) no more than once with respect to the achievement of the applicable milestone event for the first two (2) Licensed Products, and (c) within 45 days after the applicable milestone event is achieved:
  - **50.000 EURO** upon the grant of a Joint Patent in the U.S. (or another jurisdiction chosen by Coronado), which includes at least one Issued Patent Claim covering a composition or its use, which includes one or more substances that are secreted or excreted by *T. suis* larvae and which have been shown by functional characterization as having immunomodulatory properties *in vivo* in mice along the lines observed in human subjects after oral administration of TSO;
  - 80.000 EURO upon acceptance for filing of IND for a Licensed Product;
  - 100.000 EURO upon successful completion of Phase I Study with a Licensed Product;
  - 200.000 EURO upon successful completion of Phase II Study with a Licensed Product;
  - 400.000 EURO upon successful completion of Phase III Study with a Licensed Product;
  - 2.000.000 EURO upon Regulatory Approval of a Licensed Product in the U.S; and
  - **1.000.000 EURO** upon first Regulatory Approval of a Licensed Product in Europe (including obtaining approvals to market in at least Germany, France, United Kingdom, Italy and Spain).

### 6.3. Royalties on Net Sales

6.3.1. Subject to the provisions of this Section 5.3, during the Royalty Term, Coronado will pay FU Berlin royalties on Net Sales in the Territory in each Royalty Year ("Annual Net Sales") at the following rates:

For Portion of Annual Net Sales in the Territory:	Royalty Rate
Less than US\$500,000,000	1%
Greater than or equal to US\$500,000,000 and less than US\$1,000,000,000	1.5%
Greater than or equal to US\$1,000,000,000 and less than US\$2,000,000,000	2%
Greater than or equal to US\$2,000,000,000	2.5%

For example, if Annual Net Sales in a Royalty Year are US\$1,800,000,000, the royalties payable for such Royalty Year would total US\$28,500,000, calculated as follows: 1% of first US\$500,000,000 (or US\$5,000,000) plus 1.5% of next US\$500,000,000 (or US\$7,500,000) plus 2% of next US\$800,000,000 (or US\$16,000,000).

- 6.3.2. No multiple royalties shall be payable if a Licensed Product shall be covered by more than one Issued Patent Claim of a Joint Patent or a Patent included in Licensed IP. After the expiration of the Royalty Term in any country in the Territory, Coronado shall have a perpetual, fully paid license to the rights licensed hereunder in such country without any further consideration payable to FU Berlin.
- 6.3.3. Royalties shall be payable within sixty (60) days after the end of each calendar quarter during the Royalty Term in which there are Net Sales.
- 6.4. Tax Withholding. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article 6, FU Berlin shall provide Coronado, prior to any such payment, annually or more frequently if required, with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder (including, but not limited to Form W-8BEN or any successor forms) and Coronado shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this Article 6. Coronado will reasonably cooperate with FU Berlin to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries.
- 6.5. Payments in US Dollars; Currency Conversion; Exchange Controls. All payments hereunder shall be made in United States Dollars. For purposes of computing royalties based on Net Sales in any country outside the United States, such Net Sales shall be converted to United States Dollars using the relevant rate of exchange for United States Dollars used by Coronado for its internal financial accounting purposes in preparing its audited financial statements. If at any time legal restrictions prevent the prompt remittance of part or all of the royalties with respect to Net Sales in any country, payment shall be made through such lawful means or methods as Coronado may determine.
- 6.6. Third Party Obligations. As between the Parties, FU Berlin shall be responsible for any amounts payable to, and shall perform its obligations under applicable law to or any agreement between FU Berlin (or any Affiliate of FU Berlin or any FU Berlin Personnel) and Ovamed and/or any

other person (including any inventor) or entity relating to TSO, Licensed Product, Joint Patents or any intellectual property rights relating to any of the foregoing, including any agreement under which it obtained funding or materials ("**Third Party Agreements**"). Third Party Agreements shall include, without limitation, the Ovamed MTA.

### 7. ARTICLE 7 - EXCHANGE OF INFORMATION

- 7.1. Within ten (10) days after the Effective Date, FU Berlin shall disclose to Coronado in writing any FU Berlin Intellectual Property not previously made available to Coronado.
- 7.2. During the Term, and in addition to the reports required under the Research Agreement, FU Berlin shall promptly disclose to Coronado in writing on an ongoing basis any Inventions, developments or improvements relating to the Licensed IP or Licensed Product.

### 8. ARTICLE 8 - REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

- 8.1. Each Party represents and warrants to the other Party that:
  - 8.1.1. it has the legal right, title, authority and power to enter into this License Agreement and the Research Agreement and to perform its obligations hereunder and thereunder;
  - 8.1.2. it has taken all necessary action to authorize the execution, delivery and performance of this License Agreement
  - 8.1.3. the performance of its obligations under this License Agreement will not conflict with or result in the breach of any agreements, contracts or other arrangements to which it is a Party.
- 8.2. In addition to the representations and warranties in Article 8.1, FU Berlin represents and warrants to Coronado that:
  - 8.2.1. FU Berlin is the sole and exclusive owner of the FU Berlin Intellectual Property, free and clear of any liens, charges and encumbrances, and no other person, corporate or other entity, or governmental entity or subdivision thereof, has any claim or ownership interest in, to or under the FU Berlin Intellectual Property whatsoever, except that as set forth in the Ovamed MTA, Ovamed has a 10% interest in FU Berlin's interest in Joint Patents in the Ovamed Territory;
  - 8.2.2. without limiting the generality of the foregoing, any and all Inventions and intellectual property relating thereto that have been or are made, conceived, created and/or reduced to practice by any FU Berlin Personnel, including Prof. Dr. Susanne Hartmann, those under Prof. Dr. Hartmann's supervision and control, or any other person performing services under the Research Agreement, have been or are contractually assigned to and are owned solely by FU Berlin;
  - 8.2.3. FU Berlin has not (a) assigned, transferred, conveyed or otherwise encumbered its right, title and interest in and to the FU Berlin Intellectual Property or the Joint Intellectual Property, except that as

FU Berlin - License Agreement final execution

- set forth in the Ovamed MTA, Ovamed has a 10% interest in FU Berlin's interest in Joint Patents in the Ovamed Territory; (b) granted any license or other rights to or under the FU Berlin Intellectual Property or the Joint Intellectual Property; or (c) entered into any agreement with any third party which relates to the Project or is inconsistent or in conflict with the rights granted to Coronado hereunder or which would otherwise interfere with the practice of the Licensed IP by Coronado as contemplated under this License Agreement;
- 8.2.4. FU Berlin has disclosed to Coronado all information known by it that is reasonably believed by FU Berlin to be related to the FU Berlin Intellectual Property or the Project and the rights and licenses granted under this License Agreement and the activities contemplated under the Research Agreement; and
- 8.2.5. there are no pending or threatened actions, suits, investigations, claims, judgments, settlements or proceedings relating to the FU Berlin Intellectual Property.
- 8.3. <u>LIMITATION OF LIABILITY.</u> EXCEPT AS OTHERWISE SET FORTH HEREIN OR IN THE RESEARCH AGREEMENT, NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY. This limitation of liability shall not apply to the extent that any such liability is the result of intentional acts or omissions by, or accountable to, any Party.

### 9. ARTICLE 9 - MISCELLANEOUS

- 9.1. <u>Independent Contractor.</u> All work performed by either Party or any of its employees or agents pursuant to the terms of this License Agreement will be performed solely as an independent contractor, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party is authorised or empowered to act as an agent for the other for any purpose or make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party.
- 9.2. Entire Agreement; Incorporation by Reference. This License Agreement together with the Research Agreement and the appendices thereto constitute the entire agreement between the Parties with respect to the subject matter hereof and thereof, and supersede any and all oral or written communications, understandings or term sheets relating thereto. The following provisions of the Research Agreement are hereby incorporated by reference into this License Agreement and shall survive any termination or expiration of the Research Agreement: Article 8-Intellectual Property and Article 9-Confidentiality.
- 9.3. <u>Use of Name, Disclosure of Agreement.</u> Except as may be required by law or as provided in this License Agreement or the Research Agreement, neither Party will use the name, trademarks, trade names or logos of the other Party, its Affiliates, or their respective employees in any advertising or promotional activities without the prior written permission of the other Party, which permission shall not be unreasonably withheld and which shall only apply for the first time that specific information is to be disclosed, and shall not apply to the subsequent disclosure of substantially similar

information that has previously been disclosed unless there have been material developments since the date of the previous disclosure. Notwithstanding the foregoing, it is understood and agreed by FU Berlin that Coronado may make disclosure of this License Agreement and the Research Agreement and the terms hereof and thereof (a) in any filings required by the Securities and Exchange Commission ("SEC"), other governmental authority or securities exchange, and may file this License Agreement and the Research Agreement as exhibits to any filing with the SEC, other governmental authority or securities exchange, and (b) in press releases or other public announcements as required by applicable laws. Coronado shall provide FU Berlin with notice of the initial such disclosure. Except as required by law, FU Berlin shall not make any public announcement or other disclosure to a third party concerning the existence of or terms of this License Agreement or the Research Agreement or with respect to the Project or Licensed Product without the prior written consent of Coronado.

