UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act 1934

Date of Report (Date of earliest event reported): March 20, 2012

Coronado Biosciences, Inc.

(Exact name of registrant as specified in charter)

Delaware

(State or other jurisdiction of incorporation)

Delaware (State or Other Jurisdiction of Incorporation) 000-54463 (Commission File Number) 20-5157386 (IRS Employer Identification No.)

15 New England Executive Park, Burlington, MA (Address of Principal Executive Offices)

01803 (Zip Code)

Registrant's telephone number, including area code: (781) 238-6621

(Former Name or Former Address, is Changed Since Last Report)

ck the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of following provisions:
Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
Soliciting material pursuant to Rule 14a-12(b) under the Exchange Act (17 CFR 240.14a-12(b))
Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Item 1.01 Entry into a Material Definitive Agreement

On March 22, 2012, Coronado Biosciences, Inc. (the "Company") announced that it has entered into a Collaboration Agreement (the "Agreement") with Dr. Falk Pharma GmbH and OvaMed GmbH for the development of TSO (Trichuris suis ova or CNDO-201) for Crohn's disease. The Agreement reflects the collaboration contemplated by the binding Terms of Agreement executed by the parties in December 2011. The Agreement and the press release are attached as Exhibits 10.36 and 99.1, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

Item 9.01 Financial Statements and Exhibits

(d) Exhibits

- 10.36 Collaboration Agreement among the Company, Dr. Falk Pharma GmbH and OvaMed GmbH dated March 20, 2012 *
- 99.1 Press Release dated March 22, 2012
- * Confidential treatment has been requested with respect to portions of this exhibit.

SIGNATURES

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

CORONADO BIOSCIENCES, INC.

By: /s/ Dale Ritter

Name: Dale Ritter

Title: Senior Vice President, Finance

Dated: March 23, 2012

Exhibit Index

Exhibit No.	<u>Description</u>
10.36	Collaboration Agreement among the Company, Dr. Falk Pharma GmbH and OvaMed GmbH dated March 20, 2012 *
99.1	Press Release dated March 22, 2012

^{*} Confidential treatment has been requested with respect to portions of this exhibit.

CONFIDENTIAL TREATMENT REQUESTED. INFORMATION FOR WHICH CONFIDENTIAL TREATMENT HAS BEEN REQUESTED IS OMITTED AND MARKED WITH "[*******]" OR OTHERWISE CLEARLY INDICATED. AN UNREDACTED VERSION OF THIS DOCUMENT HAS ALSO BEEN PROVIDED TO THE SECURITIES AND EXCHANGE COMMISSION.

COLLABORATION AGREEMENT

Between

CORONADO BIOSCIENCES, INC.

("CORONADO")

and

OVAMED GMBH

("OVAMED")

and

Dr. FALK PHARMA GMBH

("FALK")

COLLABORATION AGREEMENT

This Collaboration Agreement ("Agreement") dated as of March 20, 2012 (the "Effective Date"), by and among:

Coronado Biosciences, Inc., a corporation organized and existing under the laws of the State of Delaware, United States, and having its principal place of business at 15 New England Executive Park, Burlington, MA 01803, USA ("CORONADO"),

Ovamed GmbH, a German corporation registered with the Commercial Register of Amtsgericht Reinbek under HRB 3577 having its principal office at Kiebitzhörn 31, 22885 Barsbüttel, Germany ("**OVAMED**"), and

Dr. Falk Pharma GmbH, a German corporation registered with the Commercial Register of Amtsgericht Freiburg im Breisgau under HRB 3266 having its principal office at Leinenweberstraße 5, 79041 Freiburg, Germany ("FALK").

CORONADO, OVAMED and FALK are sometimes referred to herein individually as a "Party" and collectively as the "Parties."

Article 1. Recitals

- 1. Whereas, OVAMED and FALK are parties to the OVAMED FALK License related to Development, Commercialization, manufacturing and supply of Product in the FALK Territory (as each such term is defined herein), which includes a sublicense of OVAMED rights under a License Agreement dated September 20, 2003 between OVAMED and the University of Iowa Research Foundation ("UIRF"), as amended.
- 2. Whereas, OVAMED and CORONADO are parties to the OVAMED CORONADO Agreements related to Development, Commercialization, manufacturing and supply of Product in the CORONADO Territory (as each such term is defined herein), which includes a sublicense of OVAMED rights under a License Agreement dated December 8, 2005 between OVAMED and UIRF, as amended.
- 3. Whereas, consistent with FALK's and OVAMED's rights and obligations under the OVAMED FALK License and CORONADO's and OVAMED's rights and obligations under the OVAMED CORONADO Agreements, the Parties desire to collaborate and cooperate with each other in good faith in connection with Development of Product for Crohn's disease, to grant each other certain rights and licenses, and to coordinate with OVAMED issues relating to Product manufacturing, all on the terms and conditions set forth herein.
- 4. Whereas, the Parties entered into the Terms of Agreement dated December 22, 2011 (hereinafter "**Terms of Agreement**") setting forth the general agreements with respect to a collaboration and associated transactions by and among the Parties and providing the framework for a collaboration agreement to be entered into by and among the Parties.

[This space is intentionally left blank.]

Agreement

NOW, THEREFORE, in consideration of the premises and the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties, intending to be legally bound hereby, do hereby agree as follows:

Article 2. Definitions

The following capitalized terms, whether used in the singular or the plural, shall have the following meanings as used in this Agreement unless otherwise specifically defined herein:

- **2.1 "Affiliate"** shall mean any corporation, firm, limited liability company, partnership or other entity, which directly or indirectly controls or is controlled by or is under common control with a Party to this Agreement. For the purposes of this *Article 2.1*, "control" means ownership, directly or through one or more Affiliates, of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interests in the entity, in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby a party controls or has the right to control the direction of the management or policies of an entity, whether through the ownership of voting securities, by contract or otherwise. For the avoidance of doubt, the Parties agree that a company is deemed to be under "common control with" another company if the two companies are owned or controlled by the same group of individuals.
 - 2.2 "Bulk Drug Product" shall mean Product, prior to being in its labeled and packaged form.
- **2.3** "Business Day" shall mean any day that is not a Saturday, a Sunday, a day on which the New York Stock Exchange is closed, or other day on which banks are required or authorized by law to be closed in Freiburg, Germany.
- **2.4 "Clinical Data"** shall mean all information, data, and results owned or Controlled by the applicable Party and Developed or obtained in connection with a Clinical Trial involving the administration of Product for Crohn's disease, including but not limited to minutes of meetings with, and scientific advice of, any regulatory authority (including, in the United States, the FDA, and in Europe, the EMA), case report forms, electronic databases, and clinical study reports or summaries.
- **2.5 "Clinical Trial"** shall mean any investigation of Product in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamic effects of the Product, and/or to identify any adverse reactions to the Product and/or to study absorption, distribution, metabolism and excretion of the Product with the object of ascertaining its safety and/or efficacy.
 - **2.6 "CMC"** shall mean chemistry, manufacturing and controls.
- **2.7 "Commercialization"** (including variations such as "Commercialize" and the like) shall mean those activities directed to the marketing, promotion, selling or offering for sale of Product.

- 2.8 "Commercially Reasonable and Diligent Efforts" shall mean with respect to Development, a Party's use of commercially reasonable efforts and resources for a company of its size consistent with (i) the rights and obligations of such Party under this Agreement and, as applicable, the OVAMED FALK License and/or the OVAMED CORONADO Agreements; (ii) the exercise of prudent scientific and business judgment for a product of its type; (iii) such Party's efforts with respect to other products in its product pipeline, and in each case taking into consideration the impact of such efforts and resources on the Development of the Product as a whole.
- **2.9 "Competing Product"** shall mean a biological product marketed by a Third Party that (a) has been approved as "biosimilar" to Product or "interchangeable" with Product (as such terms are defined under the United States Biologics Price Competition and Innovation Act of 2009 and the regulations or guidances thereunder), and (b) has achieved a market share in the applicable country in the Coronado Territory of [*******] in such country.
 - **2.10 "Confidential Information"** shall mean information as defined under *Article 15.1*.
- **2.11 "Controlled"** with respect to Intellectual Property Rights shall mean the ability of a Party to grant a license or sublicense to such Intellectual Property Rights as provided for herein without violating the terms of any agreement or other arrangement with any Third Party existing and in effect at the time such Party is or would be required hereunder to grant the other Party such license or sublicense.
 - 2.12 "CORONADO Territory" shall mean the countries and territories listed in Exhibit 2.
- **2.13 "Development"** (including variations such as "Develop" and the like) shall mean those activities as are customary for a company in the pharmaceutical industry as part of the process of obtaining Regulatory Approval, including conducting research, preclinical development and/or Clinical Trials.
 - **2.14 "Development Plan"** shall mean the plan defined under *Article 3.2*.
- **2.15 "Drug Approval Application"** shall mean an application for Initial Regulatory Approval (including a Marketing Authorization Application in Europe and a Biologics License Application in the United States).
 - **2.16 "Effective Date"** shall mean the date first written above.
 - 2.17 "EMA" shall mean the European Medicines Agency.
 - **2.18 "European Commission"** shall mean the Commission of the European Union.
- **2.19 "FALK Patent Rights"** shall mean FALK's rights in the following: (a) U.S. Patent Application Nos. 12/594,074 and 12/993,517 related to the Product; (b) U.S. patents issuing thereon or issuing from non-U.S. counterparts thereof; (c) any division, continuation-in-part, continuation, reissue and reexamination applications, and extensions or restorations related to any of the foregoing; (d) any patents, patent applications, or other rights of FALK issuing from, or based on or claiming priority to or from any of the foregoing; and (e) any foreign counterparts to any of the foregoing; in each case in the CORONADO Territory.