- 9.4. <u>Amendments.</u> No amendments or additions to this License Agreement (including to this Article 9.4) will be binding on the Parties unless made in writing and signed by a duly authorised representative of each Party.
- 9.5. Assignment. This License Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred by either Party, without the prior written consent of the other Party, which consent shall not be unreasonably withheld except that without such consent of FU Berlin, Coronado may assign or transfer this License Agreement (or any part hereof) to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets related to TSO or Licensed Product or in the event of a merger, consolidation, change in control or similar corporate transaction Any permitted assignee shall assume all obligations of its assignor under this License Agreement. In connection with the foregoing, Coronado shall provide notice to FU Berlin of any such assignment.
- 9.6. <u>Costs.</u> Each Party will bear its respective costs and expenses, including but not limited to all fees and expenses of accountants, counsel and other external advisors, incurred in connection with negotiations, execution and performance of this License Agreement and any ancillary agreements between the Parties, including, without limitation, the fees and expenses of its respective advisors.
- 9.7. Force Majeure. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this License Agreement for failure or delay in fulfilling or performing any term of the License Agreement during the period of time when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, factory shutdowns, failure of public utilities or common carriers, act of God or act, omission or delay in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable.
- 9.8. Severability. If, under applicable law, any provision of this License Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this License

Agreement, the Parties mutually agree that this License Agreement shall endure except for such provision. The Parties shall consult and use their best efforts to agree upon a valid and enforceable provision that shall be a reasonable substitute for such invalid and/or unenforceable provision provision in light of the overall intent and purposes of this License Agreement.

- 9.9. No Third Party Beneficiaries. No provision of this License Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any party other than the Parties and their respective successors and assigns.
- 9.10. Counterparts; Signatures. This License Agreement may be executed in counterparts, each of which shall be deemed an original, but each of which together shall constitute one and the same instrument. Signatures to this License Agreement transmitted by fax, by email in "portable document format" (".pdf") or by any other electronic means intended to preserve the original graphic and pictorial appearance of this License Agreement shall have the same effect as physical delivery of the paper document bearing an original signature.

### 10. ARTICLE 10 - NOTICES

10.1. Any notice, report, request, approval, consent or other communication required or permitted to be given under this License Agreement will be in writing and will for all purposes be deemed to have been fully given and received if delivered in person or sent by overnight courier or registered or certified mail, postage prepaid, return receipt requested, or by electronic mail, or by fax transmission (with an appropriate transmission receipt) to the respective Parties at the following addresses:

If to Coronado: 24 New England Executive Park

Burlington, MA 01803

Attn: President

 $\underline{bsandage@CoronadoBioSciences.com}$ 

Fax: +1-781-652-4545

If to FU Berlin: Freie Universität Berlin

Kaiserswerther Straße 16-18

14195 Berlin

Att: Prof. Dr. Susanne Hartmann susanne.hartmann@fu-berlin.de

Fax: 30 2093 6051

### 11. ARTICLE 11 - TERM AND TERMINATION

11.1. This License Agreement shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Article 11, shall continue in each country in the Territory until the last-to-expire Patent in such country (including any regulatory extensions of patent term) containing an Issued Patent Claim covering Licensed Product, has expired or been revoked without a right of further appeal (the "Term"). Upon expiration of this License Agreement on a country by country basis, all

- rights and licenses granted to Coronado hereunder shall be deemed fully paid up and shall survive such expiration and Coronado shall be free to use the Know-How, Project Results, Licensed Products and Licensed IP without restriction or compensation to FU Berlin.
- 11.2. Either Party shall be entitled to terminate this License Agreement or suspend its obligations, and without any compensation becoming due, in the event of the following:
  - 11.2.1. if either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this License Agreement, the Non-Breaching Party may deliver notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach within the sixty (60) day period after the Breaching Party's receipt of such notice, the Non-Breaching Party may terminate this License Agreement upon written notice to the Breaching Party; provided however, that if such breach relates solely to a particular country or jurisdiction in the Territory, then the non-breaching Party shall have the right to terminate this License Agreement solely with respect to such country or jurisdiction
  - 11.2.2. upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof.

FU Berlin - License Agreement final execution

- 11.3. Notwithstanding anything contained herein to the contrary, Coronado shall have the right to terminate this License Agreement at any time (a) by giving sixty (60) days written notice to FU Berlin in the event of any event, condition or regulatory action that affects the safety or efficacy or marketability of Licensed Product or in the event Coronado is unable to obtain sufficient quantities of GMP material to conduct clinical trials, or (b) in its entirety or on a country-by-country basis for any reason by giving one hundred eighty (180) days prior written notice to FU Berlin. In the event of any such termination, the rights and obligations hereunder, including any payment obligations not due and owing as of the termination date, shall terminate with respect to the License Agreement in its entirety or with respect to the particular country or jurisdiction in the Territory, as applicable.
- 11.4. In case of early effective termination of this License Agreement, other than a termination pursuant to Section 11.3(a), the Parties will negotiate in good faith an agreement between them relating to the use of the Project Results and any Joint Patents.
- 11.5. In addition to any obligations and rights of a Party that expressly or by nature shall survive any termination or expiration of this License Agreement, the following provisions of this License Agreement shall survive any termination or expiration of this License Agreement: Article 1, Article 2, Article 3, Article 8, Article 10, Article 11 and Article 12.

### 12. ARTICLE 12 - DISPUTE RESOLUTION AND GOVERNING LAW

- 12.1. The Parties will use commercially reasonable efforts to settle all matters in dispute amicably. The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this License Agreement or the Research Agreement (a "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) Business Days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of Coronado and the Chancellor of FU Berlin. Such individuals shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) Business Days after such notice is received by the Party to whom the notice was sent. If such individuals are unable to settle the Dispute between themselves within twenty (20) Business Days, they shall so report to the parties in writing. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.
- 12.2. Any Dispute which has not been resolved by negotiation as provided in sub-section 12.1 within twenty (20) Business Days, shall be finally resolved under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The arbitration will take place in Berlin and will be conducted in the English language. The award of the arbitrator(s) will be final and binding on both Parties. The Parties bind themselves to carry out the awards of the arbitrator(s).
- 12.3. Notwithstanding, without resorting to prior arbitration and in addition to any other remedies provided by law, Coronado will be entitled to seek temporary and permanent injunctive relief against any threatened or actual breach of this License Agreement or the continuation of any such breach in any court of competent jurisdiction.

12.4. This License Agreement will as far as legally possible be construed and interpreted pursuant to the laws of Germany without reprinciples of conflicts of law.	gard to
FU Berlin – License Agreement final execution	16/19

IN WITNESS WHEREOF, the Parties have executed this License Agreement as of the dates set forth below:

### SIGNED BY:

### Freie Universität Berlin

By: /s/ Peter Lange

Name: Peter Lange

Title: Director of Administration and Finance

Date: 22.02.2013

### Coronado Biosciences, Inc.

By: /s/ Harlan F. Welsman
Name: Harlan F. Welsman
Title: Chairman and CEO
Date: February 22, 2013

Read and acknowledged:

Project Director for Coronado

Project Director for FU Berlin

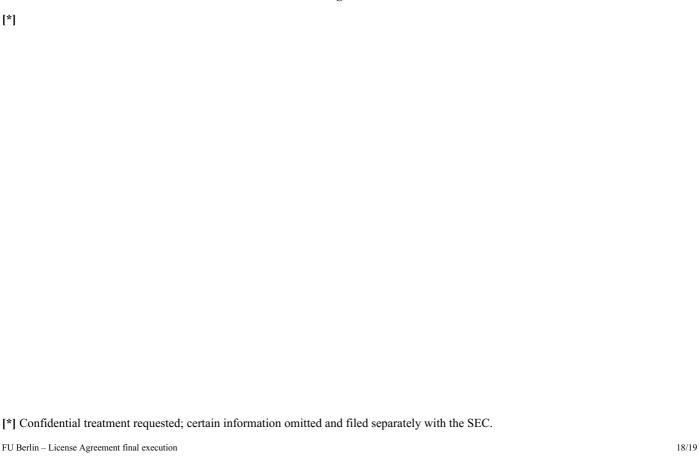
/s/ Bobby Sandage By: Dr. Bobby Sandage,

Principal Scientist

/s/ S. Hartmann
By: Prof. Dr. Susanne Hartmann
Principal Scientist / Group Leader

FU Berlin - License Agreement final execution

## Schedule 1.1.4 FU Berlin Background Know-How





[\*]

[\*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

Portions of this document marked [\*] are requested to be treated confidentially.

### **EXECUTION COPY**

### LICENSE AND SUBLICENSE AGREEMENT

between Coronado Biosciences, Inc.

24 New England Executive Park

Burlington, MA 01803

(hereinafter referred to as "Coronado")

and

**OVAMED GMBH** Kiebitzhörn 31, 22885 Barsbüttel, Germany

(hereinafter referred to as "Ovamed")

Coronado and Ovamed are hereinafter also referred to individually as "Party" and collectively as the "Parties".

This License and Sublicense Agreement ("Agreement") is entered into by and between the Parties as of the Effective Date (as defined herein).