- 2.20 "FALK Patent Rights License" shall mean the license defined under Article 6.1.
- **2.21 "FALK Phase II Trial"** shall mean the current Phase II Clinical Trial titled "Double-blind, randomised, placebo-controlled, multi-centre phase II study to evaluate the efficacy and safety of three different dosages of oral *Trichuris suis* ova (TSO) suspension in active Crohn's disease" sponsored by FALK.
 - 2.22 "FALK Pre-Clinical Data Package" shall mean the IMPD.
- **2.23 "FALK Pre-Clinical Know-How"** shall mean the FALK Pre-Clinical Data Package and the Know-How and Pre-Clinical Data included therein.
 - 2.24 "FALK Pre-Clinical Know-How License" shall mean the license defined under Article 6.1.
 - 2.25 "FALK Territory" shall mean Germany and the countries and territories listed in Exhibit 1.
 - 2.26 "FDA" shall mean the United States Food and Drug Administration.
 - 2.27 "Field" shall mean the prevention, treatment or cure of Crohn's disease and/or ulcerative colitis.
- **2.28 "IMPD"** shall mean the Investigational Medicinal Product Dossier filed by FALK with the German Federal Institute for Drugs and Medical Devices, together with the application for the authorization of the FALK Phase II Trial, reports mentioned therein and updates of such reports, and all supplements and amendments thereto.
- **2.29 "Initial Regulatory Approval"** shall mean the first authorization or approval of Drug Approval Applications for marketing or commercial sale of Product for Crohn's disease in Europe and in the United States by the European Commission and the FDA, respectively.
- **2.30 "Intellectual Property Rights"** shall mean any and all intellectual property rights including but not limited to patents and patent applications (including the FALK Patent Rights), Know-How (including the FALK Pre-Clinical Know-How, Pre-Clinical Data and Clinical Data), Inventions (whether patentable or not) and/or trademarks.
- **2.31 "Invention"** shall mean discoveries, processes, methods, technologies or improvements and Know-How related to the formulation, delivery, presentation or manufacture of a Product first reduced to practice or created newly on or after the Effective Date.
- 2.32 "Know-How" shall mean all proprietary, non-patented, practical information owned or Controlled by a Party and relating to the Product including but not limited to trade secrets, techniques, data (including Confidential Information as defined in *Article 15*), discoveries, formulae, materials, practices, methods, processes, experience, test data (including pharmacological, toxicological and Clinical Data), analytical and quality control data, marketing, pricing, distribution, cost and sales data or descriptions which is secret, substantial and identified; in this context, "Secret" means that the Know-How, as a body or in the precise configuration and assembly of its components, is not generally known or easily accessible; "Substantial" means that the Know-How includes information which is significant and

useful to the user for the intended use including but not limited to manufacturing, commercialization, marketing, sale and distribution; "Identified" means that the Know-How must be described in a sufficiently comprehensive manner so as to make it possible to verify that it fulfils the criteria of secrecy and substantiality.

- **2.33 "Launch Date"** shall mean the date determined by CORONADO to start with distribution and/or sale of the Product within a country in the CORONADO Territory.
 - **2.34 "Losses"** shall have the meaning according to the definition under *Article 17.1*.
- **2.35 "Mutual Non Disclosure Agreement"** shall mean the Mutual Non Disclosure Agreement dated December 7, 2011 and entered into between CORONADO and FALK.
- 2.36 "Net Sales" shall mean the total gross receipts for sales of the Product by or on behalf of CORONADO or its Affiliates or by or on behalf of sublicensees (including distributors) of CORONADO or Affiliates of CORONADO (as applicable), whether invoiced or not, less only the sum of the following: (a) usual trade discounts to customers; (b) sales, tariff duties and/or taxes directly imposed and with reference to particular sales; (c) amounts allowed or credited on returns or rejections; (d) bad debt deductions actually written off during the accounting period; (e) outbound transportation prepaid or allowed and transportation insurance; (f) sales commissions; and (g) packaging and freight charges. Sales between or among CORONADO or its Affiliates or sublicensees (including distributors) shall be excluded from the computation of Net Sales provided such parties are not the end-user of the Product, but sales by such entities to their non-affiliated customers shall be included in such computation. Net Sales does not include sales of Product at or below the fully-burdened manufacturing cost solely for (i) non-profit research or clinical testing or (ii) indigent or similar public support or compassionate use programs.
- 2.37 "OVAMED CORONADO Agreements" shall mean (a) the Exclusive Sublicense Agreement dated December 12, 2005, and (b) the Manufacturing and Supply Agreement dated March 29, 2006, each as amended by, and including (i) the Letter Agreement dated November 8, 2007, (ii) the Term Sheet dated June 8, 2010, and (iii) the Amendment and Agreement dated January 7, 2011, the parties to each of which are OVAMED and CORONADO (including any predecessors of CORONADO), and (iv) the Side Agreement effective as of November 15, 2011 by and among CORONADO, OVAMED and UIRF; as each such agreement may be further amended during the Term of this Agreement.
- **2.38 "OVAMED FALK License"** shall mean the Development, Manufacturing and Commercialization Agreement by and between OVAMED and FALK dated as of January 9, 2004, as amended on March 20, 2012, and as may be further amended during the term of this Agreement.
- **2.39 "ParaTech"** shall mean Parasite Technologies A/S, a Danish corporation registered with the Danish Commerce and Companies Agency under company registration number 27 97 18 22 with its principal office at Vallerød Banevej 12, DK2960 Rungsted Kyst.
 - 2.40 "Party" shall mean OVAMED, FALK, or CORONADO and, when used in the plural, shall mean all three of them.
- **2.41 "Patent Costs"** shall mean the reasonable direct fees and expenses actually paid by a Party to Third Parties, including attorneys and patent offices, that are specifically identifiable and incurred for the filing, prosecution, and maintenance of the specified patents and/or patent applications in accordance with the terms of this Agreement.