### **PREAMBLE**

WHEREAS Freie Universität Berlin ("FU Berlin") and Coronado have on the Effective Date entered into the Research Agreement and the License Agreement related to the Project (each as defined herein);

WHEREAS FU Berlin and the Parties have on the Effective Date entered into a letter agreement (the "Letter Agreement") amending the Ovamed MTA and providing for certain additional agreements among the Parties and FU Berlin; and

WHEREAS Coronado wishes to grant Ovamed the exclusive right, license and/or sublicense to exploit the Licensed IP (each as defined herein) in the Ovamed Territory on the terms and conditions set forth in this Agreement;

NOW THEREFORE, in consideration of the premises and the mutual covenants set forth herein, the Parties hereto agree to the following:

### 1. ARTICLE 1 - DEFINITIONS

- 1.1. In this Agreement, the following capitalized terms will have the meaning set forth in this Article 1.1, unless otherwise set forth or defined herein.
  - 1.1.1. "Affiliate(s)" means any corporation, company, partnership, joint venture or other entity which Controls, is controlled by, or is under common Control with a Party. "Control" means the ownership of more than fifty percent (50%) of the issued share capital or the legal power to direct or cause the direction of the general management and policies of a Party.
  - 1.1.2. **"Annual Net Sales"** means, as applicable, Net Sales in the Ovamed Territory or Net Sales (as defined in the License Agreement) in the Coronado Territory, in each case for a particular Royalty Year.
  - 1.1.3. "Committee" shall have the definition set forth in Article 6.4.
  - 1.1.4. "Coronado Intellectual Property" means any intellectual property, including Patents and Know-How, that is or becomes during the Performance Period owned or controlled by Coronado or its Affiliates and relates to the Project, the Research Agreement or any Licensed Product, including Coronado's right, title and interest in any Project Results and/or Joint Patents that for any reason, do not become or remain during the Performance Period or under the License Agreement, jointly owned by FU Berlin and Coronado.
  - 1.1.5. **"Coronado Territory"** means North America, South America and Japan, and such other countries or jurisdictions as may be agreed to from time to time between Coronado and Ovamed in writing.
  - 1.1.6. "Effective Date" means the commencement date of this Agreement which is the date of the last signature hereto.
  - 1.1.7. **"FU Berlin Background Know-How"** means the Know-How that has been created by, is owned or controlled by or has been reduced to practice by FU Berlin or FU Berlin Personnel related to the project "Functional characterization of T. suis larval products in mice" prior to the Effective Date, whether or not patentable, as summarized on Schedule 1.1.4 to the License Agreement.
  - 1.1.8. **"FU Berlin Intellectual Property"** means any intellectual property, including Patents and Know-How, that (a) is included in or covers FU Berlin Background Know-How, or (b) becomes during the Term owned or controlled by FU Berlin or its Affiliates and relates to the Project, the Research Agreement or any Licensed Product, including FU Berlin's right, title and interest in any Project Results and/or Joint Patents that for any reason, do not become or remain during the Term jointly-owned by FU Berlin and Coronado.
  - 1.1.9. "Issued Patent Claim" means a claim of any granted Patent that has not: (i) lapsed, expired or been withdrawn, canceled, abandoned or admitted to be invalid or unenforceable through reissue, disclaimer or otherwise; (ii) been finally rejected or held invalid by a final decision of a Patent Authority from which no appeal has been or can be taken; or (iii) been held invalid or unenforceable in an unappealable decision of a court or competent body having jurisdiction (including a decision which was appealable, but which was not timely appealed).

- 1.1.10. "Joint Intellectual Property" means all Project Results and Joint Patents, including all rights, title and interest thereon and any Inventions relating thereto or claimed therein.
- 1.1.11. "Joint Patent" means any and all Patents that embody, disclose or claim an invention or discovery (an "Invention") first made, conceived, created and/or reduced to practice solely or jointly by one or more employees and/or agents (including professors, students and/or any other Project staff) of FU Berlin ("FU Berlin Personnel") or jointly by FU Berlin Personnel and one or more employees of Coronado in the course of or in furtherance of conducting or performing the Project or pursuant to the Research Agreement.
- 1.1.12. **"Know-How"** means results, data, ideas, concepts, discoveries, Inventions (whether patentable or not) developments, methods, processes and trade secrets, techniques, methodologies, modifications, innovations, improvements, enhancements, design and design concepts, formulations, biological samples, tissues, animals, organisms, compounds, intermediates, and all other tangible and intangible materials and information.
- 1.1.13. "License Agreement" means the Joint Ownership and Exclusive License Agreement entered into as of the Effective Date by and between FU Berlin and Coronado, as may be amended in accordance with the terms thereof and hereof.
- 1.1.14. "Licensed IP" means, collectively, FU Berlin Intellectual Property and Coronado Intellectual Property.
- 1.1.15. "Licensed Product" means a pharmaceutical or biologic product in final form, the use or sale of which in a particular country would, in the absence of the rights and licenses granted hereunder, infringe an Issued Patent Claim of a Joint Patent or Patent included in Licensed IP in such country.
- 1.1.16. "Net Sales" means the actual gross amount invoiced for sales of Licensed Products in the Ovamed Territory, less the sum of the following: (a) quantity or other trade discounts; (b) sales, excise, VAT, custom or tariff duties and/or taxes; (c) amounts allowed or credited on returns or rejections (including as a result of recalls, market withdrawals or other corrective actions), and retroactive price reductions or allowances; (e) outbound transportation prepaid or allowed, packaging and freight charges and transportation insurance; (f) rebates or similar payments paid in connection with sales of Licensed Product to any governmental or regulatory authority in the Ovamed Territory, patient discount programs, administrative fees and chargebacks or similar price concessions, and sales commissions; and (g) allowances for bad debt. Net Sales does not include sales of Licensed Product solely for non-profit research or clinical testing or for indigent or similar public support or compassionate use programs. A Licensed Product shall be considered "sold" only when billed or invoiced.
- 1.1.17. "Ovamed MTA" means the Material Transfer Agreement by and between Ovamed and FU Berlin, together with and as amended as of the Effective Date by the Letter Agreement by and among the Parties and FU Berlin, each attached hereto as Appendix 1.1.17.
- 1.1.18. "Ovamed Territory" means all countries outside the Coronado Territory.

- 1.1.19. "Patent(s)" means any patents, patent applications (including provisional applications), certificates of invention, or applications for certificates of invention and any supplementary protection certificates, together with any extensions, registrations, confirmations, patents of addition, reissues, substitutions, divisions, continuations or continuations-in-part, reexaminations or renewals thereof or thereto.
- 1.1.20. **"Performance Period"** means the period for performing the Project, which shall commence on the Effective Date and expire, unless earlier terminated as set forth in the Research Agreement, four (4) years thereafter.
- 1.1.21. **"Project"** means the research project as described in Appendix B attached to the Research Agreement entitled "Functional characterization of secretory T. suis larval products in mice".
- 1.1.22. **"Project Results"** means any and all Know-How in any form that is (a) conceived, developed or otherwise generated by or on behalf of FU Berlin or Coronado in the course of performing the Project or pursuant to the Research Agreement; or (b) generated within (6) months after the expiration or termination of the Performance Period from an analysis of the data generated in the performance of the Project.
- 1.1.23. "Qualified Pharmaceutical Company" means a company that, at the time Ovamed provides notice to Coronado of a proposed sublicense or assignment, as applicable, to such company, is actively engaged in the marketing of pharmaceutical products in those countries of the Ovamed Territory where such assignment or sublicense is proposed and has the internal capability to achieve substantial market penetration and optimize sales of Licensed Product in such countries, taking into account the stage of development and market potential of Licensed Product as well as other relevant factors at that time.
- 1.1.24. "Regulatory Approval" means all approvals (including pricing and reimbursement approvals required for marketing authorization), product and/or establishment licenses, registrations or authorizations of all regional, federal, state or local regulatory agencies, departments, bureaus or other governmental entities, necessary for the manufacture, use, storage, import, export, transport and sale of a Licensed Product in a regulatory jurisdiction.
- 1.1.25. **"Research Agreement"** means the Research Agreement entered into as of the Effective Date by and between FU Berlin and Coronado, as may be amended in accordance with the terms thereof.
- 1.1.26. "Royalty Term" means, with respect to a Licensed Product in each country in the Ovamed Territory, the period commencing on the date of first commercial sale of such Licensed Product in the applicable country and expiring on the expiration or invalidation of the last Issued Patent Claim covering such Licensed Product in the applicable country in the Ovamed Territory.
- 1.1.27. "Royalty True-Up" and "Royalty True-Up Year" have the respective meanings set forth in Article 5.3.3.
- 1.1.28. "Royalty Year" means (a) for the year in which the first commercial sale of Licensed Product occurs, the twelve (12) month

period commencing on the first day of the calendar quarter in which such first commercial sale occurs and expiring on the last day of the twelfth (12th) month following such first day; and (b) for each subsequent year, each successive twelve (12) month period.

- 1.1.29. "Territory" means worldwide.
- 1.1.30. "Territory Net Sales" means the sum of Net Sales in the Ovamed Territory and Net Sales (as defined in the License Agreement) in the Coronado Territory.
- 1.1.31. "TSO" means Trichuris suis ova, incorporated into any formulation or delivery system.

### 2. ARTICLE 2 - PATENT PROSECUTION, MAINTENANCE AND ENFORCEMENT

- 2.1. Coronado or its designees will have the first right and responsibility for preparation, filing, prosecution and maintenance and protection (including handling of oppositions, re-examinations and interferences) of any Joint Patent or other Patent included in or, if filed in the Ovamed Territory, would be included in the Licensed IP. Ovamed shall reimburse Coronado or any such designee for reasonable direct fees and expenses paid by Coronado or such designee to third parties, including attorneys and patent offices, that are identifiable and incurred for the filing, prosecution, and maintenance of such Patents in the Ovamed Territory in accordance with the terms of this Agreement.
- 2.2. If Coronado or its designees decide not to file any such Patent or to discontinue prosecution or maintenance of any such Patent in a particular country or jurisdiction in the Ovamed Territory, it shall advise Ovamed of such decision and Ovamed shall then have the right, but not the obligation, in that case take over the filing, prosecution and maintenance of such Patent in such country or jurisdiction in the Ovamed Territory at its own expense.
- 2.3. Coronado will inform Ovamed at least 90 days after Coronado receives a written notice of invention or invention disclosure if a patent application will be filed. Coronado acknowledges and agrees that in the event of any patentable Inventions it would expect to file patent applications on such patentable Invention in at least one jurisdiction in Europe. Ovamed will cooperate with and provide assistance to Coronado including by executing or causing to be executed on a timely basis all documents, and performing all acts reasonably necessary, for Coronado to prepare, file and prosecute such patent applications and maintain, protect, defend and enforce such Patents in the Ovamed Territory.
- 2.4. A Party having the right to prosecute and maintain Patents in the Ovamed Territory (including if such Party is Coronado, Patents filed in the Coronado Territory which may later on be filed also within the Ovamed Territory under the rules of claiming priority from the first filing) is referred to herein as the "Prosecuting Party". The Prosecuting Party agrees to keep the other Party informed of the course of patent prosecution or other proceedings, including by providing such other Party with a draft patent application for review sufficiently in advance of the planned filing date in order for the other Party to have the opportunity to comment thereon, and shall take such comments into consideration in the application filed. If the Prosecuting Party is Coronado, and Ovamed reasonably disagrees with a prosecution decision made by Coronado on

filing, prosecution, maintenance or protection (including handling of oppositions, re-examinations and interferences), the Parties shall use good faith efforts to allocate between them that portion of the otherwise reimbursable Patent costs that are identifiable and incurred for the disputed portion of the filing, prosecution, maintenance or protection, thereof. The Prosecuting Party shall promptly furnish the other Party with copies of office actions and communications received by the Prosecuting Party from, and communications sent by the Prosecuting Party to, the patent offices concerning such Patents and shall take each other Party's comments and suggestions into consideration when framing responses and submissions to such patent offices. The Prosecuting Party shall timely inform the other Party of any Patent issuing or granting from a patent application filed hereunder.

- 2.5. Each Party shall inform the other Party promptly if it becomes aware of any infringement or potential infringement of any Licensed IP in the Ovamed Territory. Ovamed shall have the unilateral right, but not the obligation, to take legal or other action against any third party to enforce and defend such Licensed IP in the Ovamed Territory at its sole discretion and expense. If Ovamed does not bring such an action or proceeding within sixty (60) days of being notified of such infringement, then Coronado shall have the right, but not the obligation, to bring such action. Any damages or other monetary awards or amounts recovered from settlement or judgment from such an action or proceeding shall be allocated first to reimburse the Party bringing such action for the reasonable out-of pocket costs and expenses of the action or proceeding incurred by such Party, with the remainder to be shared equally between the Parties.
- 2.6. If any warning letter or other notice of infringement is received by a Party, or legal action is brought against a Party, alleging infringement of third party rights in the manufacture, use or sale of any Licensed Product or use of any Joint Patents or Patents included in Licensed IP in the Ovamed Territory, that Party shall promptly inform the other Party and the Parties shall discuss how to respond. Ovamed shall have the initial right but not the obligation to defend such action and shall have the right but not the obligation to settle with such third party at its own expense, provided that Ovamed does not concede invalidity, non-infringement or unenforceability of any of the Joint Patents or Patents included in Licensed IP without first consulting with Coronado.
- 2.7. If either Party is unable to initiate, prosecute, or defend any actions referred to in this Article 2 solely in its own name, the other Party will join such action voluntarily and will execute on a timely basis all documents necessary for the first Party to prosecute, defend and maintain such action.
- 2.8. The Parties shall cooperate with each other in obtaining patent term extensions or restorations or supplemental protection certificates or their equivalents in any country in the Ovamed Territory where applicable. If elections with respect to obtaining such extension or supplemental protection certificates are to be made, Ovamed shall have the right but not the obligation to make the election in the Ovamed Territory.
- 2.9. Ovamed shall not (a) sell, transfer, assign, encumber or otherwise dispose of or grant any third party any rights or licenses in or to, any of Ovamed's right, title and interest in or to any Joint Patent, or (b) take any

other action or enter into any agreement or arrangement with any third party with respect to any Joint Patent that is inconsistent or in conflict with the overall intents and purposes of the Parties under this Agreement.

### 3. ARTICLE 3 - EXCLUSIVE LICENSE AND SUBLICENSE

- 3.1. In consideration of the commitments and undertakings of Ovamed under this Agreement, Coronado hereby grants to Ovamed in the Ovamed Territory an exclusive (a) license to practice under Coronado's interest in Licensed IP, and (b) sublicense to practice under Licensed IP licensed to Coronado, with the right to sublicense in accordance with Article 3.2 hereof; in each case to develop, make, have made, use, import, export, market, offer for sale and sell Licensed Product only in and for the Ovamed Territory; provided, however, that Coronado shall retain such rights in and for the Ovamed Territory as are reasonably necessary for it to exercise its rights and perform its obligations as set forth in this Agreement, the License Agreement and the Research Agreement.
- 3.2. Ovamed shall have the right to grant sublicenses of any of the rights granted to Ovamed under Article 3.1 to Affiliates or any third party; provided, however, that (a) any sublicensee is bound by all of the terms and conditions of this Agreement that protect or benefit Coronado's rights and interests, including under the License Agreement and the Research Agreement; (b) Ovamed shall remain responsible for the performance by the sublicensee of such obligations; and (c) Ovamed obtains the prior written consent of Coronado to the sublicense and the sublicensee, which consent shall not be unreasonably withheld nor delayed, provided, however, that Coronado shall not withhold nor delay its consent in the event Ovamed seeks to sublicense to a Qualified Pharmaceutical Company. Ovamed shall provide prior written notice to Coronado of its intention to sublicense any such rights and, if requested by Coronado, shall engage in good faith discussions with Coronado with respect to a potential sublicense of such rights to Coronado.
- 3.3. Ovamed acknowledges that it is a sublicensee under the License Agreement and that notwithstanding anything to the contrary in this Agreement, the rights and licenses granted by Coronado to Ovamed hereunder are subject to the terms, conditions and provisions of the License Agreement and the Research Agreement, such that Ovamed shall be subject to any restrictions or limitations on the rights granted to Coronado under such agreements. In particular, Ovamed acknowledges and agrees that FU Berlin retains the non-exclusive and non-transferable right to use the Licensed IP solely for its own internal non-commercial, academic, research and teaching purposes under the terms and conditions of the License Agreement. Notwithstanding the foregoing, Coronado shall not enter, without Ovamed's prior written consent, into any amendment to the License Agreement and/or Research Agreement which reduces the scope of the license and sub-license rights granted to Ovamed hereunder.
- 3.4. All rights not granted herein are reserved and retained by Coronado. Nothing in this Agreement shall be deemed to constitute the grant of any license or other right in either Party, to or in respect of any product, Patent, trademark, confidential information, trade secret or other data or any other intellectual property of the other Party, except as expressly set forth herein. Without limiting the foregoing, no licenses are granted by

Coronado to Ovamed other than with respect to Licensed Product in the Ovamed Territory as expressly set forth in Article 3.1 hereof.

### 4. ARTICLE 4 - PROVISIONS RELATING TO OVAMED MTA

- 4.1. The Parties acknowledge and agree that in accordance with the terms of the Ovamed MTA, (a) FU Berlin's rights, title and interest in Joint Patents in the Ovamed Territory are subject to Ovamed's 10% interest therein, and (b) Ovamed has no right, title or interest in any Joint Intellectual Property (i) in the Coronado Territory, or (ii) in the Ovamed Territory except for its 10% interest in FU Berlin's interest in Joint Patents in the Ovamed Territory as set forth in the preceding clause (a), and the licenses and sublicenses in the Ovamed Territory granted by Coronado to Ovamed pursuant to Article 3.1 hereof.
- 4.2. Ovamed shall continue to supply FU Berlin with TSO free of charge as reasonably requested by FU Berlin from time to time during the Performance Period and necessary for FU Berlin to perform the Project.