- **2.42 "Pharmacovigilance Data"** shall mean information generated by or on behalf of a Party in connection with its pharmacovigilance duties related to the Product including but not limited to information generated in connection with adverse reaction reporting, development safety update reports, periodic safety update reports and post-authorisation safety studies.
- **2.43 "Pre-Clinical Data"** shall mean technical, analytical, stability, quality control data, and CMC data relating to the Product and/or results of physico-chemical, pharmaceutical, biological including microbiological, toxicological and pharmacological tests of the Product.
- **2.44 "Product"** shall mean any pharmaceutical or medicinal product containing *Trichuris suis* ova (TSO) as the active ingredient, incorporated into any formulation or delivery system, intended for use in the prevention, treatment or cure of any human disease or condition.
- **2.45 "Regulatory Approval"** shall mean any approvals (including pricing and reimbursement approvals), licenses, registrations or authorizations of national or international or local regulatory agency, department, bureau or other governmental entity necessary for the marketing or commercial sale of the Product in the Respective Territory.
- **2.46 "Regulatory Filing"** shall mean any submission, filing or application with any regulatory authority (including, in the United States, the FDA, and in Europe, the EMA) required to obtain or maintain authorization to conduct Clinical Trials with Product and/or authorization and approval to market or sell Product in the CORONADO Territory or the FALK Territory, as applicable.
- **2.47** "Respective Territory" shall mean, when the applicable Party is explicitly or implicitly FALK, the FALK Territory, and when the applicable Party is explicitly or implicitly CORONADO, the CORONADO Territory.
 - **2.48 "Royalty"** shall mean the royalty defined under *Article 7.1(d)*.
 - 2.49 "Royalty Term" shall have the meaning as defined under Article 19.1(d).
 - 2.50 "SEC" shall mean the United States Securities and Exchange Commission, or any successor agency.
- **2.51 "Specifications"** shall mean the quality assurance, quality process parameters and quality release standards and procedures for the Bulk Drug Product, as set forth in Regulatory Filings.
 - **2.52 "Steering Committee"** shall mean that body established pursuant to *Article 4.1*.
 - 2.53 "Successor" shall mean Affiliates and other successors as defined under Article 22.1.
- **2.54 "Third Party"** shall mean any entity other than CORONADO and Affiliates and sublicensees of CORONADO, OVAMED and Affiliates and sublicensees of OVAMED, and FALK and Affiliates and sublicensees of FALK.

- 2.55 "Trichuris suis ova" shall mean the ova or eggs of the Trichuris suis worm.
- 2.56 "TSO" shall mean Trichuris suis ova.

Article 3. Scope of the Collaboration

- **3.1 General Goals.** The Parties agree, pursuant and subject to the terms of this Agreement and, as applicable, of the OVAMED FALK License, and of the OVAMED CORONADO Agreements, to further Develop the Product for Crohn's disease with the goal to obtain the Initial Regulatory Approvals (the "**Development Collaboration**").
- **3.2 Development Plan.** The overall strategy for the Development Collaboration to reach the general goals according to *Article 3.1* shall be set forth in a written plan (hereinafter the "**Development Plan**"). The Development Plan will be established by the Steering Committee and reviewed and adapted periodically by the Steering Committee and shall be discussed at Steering Committee meetings. Notwithstanding the foregoing, (a) in the event any provision set forth in the Development Plan conflicts with or is inconsistent with a provision of this Agreement, the provisions of this Agreement shall control; and (b) the Development Plan shall not impose obligations on a Party, except to the extent provided for in this Agreement, without such Party's consent.

Article 4. Management of the Collaboration

4.1 Establishment of Steering Committee.

- (a) The Parties hereby establish a Steering Committee to function as a forum for the Parties to inform and consult with one another concerning the Development Collaboration. The Steering Committee will be composed of three (3) representatives of each Party, who shall be appointed (and may be replaced at any time) by such Party on written notice to the other Party in accordance with this Agreement. Such representatives shall include individuals within the senior management of each Party with expertise and responsibilities in the areas of Development, process sciences, manufacturing or regulatory affairs, as applicable to the stage of Development of the Product. Any member of the Steering Committee may designate a substitute to attend and perform the functions of that member at any meeting of the Steering Committee. Additional representatives or designees of a Party may from time to time be invited to attend Steering Committee meetings, with the consent of the other Parties, which consent shall not be unreasonably withheld.
- **(b)** One of the three representatives for each Party shall be designated as that Party's General Manager. Although the members of the Steering Committee can and should change as the life cycle of the Product changes, the Parties will endeavor to keep the General Managers consistent for each Party throughout the Development Collaboration to maintain continuity in the collaboration.
- (c) The initial Steering Committee members, including the General Manager, from each Party are listed on <u>Exhibit 3</u> attached hereto.
 - 4.2 Meetings of Steering Committee. The Steering Committee will meet at least

twice each year (face-to-face) during the term of this Agreement, or at any frequency agreed by the Steering Committee, subject to *Article 4.6*. In any event, the Steering Committee will meet within thirty (30) days after the Effective Date or as soon as practicable as mutually agreed by the Parties.