### 5. ARTICLE 5 - PAYMENTS AND REPORTS

- 5.1. Patent Costs. Each Party will pay patent costs as set forth in Article 2.
- 5.2. <u>Milestone Payments.</u> Ovamed will pay Coronado the following non-creditable and non-refundable milestone payments, contingent upon occurrence of the specified event with respect to a Licensed Product, with each milestone payment to be made (a) for each of the first two (2) Licensed Products, (b) no more than once with respect to the achievement of the applicable milestone event for the first two (2) Licensed Products, and (c) within 45 days after the applicable milestone event is achieved:
  - **25.000 EURO** upon the grant of a Joint Patent in Europe (or any of Germany, France, United Kingdom, Italy or Spain), which includes at least one Issued Patent Claim covering a composition or its use, which includes one or more substances that are secreted or excreted by *T. suis* larvae and which have been shown by functional characterization as having immunomodulatory properties *in vivo* in mice along the lines observed in human subjects after oral administration of TSO; and
  - **1.000.000 EURO** upon first Regulatory Approval of a Licensed Product in Europe (including obtaining approvals to market in at least Germany, France, United Kingdom, Italy and Spain).

### 5.3. Royalties on Net Sales

5.3.1. Ovamed acknowledges that pursuant to the License Agreement, Coronado has agreed to pay FU Berlin royalties on Territory Net Sales in each Royalty Year ("Annual Territory Net Sales") at the following rates during the Royalty Term:

For Portion of Annual Territory Net	
Sales in the Territory:	Royalty Rate
Less than US\$500,000,000	1%
Greater than or equal to US\$500,000,000 and less than US\$1,000,000,000	1.5%
Greater than or equal to US\$1,000,000,000 and less than US\$2,000,000,000	2%
Greater than or equal to US\$2,000,000,000	2.5%

For example, if Annual Territory Net Sales in a Royalty Year are US\$1,800,000,000, the royalties payable to FU Berlin under the License Agreement for such Royalty Year would total US\$28,500,000, calculated as follows: 1% of first US\$500,000,000 (or US\$5,000,000) plus 1.5% of next US\$500,000,000 (or US\$7,500,000) plus 2% of next US\$800,000,000 (or US\$16,000,000).

- 5.3.2. For each calendar quarter of a Royalty Year, Ovamed shall pay Coronado royalties on Annual Net Sales in the Ovamed Territory at the same royalty rates as set forth in Article 5.3.1; provided, however, that if a Royalty Year is a Royalty True-up Year, Ovamed shall pay Coronado for such Royalty Year additional royalties in an amount calculated by implementing the Royalty True-Up.
- 5.3.3. The Parties acknowledge and agree that because of the tiered royalty rates, it is possible that Annual Territory Net Sales in a Royalty Year (a "Royalty True-Up Year") may trigger a higher overall royalty rate and/or additional royalties payable to FU Berlin under the License Agreement than would otherwise have been achieved based solely on either Party's Annual Net Sales in its respective territory. Accordingly, within the first 12 months after establishing the Committee, the Parties shall use good faith efforts to reach mutually acceptable agreement on a formula, mechanism and procedure to address and allocate between the Parties the responsibility for payment of any such additional royalties for a Royalty True-up Year (the "Royalty True-Up"), provided, however, that the underlying principle of the Royalty True-Up shall be that as between the Parties, for a Royalty True-Up Year, each Party shall be responsible for the same percentage of additional royalties payable under the License Agreement as Annual Net Sales in such Party's territory bear to Annual Territory Net Sales.
- 5.3.4. No multiple royalties shall be payable if a Licensed Product shall be covered by more than one Issued Patent Claim of a Patent.

### 5.4. Reports and Payments.

5.4.1. Within thirty (30) days after the end of each calendar quarter during the Royalty Term, starting with the first calendar quarter in which the first commercial sale of a Licensed Product in the Ovamed Territory occurs, Ovamed shall deliver to Coronado a written report showing (a) gross sales and Net Sales in the Ovamed Territory during

- such calendar quarter (including a detailing of all deductions taken in the calculation of Net Sales) in each country's currency, (b) the applicable exchange rate to convert from each country's currency to United States Dollars, and (c) the formula used in the calculation of the royalties owed thereon and the amount of royalties payable to Coronado for such calendar quarter in accordance with Article 5.3. Each such report shall be accompanied by payment of the royalties due for such calendar quarter.
- 5.4.2. Within ten (10) days after Coronado's receipt of such report for the fourth calendar quarter of a Royalty Year, Coronado shall deliver to Ovamed a report (the "True-up Report") showing (a) the actual Royalty Rates payable to FU Berlin under the License Agreement for such Royalty Year based on Annual Territory Net Sales for such Royalty Year, and (b) if such Royalty Year is a Royalty True-up Year, the amount of additional royalties payable by Ovamed in accordance with the Royalty True-Up. If the True-Up Report indicates that additional royalties are payable by Ovamed with respect to such Royalty Year, Ovamed shall pay Coronado such additional royalties within fifteen (15) days after Ovamed's receipt of the True-up Report. Ovamed shall keep complete and accurate records in sufficient detail to enable the payable hereunder to be determined.
- 5.5. Tax Withholding. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Article 5, Coronado shall provide Ovamed, prior to any such payment, annually or more frequently if required, with all forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit thereunder and Ovamed shall make such withholding payments as required and subtract such withholding payments from the payments set forth in this Article 5. Ovamed shall submit appropriate proof to Coronado of payment of the withholding taxes within a reasonable period of time. Coronado will reasonably cooperate with Ovamed to ensure that any withholding taxes imposed are reduced as far as possible under the provisions of the current or any future taxation treaties or agreements between foreign countries.
- 5.6. <u>Currency Conversion.</u> All payments to Coronado under this Agreement shall be made in United States dollars unless Coronado notifies Ovamed at least five (5) business days before such payment is due that payments should be made in Euros. In the event a currency conversion is required, (a) then royalties shall be based on Net Sales first calculated in the currency in which sales took place and each of such amounts shall then be converted to United States Dollars, and (b) such conversion shall be made by using the exchange rate prevailing at Citibank, N.A. in New York, New York on the last business day of the calendar quarterly reporting period to which such payments relate. If at any time legal restrictions prevent the prompt remittance of part or all of the royalties with respect to Net Sales in any country, payment shall be made through such lawful means or methods as Coronado may reasonably determine.

5.7. Records. Each Party will maintain complete and accurate records which are relevant to Net Sales under this Agreement, and, upon the written request of the other Party, such records shall be open during reasonable business hours for a period of three (3) years from creation of such records for examination, but not more often than once each year, by an independent certified public accountant selected by the requesting Party to verify the accuracy of the reports under this Article 5. The cost of the services of such public accountant shall be born by the requesting Party unless the audit establishes a material infringement of the other Party's obligations under this Agreement.

### 6. ARTICLE 6 - EXCHANGE OF INFORMATION, DEVELOPMENT AND COMMERCIALIZION

- 6.1. Each Party shall promptly disclose to the other Party in writing on an ongoing basis any Inventions, Know-How, developments or improvements owned or controlled by it and relating to the Licensed IP or Licensed Product. In case Coronado or Ovamed during the term of this Agreement own or control any intellectual property rights in such Inventions, Know-How, developments or improvements relating to the Licensed IP or Licensed Product which do not fall under the definition of "Licensed IP" ("Additional IP"), then each of them, if requested by the other Party, shall engage in good faith discussions between the Parties with respect to the grant of an exclusive license in the Ovamed Territory or the Coronado Territory, as applicable, under such Additional IP to develop, make, have made, use, import, export, market, offer for sale and sell Licensed Product, on commercially reasonable terms and conditions as are customary in the pharmaceutical industry as applicable to the stage of development and/or commercialization of Licensed Product at such time.
- 6.2. Coronado shall promptly forward true and complete copies of all progress reports received from FU Berlin pursuant to Article 4 of the Research Agreement; upon reasonable request of Ovamed, Ovamed shall be entitled to participate (with listening rights only) at its own expense in meetings and telephone conferences held pursuant to Article 4.2 of the Research Agreement, provided, however, that any information received by Ovamed in such meetings, telephone conferences or reports shall be deemed Coronado Confidential Information. Coronado shall inform Ovamed about any such meeting scheduled as soon as practicable after the scheduling thereof about when and where such meeting will be held.
- 6.3. Except as specifically set forth herein, as between the Parties, each Party shall (a) be responsible for development and commercialization of Licensed Product in its respective territory, and (b) own, control and have financial responsibility for the preparation and filing of all regulatory applications required to obtain Regulatory Approval to develop, sell and use Licensed Product in its respective territory.
- 6.4. Prior to commencing clinical development of a Licensed Product, the Parties shall establish a joint steering or development committee to function as a forum for the Parties to inform and consult with one another concerning the clinical development of Licensed Products (the "Committee").

6.5. The Parties shall exchange with each other all relevant information that relates to the safety of Licensed Product, including all adverse drug experience reports, and shall agree on operating procedures for the exchange of safety information sufficient to enable each Party to comply with its reporting obligations to regulatory authorities in its respective territory. Each Party shall have the right to reference or use in any regulatory filing any safety information relating to Licensed Product provided to it by the other Party.