- **4.3 Responsibilities of Steering Committee.** The Steering Committee shall be the primary vehicle for interaction between the Parties with respect to the Development Collaboration. In particular, the Steering Committee shall perform the following functions:
- (a) Oversee the Development Collaboration, including establishment of the Development Plan and review of draft study protocols for Clinical Trials of Product for Crohn's disease, with the goal of: (i) coordinating Development such that FALK and CORONADO are each responsible for Clinical Trials of Product for Crohn's disease on approximately 50% of the aggregate number of patients required for the Initial Regulatory Approvals in the United States and Europe, and (ii) in the event additional Development is required to be conducted after the Effective Date in order to obtain additional Pre-Clinical Data required for such Initial Regulatory Approvals, approving a Development Plan and budget and allocating responsibility for conducting such Development; in each case consistent with the terms and overall intents and purposes of this Agreement;
 - **(b)** Facilitate the exchange of Pre-Clinical Data, Clinical Data and other information;
 - (c) Review regulatory communications and strategies;
- (d) Discuss manufacturing and supply issues, including scale-up of manufacturing process and Product formulation and improvements;
 - (e) Evaluate Commercialization strategies and post-marketing studies for Product for Crohn's disease; and
- (f) Serve as the initial forum for resolving disputes, it being agreed however, that each of FALK and CORONADO, in light of their rights and obligations under this Agreement related to the Development and Commercialization in their Respective Territories, will retain final decision-making authority according to (and subject to OVAMED's rights under) the OVAMED FALK License and the OVAMED CORONADO Agreements with respect to the FALK Territory and the CORONADO Territory, respectively; provided, however, that the Steering Committee shall attempt in good faith to reach agreement with respect to matters that come before it for decision and shall give consideration to the views, positions and recommendations of each Party on such matters.
- **4.4 Steering Committee Procedures.** FALK shall designate a Chairperson of the Steering Committee who will serve as such. The Chairperson shall send notices (not less than 15 Business Days in advance of such meetings) and agendas for all regular Steering Committee meetings to all Steering Committee members; *provided, however*, that any Party may request that specific items be included on the agenda or that additional meetings be scheduled. The location of regularly scheduled Steering Committee meetings shall be in Hamburg, Germany, unless otherwise agreed. Meetings may be held telephonically, but each member shall attend at least one meeting in person each year. The Party hosting any Steering Committee meeting shall appoint one person (who need not be a member of the Steering Committee) to attend the meeting and record the minutes of the meeting. Such minutes shall be circulated to the Parties promptly following the meeting for review, comment and distribution.

- **4.5 Costs**. Each Party shall bear its own costs relating to the Steering Committee including but not limited to the travel and related costs of its representatives at the Steering Committee.
- **4.6 Disbanding of Steering Committee**. The Steering Committee shall be automatically disbanded effective on the tenth (10th) anniversary of the Effective Date unless the Parties mutually agree to (a) disband the Steering Committee prior to the expiration of such ten (10) year period, or (b) extend such period prior to the expiration of such ten (10) year period.

Article 5. Development, Specifications and Manufacturing Methods

- **5.1 Development Efforts.** The Parties shall use Commercially Reasonable and Diligent Efforts to Develop the Product for Crohn's disease with a goal to obtain the Initial Regulatory Approvals in accordance with the terms of this Agreement and, as applicable, of the OVAMED FALK License and of the OVAMED CORONADO Agreements.
- **5.2 Development Responsibility and Decisions.** Responsibility regarding the Development and management of regulatory activity shall be allocated, and decisions regarding such Development and management of regulatory activity shall be made (a) by FALK, according to the rights and allocations of responsibilities under the OVAMED FALK License, with respect to Development in the FALK Territory, and (b) by CORONADO, according to the rights and allocation of responsibilities under the OVAMED CORONADO Agreements, with respect to Development in the CORONADO Territory. Except as provided for in this Agreement, the Parties will operate independently in their activities for their respective Development of Product. Each Party shall keep the Steering Committee informed of the progress of its part of the Development Collaboration, including time lines and Development Collaboration work, and will discuss with the Steering Committee Development and decisions that each Party anticipates will have a significant impact on the Initial Regulatory Approvals.
- **5.3 Collaboration and Cooperation.** Notwithstanding their respective rights and responsibilities under the OVAMED FALK License and under the OVAMED CORONADO Agreements, the Parties shall collaborate and cooperate with each other in good faith in connection with the Development Collaboration in accordance with the terms of this Agreement.
- **5.4 Specifications.** The Parties shall, as far as reasonable according to each Party's discretion and in accordance with the overall intents and purposes of the Development Collaboration and applicable laws, aim for uniform Specifications for the FALK Territory and the CORONADO Territory.