### 7. ARTICLE 7 - REPRESENTATIONS AND WARRANTIES; LIMITATION OF LIABILITY

- 7.1. Each Party represents and warrants to the other Party that:
  - 7.1.1. it has the legal right, title, authority and power to enter into this Agreement and to perform its obligations hereunder and thereunder:
  - 7.1.2. it has taken all necessary action to authorize the execution, delivery and performance of this Agreement
  - 7.1.3. the performance of its obligations under this Agreement will not conflict with or result in the breach of any agreements, contracts or other arrangements to which it is a Party.
- 7.2. Coronado hereby represents and warrants to Ovamed that as of the Effective Date the Research Agreement and the License Agreement are in full force and effect in accordance with their terms and there have been no amendments nor side letters or other agreements thereto by and between Coronado and FU Berlin (except for the Letter Agreement mentioned in the preamble of this Agreement) that have not been provided to Ovamed; neither Coronado nor, to Coronado's knowledge without any inquiry, FU Berlin are in breach or violation of the Research Agreement and/or the License Agreement.
- 7.3. <u>LIMITATION OF LIABILITY.</u> EXCEPT AS OTHERWISE SET FORTH HEREIN, NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY. This limitation of liability shall not apply to the extent that any such liability is the result of intentional acts or omissions by, or accountable to, any Party.

### 8. ARTICLE 8 - CONFIDENTIALITY

8.1. Except to the extent permitted under this Agreement, the License Agreement or the Research Agreement, or with the consent of the disclosing Party, the Parties agree that the receiving Party shall hold in confidence any confidential or information or materials furnished to it and owned or controlled by the disclosing Party pursuant to this Agreement, including but not limited to any Inventions, Know-How, Patents, business

plans, or financial information (collectively, "Confidential Information"), shall not use any Confidential Information for any purpose other than in connection with the execution and performance of its rights, obligations or responsibilities according to this Agreement, and shall not publish or otherwise disclose or use the Confidential Information for any purpose, except to the extent that it can be established by the receiving Party that such Confidential Information:

- 8.1.1. is lawfully in the possession of the receiving Party prior to receiving the information from the disclosing Party under this Agreement, as evidenced by receiving Party's contemporaneous written records;
- 8.1.2. is in the public domain or is evidently not of proprietary or confidential nature at the time of the disclosure or becomes part of the public domain other than by a breach of this Agreement;
- 8.1.3. is independently developed by the receiving Party without any breach of the terms of this Agreement as evidenced by receiving Party's contemporaneous written records;
- 8.1.4. is obtained in good faith from a third party not in privity with any of the Parties hereto, and provided said third party is not under any obligation of confidentiality; or
- 8.1.5. is ordered by a court of competent jurisdiction or is otherwise required by law to be disclosed by the receiving Party, and in such event, the receiving Party shall use reasonable efforts to obtain assurances that confidential treatment will be accorded to such Confidential Information in such case.
- 8.2. Notwithstanding the foregoing the receiving Party may use and disclose Confidential Information (a) in filing or prosecuting Patents, conducting clinical trials evaluating a Licensed Product, or seeking Regulatory Approvals, in accordance with the receiving Party's rights and obligations under this Agreement, the License Agreement and the Research Agreement, as applicable, or complying with applicable laws or governmental regulations, (b) in granting sub-licenses to third parties as permitted hereunder, provided any such sublicensees are bound by confidentiality terms similar to those contained in this Agreement, and (c) to its officers, employees, agents and consultants who are bound by confidentiality terms similar to those contained in this Agreement but only to the extent required for the execution or performance of its rights, obligations or responsibilities according to this Agreement, the License Agreement or the Research Agreement, as applicable.

## 9. ARTICLE 9 - MISCELLANEOUS

- 9.1. <u>Independent Contractor.</u> All work performed by either Party or any of its employees or agents pursuant to the terms of this Agreement will be performed solely as an independent contractor, and the relationship between the Parties shall not constitute a partnership, joint venture or agency. Neither Party is authorised or empowered to act as an agent for the other for any purpose or make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party.
- 9.2. Entire Agreement; Incorporation by Reference. This Agreement and the Letter Agreement constitute the entire agreement between the Parties

with respect to the subject matter hereof, and supersede any and all oral or written communications, understandings or term sheets relating thereto.

- 9.3. <u>Disclosure of Agreement.</u> It is understood and agreed by Ovamed that Coronado may make disclosure of this Agreement and the terms hereof and thereof (a) in any filings required by the Securities and Exchange Commission ("SEC"), other governmental authority or securities exchange, and may file this Agreement as exhibits to any filing with the SEC, other governmental authority or securities exchange, and (b) in press releases or other public announcements as required by applicable laws. Coronado shall provide Ovamed with notice of the initial such disclosure. Except as required by law, Ovamed shall not make any public announcement or other disclosure to a third party concerning the existence of or terms of this Agreement or with respect to the Project or Licensed Product without the prior written consent of Coronado.
- 9.4. <u>Amendments.</u> No amendments or additions to this Agreement (including to this Article 9.4) will be binding on the Parties unless made in writing and signed by a duly authorised representative of each Party.
- 9.5. Assignment. This Agreement may not be assigned or otherwise transferred, nor may any right or obligation hereunder be assigned or transferred by either Party, without the prior written consent of the other Party, which consent shall not be unreasonably withheld nor delayed except that (a) without such consent of Ovamed, Coronado may assign or transfer this Agreement (or any part hereof) to an Affiliate or in connection with the transfer or sale of its business or all or substantially all of its assets related to TSO or Licensed Product or in the event of a merger, consolidation, change in control or similar corporate transaction (a "Corporate Transaction"), and (b) Coronado shall not withhold nor delay its consent in the event Ovamed seeks to assign or transfer this Agreement (or any part hereof) to a Qualified Pharmaceutical Company in connection with a Corporate Transaction. In connection with the foregoing, the Party proposing such assignment shall provide notice to the other Party of any such assignment. Any permitted assignee shall assume all obligations of its assignor under this Agreement.
- 9.6. <u>Costs.</u> Each Party will bear its respective costs and expenses, including but not limited to all fees and expenses of accountants, counsel and other external advisors, incurred in connection with negotiations, execution and performance of this Agreement and any ancillary agreements between the Parties, including, without limitation, the fees and expenses of its respective advisors.
- 9.7. <u>Force Majeure.</u> Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of the Agreement during the period of time when such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including, but not limited to, fire, flood, embargo, war, acts of war (whether war be declared or not), terrorism, insurrection, riot, civil commotion, strike, lockout or other labor disturbance, factory shutdowns, failure of public utilities or common carriers, act of God or act, omission or delay in acting by any governmental authority or the other Party. The affected Party shall notify the other Party of such force majeure circumstances as soon as reasonably practicable.

- 9.8. Severability. If, under applicable law, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement, the Parties mutually agree that this Agreement shall endure except for such provision. The Parties shall consult and use their best efforts to agree upon a valid and enforceable provision that shall be a reasonable substitute for such invalid and/or unenforceable provision provision in light of the overall intent and purposes of this Agreement.
- 9.9. No Third Party Beneficiaries. No provision of this Agreement is intended to confer any rights, benefits, remedies, obligations or liabilities hereunder upon any party other than the Parties and their respective successors and assigns.
- 9.10. Counterparts; Signatures. This Agreement may be executed in counterparts, each of which shall be deemed an original, but each of which together shall constitute one and the same instrument. Signatures to this Agreement transmitted by fax, by email in "portable document format" (".pdf") or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing an original signature.

#### 10. ARTICLE 10 - NOTICES

10.1. Any notice, report, request, approval, consent or other communication required or permitted to be given under this Agreement will be in writing and will for all purposes be deemed to have been fully given and received if delivered in person or sent by overnight courier or registered or certified mail, postage prepaid, return receipt requested, or by electronic mail, or by fax transmission (with an appropriate transmission receipt) to the respective Parties at the following addresses:

If to Coronado: 24 New England Executive Park

Burlington, MA 01803

Attn: President

Fax: +1-781-652-4545

If to Ovamed: Kiebitzhörn 31, 22885

Barsbüttel, Germany Att: Managing Director Fax: +49 40 675 095 58

#### 11. ARTICLE 11 - TERM AND TERMINATION

11.1. This Agreement shall come into effect on the Effective Date and, unless terminated earlier in accordance with this Article 11, shall continue in each country in the Territory until the last-to-expire Patent in such country (including any regulatory extensions of patent term) containing an Issued Patent Claim covering Licensed Product, has expired or been revoked without a right of further appeal (the "Term"). Upon expiration of this Agreement on a country by country basis, all rights and licenses granted to Ovamed hereunder shall be deemed fully paid up and shall survive such expiration and Ovamed shall be free to use the Know-How,

Project Results, Licensed Products and Licensed IP in the Ovamed Territory without restriction or compensation to Coronado.