Article 6. FALK Pre-Clinical Know-How License and FALK Patent Rights License; Data Delivery

6.1 License to CORONADO. Subject to the terms hereof, FALK hereby grants to

CORONADO a royalty-bearing, exclusive right and license (including the right to grant sublicenses as set forth in *Article 9.5*) under the FALK Pre-Clinical Know-How (the "FALK Pre-Clinical Know-How License") and under the FALK Patent Rights (the "FALK Patent Rights License") to (a) Develop, use, Commercialize, sell, offer for sale and import Product in the CORONADO Territory, and (b) subject, as between CORONADO and OVAMED, to the terms of the OVAMED CORONADO Agreements, have Product made by OVAMED, make and have made Product.

- **6.2 FALK Pre-Clinical Data Package.** Within ten (10) Business Days after the Effective Date, FALK will deliver the FALK Pre-Clinical Data Package to CORONADO by permitting CORONADO Internet-based access to an electronic data room containing the FALK Pre-Clinical Data Package. FALK consents to CORONADO's right of reference and use of the FALK Pre-Clinical Know-How in connection with any Regulatory Filing in the CORONADO Territory.
- **6.3 Disclosure of FALK Pre-Clinical Know-How.** FALK will disclose to CORONADO all FALK Pre-Clinical Know-How in addition to the FALK Pre-Clinical Data Package as soon as such FALK Pre-Clinical Know-How becomes available to FALK.

Article 7. Consideration for FALK Pre-Clinical Know-How and FALK Patent Rights License

- **7.1 Consideration.** Subject to the other terms and conditions of this Agreement, and as consideration for the FALK Pre-Clinical Know-How License and the FALK Patent Rights License granted to CORONADO by FALK under this Agreement, CORONADO shall pay to FALK:
- (a) One million Euros (€1 million) payable five (5) Business Days after the Business Day that is within ten (10) Business Days after the Effective Date, on which FALK grants CORONADO Internet-based access to an electronic data room containing the FALK Pre-Clinical Data Package;
- (b) One million five hundred thousand Euros (€1,500,000) payable five (5) Business Days after the Business Day at which FALK grants CORONADO Internet-based access to an electronic data room containing the recommendation of the independent data monitoring committee of the FALK Phase II Trial based on the interim Clinical Data (blinded for FALK) resulting from the FALK Phase II Trial (the "Committee Recommendation") independent from the results of the FALK Phase II Trial;
- (c) Two million five hundred thousand Euros (€2,500,000) payable five (5) Business Days after the Business Day at which FALK grants CORONADO Internet-based access to an electronic data room containing the final written Clinical Study Report of the FALK Phase II Trial, independent from the results of the FALK Phase II Trial; and
- (d) During the Royalty Term, a royalty equal to one percent (1%) of Net Sales of Product in the CORONADO Territory (the "Royalty").
- **7.2 Past Due Amounts.** Any failure by a Party to make a payment required by this Agreement within [******] Business Days after the date when due shall obligate such Party to pay interest at an annual rate equal to [******] per annum in each case calculated on the number of days such a payment is overdue.

- **7.3 Reports**. Starting with the first calendar quarter in which the Launch Date of a Product in the CORONADO Territory occurs, within [*******] after the end of each calendar quarter, CORONADO shall deliver to FALK (a) a written report accounting for all Net Sales during, and calculating the Royalty payable for, the preceding calendar quarter in the CORONADO Territory; and (b) a copy of, or Internet reference link to, CORONADO's Quarterly Report on Form 10-Q as filed with the SEC with respect to the preceding calendar quarter (*provided, however*, that for the last quarter of CORONADO's fiscal year, such copy or link shall be to CORONADO'S Annual Report on Form 10-K as filed with the SEC for such fiscal year and shall be provided after the date that such report is filed with the SEC).
- **7.4 Records**. CORONADO will maintain complete and accurate records which are relevant to Net Sales under this Agreement, and, upon the written request of FALK, such records shall be open during reasonable business hours for a period of three (3) years from creation of individual records for examination, but not more often than once each year, by an independent certified public accountant selected by FALK to verify the accuracy of the reports under *Article 7.3(a)*. The cost of the services of such public accountant shall be born by FALK unless the audit establishes a material infringement of CORONADO's obligations under this Agreement.
- **7.5 Currency.** Royalties due for any calendar quarter shall be converted into Euros using the rate of exchange published in The Wall Street Journal, Eastern edition (if available), or any other publication agreed to between CORONADO and FALK, on the last Business Day of the calendar quarter.
- **7.6 Royalty Payments.** Simultaneous with transmitting reports according to *Article 7.3* to FALK, CORONADO shall pay all Royalties due in Euro by wire transfer to a bank account designated by FALK.
- 7.7 Taxes, etc. If laws, rules or regulations require withholding of income taxes or other taxes imposed upon payments set forth in this Agreement, the Party receiving such payment shall provide the Party required to make such payment, 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). The Parties agree to co-operate, consistent with its respective usual business practices, 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. The Party making such payment shall pay to the relevant authorities the full amount to be deducted or withheld according to the applicable tax law. Any such required tax, charges and other duties actually paid on behalf of the Party receiving such payment shall be deducted from the sums due to the receiving Party under this Agreement.
- **7.8 No Guaranty of OVAMED.** Nothing herein shall be construed as any guarantee or assumption of liability by OVAMED for any royalties, payments or other amounts payable by CORONADO to FALK as contemplated by this Agreement.

Article 8. Exchange of CMC Information and Inventions

8.1 CMC Information.

- (a) Each Party shall submit to each other Party all CMC information related to the Product as soon as such CMC data becomes available.
- **(b)** CORONADO and its designees shall have the right to access, and the right of reference or use, and each other Party hereto consents to such reference and/or use of, any such CMC data owned or Controlled by such other Party, in connection with any Regulatory Filing in the CORONADO Territory, to the extent necessary or useful to exercise CORONADO's rights, obligations and responsibilities, including under this Agreement and the OVAMED CORONADO Agreements.
- (c) FALK and its designees shall have the right to access, and the right of reference or use, and each other Party hereto consents to such reference and/or use of, any such CMC data owned or Controlled by such other Party, in connection with any Regulatory Filing in the FALK Territory, to the extent necessary or useful to exercise FALK's rights, obligations and responsibilities, including under this Agreement and the OVAMED FALK License.
- 8.2 Ownership of Inventions. Inventorship for patentable Inventions discovered, developed, conceived or reduced to practice (hereinafter, "Created") during the course of, in furtherance of, and as a result of the Development Collaboration shall be determined in accordance with the patent laws of the country in which the patent application is filed (but at a minimum, in accordance with an individual's inventive contribution to a claimed Invention) and, except as specifically set forth in this Agreement, ownership of all such Inventions shall flow from such inventorship determination. The ownership of Inventions Created solely by (employees of) CORONADO, and patent applications and patents claiming such Inventions Created jointly by (employees of) CORONADO and OVAMED, and patent applications and patents claiming such Inventions, shall be owned jointly by OVAMED and CORONADO subject, to the extent applicable, to the OVAMED CORONADO Agreements and, with respect to OVAMED's interest therein, to the extent applicable, the OVAMED FALK License. The ownership of Inventions Created solely or jointly by (employees of) OVAMED and/or FALK, and patent applications and patents claiming such Inventions, shall be subject to the OVAMED FALK License and, with respect to OVAMED's interest therein, to the extent applicable, the OVAMED CORONADO Agreements. The ownership of Inventions Created jointly by (employees of) CORONADO and FALK or jointly by (employees) of CORONADO, OVAMED and FALK (each, a "Joint Invention"), and patent applications and patents claiming such Joint Inventions, shall be subject to Articles 8.3-8.7.
- **8.3 Ownership of Joint Inventions.** Inventions Created jointly by (employees of) CORONADO and FALK, including any Invention Created as a result of Development conducted and funded pursuant to *Article 9.4(b)* (regardless of inventorship determination with respect to any such Invention under applicable patent laws), and patent applications and patents claiming such Joint Inventions, shall be owned jointly by CORONADO and by FALK with each such Party having an undivided interest in such Joint Invention in accordance with the joint ownership rules of applicable patent laws. Inventions Created jointly by (employees)

of CORONADO, OVAMED and FALK, including any Invention Created as a result of Development conducted and funded pursuant to *Article 9.4(b)* (regardless, with respect to CORONADO's and FALK's interest therein, of inventorship determination with respect to such Invention under applicable patent laws), and patent applications and patents claiming such Joint Inventions, shall be owned jointly by CORONADO, by OVAMED and by FALK with each such Party having an undivided interest in such Joint Invention in accordance with the joint ownership rules of applicable patent laws.

- **8.4 Transfer of Invention and Patent Ownership Rights.** To achieve the Joint Invention ownership rights according to the foregoing *Article 8.3*, each Party concerned shall cause its employees and its Affiliates and its Affiliates' employees to assign, at the time of creation of any such Joint Invention, or any time thereafter, to such Party according to the ownership principles provided for in the foregoing *Article 8.3*, without any requirement of further consideration, the entire right, title, or interest it or they may have in such Joint Invention, including any patent or other intellectual property rights claiming such Joint Invention. On request of the other Party or Parties concerned, the Party concerned shall take such further actions and shall cause its employees and its Affiliates and its Affiliates' employees to take such further actions, including execution and the delivery of instruments of conveyance, as may be reasonable and appropriate to give full and proper effect to such assignment. In addition, the Parties shall cause the recordation of such executed forms of assignment or instruments of conveyance with the applicable patent offices.
- **8.5 Management and Representation.** In the event of any Joint Invention, each concerned Party will appoint a representative with patent and intellectual property expertise. Such representatives will meet (in person, by telephone or videoconference) upon request by any Party jointly owning such Joint Invention (with each Party responsible for the expenses of its representative) during the term provided for in *Article 19.1(e)* and the pendency of any patents or patent applications claiming any such Joint Invention, to coordinate, discuss, and review strategies, and allocate responsibilities and Patent Cost sharing, in good faith and according to the legitimate interest, rights, and Respective Territories of the Parties concerned, with respect to filing, prosecuting, maintaining, enforcing and defending patent applications and patents, in the names of the Parties jointly owning such Joint Invention, that claim such Joint Invention, subject to the provisions of *Article 12.1(b) and (c)*.
- **8.6** Access and Use. The Parties concerned shall have access to, and each Party shall provide the other Party(ies) concerned access to and copies of, all data, documents and other information related to the Joint Invention. Each Party concerned may use such data in accordance with the purpose of and its rights under this Agreement and, as applicable, the OVAMED CORONADO Agreements and the OVAMED FALK License, without any additional payments to any of them, except to the extent the provisions of *Article 9.4(b)* are applicable.
- **8.7 Cross-Licenses.** Notwithstanding any other provision of this Agreement, each Party owning Joint Inventions, in whole or in part, hereby grants to the other Parties a non-exclusive license under the rights resulting from the patents and patent applications claiming such Joint Inventions, and each Party shall then have a fully paid-up right to use, license, sublicense and otherwise exercise all rights under any patents, patent applications or other intellectual property on or claiming Joint Inventions without the consent of any other Party