- 11.2. Either Party shall be entitled to terminate this Agreement or suspend its obligations, and without any compensation becoming due, in the event of the following:
  - 11.2.1. if either Party (the "Non-Breaching Party") believes that the other Party (the "Breaching Party") is in material breach of this Agreement, the Non-Breaching Party may deliver notice of such breach to the Breaching Party. If the Breaching Party fails to cure such breach within the sixty (60) day period after the Breaching Party's receipt of such notice, the Non-Breaching Party may terminate this Agreement upon written notice to the Breaching Party; provided however, that if such breach relates solely to a particular country or jurisdiction in the Ovamed Territory, then the non-breaching Party shall have the right to terminate this Agreement solely with respect to such country or jurisdiction.
  - 11.2.2. upon the filing or institution of bankruptcy, reorganization, liquidation or receivership proceedings, or upon an assignment of a substantial portion of the assets for the benefit of creditors by the other Party; provided, however, in the case of any involuntary bankruptcy, reorganization, liquidation, receivership or assignment proceeding such right to terminate shall only become effective if the Party consents to the involuntary proceeding or such proceeding is not dismissed within ninety (90) days after the filing thereof.

- 11.3. Notwithstanding anything contained herein to the contrary, Coronado shall have the right to terminate this Agreement at any time
  (a) by giving sixty (60) days written notice to Ovamed in the event of any event, condition or regulatory action that affects the safety or efficacy or marketability of Licensed Product or in the event Coronado is unable to obtain sufficient quantities of GMP material to conduct clinical trials, or (b) in its entirety or on a country-by-country basis for any reason by giving one hundred eighty (180) days prior written notice to Ovamed; provided that in each case (a) or (b) Coronado simultaneously also terminates the License Agreement (in the case of (b) either in its entirety or on a country-by-country basis) by giving notice to FU Berlin as provided for in the License Agreement. In the event of any such termination, the rights and obligations hereunder, including any payment obligations not due and owing as of the termination date, shall terminate with respect to the Agreement in its entirety or with respect to the particular country or jurisdiction in the Territory, as applicable.
- 11.4. In case of early effective termination of this Agreement, other than a termination pursuant to Article 11.3(a), the Parties will negotiate in good faith an agreement between them relating to the use of the Project Results and any Licensed IP.
- 11.5. In addition to any obligations and rights of a Party that expressly or by nature shall survive any termination or expiration of this Agreement, the following provisions of this Agreement shall survive any termination or expiration of this Agreement: Article 1, Article 2, and Articles 8 -12.

## 12. ARTICLE 12 - DISPUTE RESOLUTION AND GOVERNING LAW

- 12.1. The Parties will use commercially reasonable efforts to settle all matters in dispute amicably. The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) Business Days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of Coronado and a Managing Director of Ovamed. Such individuals shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) Business Days after such notice is received by the Party to whom the notice was sent. If such individuals are unable to settle the Dispute between themselves within twenty (20) Business Days, they shall so report to the parties in writing. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence.
- 12.2. Any Dispute which has not been resolved by negotiation as provided in Article 12.1 within twenty (20) Business Days, shall be finally resolved under the Rules of Arbitration of the International Chamber of Commerce by one or more arbitrators appointed in accordance with the said Rules. The arbitration will take place in Berlin and will be conducted in the English language. The award of the arbitrator(s) will be final and binding on both Parties. The Parties bind themselves to carry out the awards of the arbitrator(s).
- 12.3. Notwithstanding, without resorting to prior arbitration and in addition to any other remedies provided by law, either Party will be entitled to seek

temporary and permanent injunctive relief against any threatened or actual breach of this Agreement or the continuation of any such breach in any court of competent jurisdiction.

12.4. This Agreement will as far as legally possible be construed and interpreted pursuant to the laws of Germany without regard to principles of conflicts of law.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the dates set forth below:

## SIGNED BY:

## Ovamed GmbH

By: /s/ Alexander Beese
Name: Alexander Beese
Title: Managing Director
Date: February 22, 2013

## Coronado Biosciences, Inc.

By: /s/ Harlan F. Weisman, M.D.
Name: Harlan F. Weisman, M.D.
Title: Chairman and CEO
Date: February 22, 2013

## Appendix 1.1.17 Letter Agreement and Material Transfer Agreement



Freie Universität Berlin Kaiserswerther Straße 16-18 14195 Berlin Absender: Ovamed GmbH Kiebitzhörn 31 D-22885 Barsbüttel

Director:

Alexander Beese

T: +49 – (0)40-67 50 95-18 F: +49 – (0)40-67 50 95-58

beesea@ovamed.de

Cc: Coronado Biosciences Inc.

Barsbüttel, den 20.02.2013

#### Ladies and Gentlemen:

Reference is made to the Material Transfer Agreement (the "Agreement"), between us effective as of May 1, 2012. The purpose of this letter agreement (this "Letter Agreement") is to clarify and confirm certain rights and obligations of Supplier and Recipient (as defined in the Agreement) and amend certain terms of the Agreement, in connection with a planned research project between Coronado Biosciences, Inc. ("Coronado") and Recipient (the "Research Project") pursuant to the Research Agreement appended hereto as <a href="Exhibit 1">Exhibit 1</a> (the "Research Agreement"), and the Joint Ownership and Exclusive License Agreement appended hereto as <a href="Exhibit 2">Exhibit 2</a> (the "JOELA"), each executed as of the date hereof by and between Recipient and Coronado. Except as otherwise defined in this Letter Agreement, all defined terms used herein shall have the meaning set forth in the Agreement.

Accordingly, Supplier and Recipient agree as follows:

- 1. Subject to the condition precedent of (i) Recipient executing this Letter Agreement and (ii) Supplier and Coronado having agreed to and executed a License and Sub-License Agreement (the "LSLA") pursuant to which Supplier is granted by Coronado exclusive licenses and sublicenses in the Ovamed Territory (as defined in the JOELA) on the terms and conditions set forth therein, Supplier:
  - a) consents under Paragraph 2 of the Agreement to Recipient undertaking the Research Project with Coronado and to the Research Agreement; and
  - b) agrees that it does not hold or own, nor is it entitled to obtain, any right title or interest in, and waives any right it may have had under the Agreement to, any such right, title or interest in, any and all FU Berlin Intellectual Property and/or Joint Intellectual Property (i) in the Coronado Territory, and (ii) in the Ovamed Territory except (A) that Supplier retains a 10% interest in Recipient's interest in Joint Patents in the Ovamed Territory, and (B) for the licenses and sublicenses granted to Supplier thereto pursuant to Article 3.1 of the LSLA in the Ovamed Territory, with each defined term used in this clause b) (except Supplier, Recipient and LSLA) to have the meaning set forth in the JOELA. Accordingly, Supplier and Recipient hereby agree that the last sentence of Paragraph 4 of the Agreement is hereby amended and restated in its entirety to read as follows: "If any Invention (as defined in the JOELA) results

Telephone	E-Mail	Bank Name	IBAN	Tax- No.	Company Reg. No.
+49-(0)40-67 50 95-0	info@ovamed.de	Sparkasse Stormarn	[*]	[*]	[*]
Telefax	internet	Bank Area Code 213 522 40	SWIFT	VAT ID	Commercial Court
+49-(0)40-67 50 95-59	www.ovamed.de	Account No. [*]	NOLADE21HOL	[*]	City of Reinbek

<sup>[\*]</sup> Confidential treatment requested; certain information omitted and filed separately with the SEC.



from the use of the Material, and such Invention is claimed in a Joint Patent (as defined in the JOELA) in the Ovamed Territory (as defined in the JOELA), the Supplier shall have a 10% share of Recipient's interest in such Joint Patent in the Ovamed Territory."

- 2. With respect to the JOELA, it is agreed among Supplier, Recipient and Coronado that, subject to the provisions of this paragraph 2, in the event (a) of any breach or default by Coronado under the JOELA, or (b) the provisions of Article 11.2.2 of the JOELA are applicable, in either case giving Recipient the right under the JOELA to terminate the JOELA, the following shall be applicable:
  - (i) in the event of a breach or default, Recipient shall provide Supplier with written notice of such breach or default (and, as applicable, failure to cure such breach or default and/or intent to terminate), in addition to any notice thereof provided to Coronado, which notice shall disclose the nature and amount of breach or default;
  - (ii) If the breach or default is a curable obligation, Supplier shall have the right, but not the obligation, to cure such breach within sixty (60) days after receiving such written notice if the breach relates to a payment obligation or within ninety (90) days after receiving such written notice if the breach relates to any non-payment obligation; provided that if Supplier cures such breach within the applicable periods, (A) any payments by Supplier to Recipient to cure such breach shall discharge the related payment obligation Coronado may have had to Recipient; (B) Supplier may, but shall not be obligated to, make future payments required to be made by Coronado to Recipient under the JOELA directly to Recipient; (C) Coronado shall reimburse Supplier for any such payments made by Supplier to Recipient and any other costs associated with curing such breach or default (or, at Supplier's option, Supplier shall be permitted to set off such payments and costs against amounts payable by Supplier to Coronado under the LSLA); and (D) Recipient shall not have the right to terminate the JOELA as a result of such breach or default; and
  - (iii) If (A) the breach or default is a non-curable obligation, and Supplier has not caused such breach or default (it being understood that Supplier will not be deemed to have caused such breach or default if such breach or default was caused initially by Coronado having breached its obligations to Supplier under the LSLA), or (B) the provisions of Article 11.2.2 are applicable, Supplier shall have the right, but not the obligation, to have the JOELA survive, provided that from and after any such election by Supplier, (1) Coronado's rights, licenses and obligations in and under the JOELA shall be deemed as assigned to and assumed by Supplier on the same terms and conditions as set forth in the JOELA; (2) all references to Coronado in the JOELA shall be construed as Supplier; and (3) Recipient shall not have the right to terminate the JOELA as a result of such breach.

Telephone	E-Mail	Bank Name	IBAN	Tax- No.	Company Reg. No.
+49-(0)40-67 50 95-	0 info@ovamed.de	Sparkasse Stormarn	[*]	[*]	[*]
Telefax	internet	Bank Area Code 213 522 40	SWIFT	VAT ID	Commercial Court
+49-(0)40-67 50 95-	59 www.ovamed.de	Account No. [*]	NOLADE21HOL	[*]	City of Reinbek

<sup>[\*]</sup> Confidential treatment requested; certain information omitted and filed separately with the SEC.



3. Paragraphs 9 and 11 of the Agreement shall apply to this Letter Agreement accordingly and are hereby incorporated herein by way of reference.

If the foregoing accurately sets forth our agreement on this subject, please sign and forward this letter to Coronado asking Coronado to sign as well and return this Letter Agreement to us (with copy to you), whereupon this Letter Agreement shall constitute a binding agreement upon Supplier, Recipient and, as applicable, Coronado.

Very truly yours,

Ovamed GmbH

By: <u>/s/ Alexander Beese</u> Name: Alexander Beese

Title: Managing Director

Accepted and Agreed:

Freie Universität Berlin

By: /s/ Peter Lange

Name: Peter Lange

Title: Director of Administration and Finance

Paragraph 2 is hereby accepted and agreed:

Coronado Biosciences Inc.

By: <u>/s/ Noah D. Beerman</u> Name: Noah D. Beerman

Title: Executive Vice President and Chief Operating Officer

Telephone E-Mail Bank Name IBAN Tax- No. Company Reg. No. 449-{0}140-67 50 95-0 info@covamed.de Sparkasse Stormarn [\*] [\*] [\*] [\*] Telefax internet Bank Area Code 213 522 40 SMIFT VAT ID Commercial Court +49-(0)40-67 50 95-59 www.ovamed.de Account No. [\*] NOLADE21HOL [\*] City of Reinbek

<sup>[\*]</sup> Confidential treatment requested; certain information omitted and filed separately with the SEC.



## **Material Transfer Agreement**

between

Ovamed GmbH Kiebitzhoern 33 - 35 22885 Marsbüttel

(hereinafter referred to as "Supplier")

and

Freie Universität Berlin represented by Peter Lange, Director of Administration and Finance Kaiserswerther Straße 16-18 14195 Berlin

(hereinafter referred to as "Recipient")

Material: Trichuris suis ova (TSO)

Recipient's contact: Prof. Dr. Susanne Hartmann (Principal Scientist)

Department of Veterinary Medicine

Institute of Immunology

Supplier's contact: Detlev Goj

Ovamed GmbH Kiebitzhoern 33 - 35 22885 Barsbüttel

## 1. Background

Recipient desires to obtain the material and/or information described in **Appendix A** (together, in the case of biological material, with all progeny, variants, fragments and unmodified derivatives, and in the case of chemical material, with all analogues, formulations, mixtures or compositions thereof, the "Material") from Supplier for use by Recipient solely for non-commercial experiments and academic research described in Appendix A (approach1 - 3) under the terms and conditions of this Agreement. Certain obligations of Recipient herein described (e.g. use and transfer of Material) will apply to any biological material that incorporates the Material or any recombinant version thereof (e.g., Supplier's gene into a vector or combination of Supplier's gene with other polynucleotides) (the "Modified Material").

## 2. The Material and the Tests

Recipient acknowledges that Supplier owns the Material. Supplier will use commercially reasonable efforts to provide Recipient with the Material described in Appendix A. Supplier has agreed to provide the Material free of charge. Recipient will use the Material and Modified Material solely for the Tests and Fields. Furthermore, the use for any commercial

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purpose, such as for production is prohibited under this Agreement. In particular, no rights are provided to use the Material or any related patents for profit-making or commercial provision of a service to a third party in exchange for consideration. The Tests of approach 1 and 2 will be conducted solely in laboratories of Freie Universität Berlin, approach 3 may also be conducted by third parties. Recipient will not use the Material for testing in or treatment of human subjects. Recipient acknowledges that the Material is experimental and will comply with all laws and regulations applicable to its handling and use. Recipient has the right to perform academic research and research with third parties with the Material, limited to the duration and purpose of the Research Project, but only upon Supplier's prior written consent, which may not be unreasonably withheld. This applies also to industrially sponsored research, in particular if Recipient is already engaged in negotiations on the Research Project with good prospects for success and the parties will negotiate in good faith terms of such a license.

## 3. Confidentiality.

Recipient shall treat in confidence, for a period of three (3) years from the date of its disclosure, any written information pertaining to the Material provided to Recipient by Supplier or Supplier's Scientist(s). Excluded from this obligation shall be any information

- (a) that was previously known to Recipient prior to receipt of information from Supplier;
- (b) that lawfully is, or becomes publicly available during said three (3) year period through no fault of Recipient;
- (c) which is disclosed to Recipient without confidentiality obligations by a third party having the right to make such disclosure; or
- (d) which is independently developed by Recipient without the use of or reference to any information received from Supplier.

Recipient may disclose information if required by law or a binding order of a court or other governmental agency, with reasonable efforts to limit the disclosure to the minimum necessary.

#### 4. Research Results.

Supplier acknowledges that the Recipient as a University must publish research results and shall take this interest into account. Recipient shall inform Supplier in confidence of Research results related to the Material, by personal communication or by providing Supplier with copies of manuscripts describing the results of such research before the manuscripts are submitted for publication. If any invention results from the collaborative effort, the Recipient agrees to notify the Supplier prior filing a patent. If any invention results from the use of the Material, the Supplier's share in the invention is 10%, if any joint invention with third parties results from the use of the Material, the Supplier's share in the invention is 10% from the Recipient's share accordingly.

#### 5. Acknowledgement.

Recipient will acknowledge Supplier and the named Supplier's contact as the source of the Material in any publication of Research results.

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#### 6. No Warranty.

Recipient acknowledges that any material delivered to it under this agreement is experimental in nature. Supplier makes no representations or extends any warranties of any kind, either expressed or implied, with respect to the material. There are no express or implied warranties of merchantability or fitness for a particular purpose, nor does Supplier represent that the use of the material will not infringe any patent, copyright, trade secret, trademark or other rights of third parties.

#### 7. Indemnification.

Supplier shall not be liable to Recipient for any loss, claim, or demand made by Recipient, or made against Recipient by any other party, due to, or arising from, the use of the Material by the Recipient. To the extent permitted by law, Recipient shall indemnify, defend and hold harmless Supplier, its trustees, assignees agents and employees or many claim asserted against them except when arising from the negligence or willful, is conduction the use of the Material by Recipient or its agents or employees.

#### 8. No obligations.

Except as provided in this agreement, no rights or licenses to trademarks, inventions, copyrights or patents are implied or granted under this Agreement.

#### 9. Final Agreement.

This Agreement and Appendix A attached hereto and hereby incorporated herein, contains the final, complete and exclusive agreement of the parties relative to the subject matter hereof and supersedes all prior and contemporaneous understandings and agreements relating to its subject matter. This Agreement may not be changed, modified, amended or supplemented except by a written instrument signed by both parties.

## 10. Start and Termination.

This Agreement enters into force as from 1.5.2012. Either party may terminate this Agreement upon ninety (90) days' prior written notice to the other party. Upon termination, Recipient will return to Supplier its Confidential Information, and any unused samples of the Material, and all of Recipient's rights to use the Material ill end, except there are still Research Projects with contractual commitments for the Recipient. In this case the parties will seek an appropriate solution in good faith until termination of the Research Project. Following termination, neither party will have any further obligations under this Agreement, except that Sections 2, 3, 5 and 6 will survive.

#### 11. Miscellaneous.

This Agreement shall be governed by the laws of Germany, excluding its conflicts of laws principles. Place of jurisdiction is Berlin, Germany.

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12. Signatures	
SIGNED BY:	
Date:	Date:
Ovamed GmbH	Freie Universität Berlin
/s/ <u>Detleve Goj</u> By: Detlev Goj	/s/ Peter Lange By: Peter Lange Director of Administration and Finance
	Acknowledged and read:
	Date: 14.Mai.2012
	Project Director for Researcher
	/s/ S. Hartmann By: Prof. Dr. Susanne Hartmann Principal Scientist / Head of the Institute of Immunology

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## Appendix A

## Material:

Trichuris suis eggs (TSO). TSO are harvested from in vitro cultivated adults T. suis worms harvested from pig gut, or via other methods deemed suitable by the Supplier.

## Test/Fields:

Description and Purpose of the tests and the fields, the institution wants to make.

[\*]

[\*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

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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)

May 9, 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)

May 9, 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 March 31, 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.

May 9, 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 March 31, 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.

May 9, 2013

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

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