and with no duty to account to any other Party, to the extent necessary or useful to exercise their rights, obligations and responsibilities including according to, to the extent applicable, and in a manner that is consistent with the licenses granted pursuant to, this Agreement, the OVAMED CORONADO Agreements, and the OVAMED FALK License.

Article 9. Cross-Licenses, Pre-Clinical Data and Clinical Data Sharing

- **9.1 Exclusive License to CORONADO**. FALK hereby (a) grants CORONADO an exclusive right and license (including the right to grant sublicenses as set forth in *Article 9.5*) to and under Pre-Clinical Data and Clinical Data that is or becomes during the term of this Agreement owned or Controlled by FALK to (i) Develop, use, import, sell, offer for sale, and Commercialize Product in the Field in the CORONADO Territory, and (ii) subject, as between CORONADO and OVAMED, to the terms of the OVAMED CORONADO Agreements, have Product made by OVAMED, make and have made Product; and (b) consents to CORONADO's right of reference and use of such Pre-Clinical Data and Clinical Data in connection with Regulatory Filings in the CORONADO Territory.
- **9.2 Exclusive License to FALK.** Subject, as between FALK and OVAMED, to such Parties' respective rights and obligations under the OVAMED FALK License, CORONADO hereby (a) grants FALK and OVAMED a co-exclusive right and license (including the right to grant sublicenses as set forth in *Article 9.5*) to and under Pre-Clinical Data and Clinical Data that is or becomes during the term of this Agreement owned or Controlled by CORONADO to Develop, have made by OVAMED, use, import, sell, offer for sale, and Commercialize Product in the Field in the FALK Territory; and (b) consents to the right of reference and use of such Pre-Clinical Data and Clinical Data in connection with Regulatory Filings in the FALK Territory by FALK and/or OVAMED.
- **9.3 Disclosure.** CORONADO and FALK will disclose to each other all Pre-Clinical Data and Clinical Data, including interim Clinical Data and including the Committee Recommendation, as soon as such Pre-Clinical Data or Clinical Data become available.
 - 9.4 Compensation. In connection with the Development Collaboration, the following shall be applicable:
- (a) Clinical Trials. In the event that (i) the Clinical Trials of Product for Crohn's disease will not result in a situation where FALK and CORONADO are each responsible for Clinical Trials of Product for Crohn's disease on approximately 50% of the aggregate number of patients required for the Initial Regulatory Approvals in the United States and Europe, and (ii) the Party (FALK or CORONADO) which is responsible for Clinical Trials of Product for Crohn's disease with significantly less than 50% of the aggregate number of patients required for Initial Regulatory Approval in the United States and Europe benefits from the fact that the other Party is responsible for Clinical Trials of Product for Crohn's disease with significantly more than 50% of the aggregate number of patients required for the Initial Regulatory Approvals in the United States and Europe by the cross-licenses provided for in this *Article 9*, then FALK and CORONADO shall negotiate in good faith a fair compensation to be paid by the benefitting Party to the other Party contemplating the rights, duties, responsibilities, fields and territories of each Party concerned.

- (b) Pre-Clinical Data. In the event that after the Effective Date and in accordance with a Development Plan and budget approved by the Steering Committee, (i) FALK and/or CORONADO conducts additional Development to obtain additional Pre-Clinical Data that is not included in the FALK Pre-Clinical Know-How but is required for the Initial Regulatory Approvals, (ii) the costs actually incurred and paid by such Parties after the Effective Date to conduct such Development will not result in a situation where FALK and CORONADO are each responsible for approximately fifty percent (50%) of the total costs authorized by the Development Plan and budget and actually incurred and paid by such Parties after the Effective Date to conduct such Development, and (iii) the Party that is responsible for significantly less than fifty percent (50%) of such total costs benefits from the fact that the other Party is responsible for significantly more than fifty percent (50%) of such total costs by the cross-licenses of such Pre-Clinical Data provided for in this *Article 9*, then FALK and CORONADO shall negotiate in good faith a fair compensation to be paid by the benefitting Party to the other Party, as applicable, contemplating the rights, duties, responsibilities, fields and territories of each Party concerned.
- 9.5 Sublicenses. Subject to the terms and conditions of this Agreement, and (a) subject to the OVAMED CORONADO Agreements, CORONADO shall have the right to sublicense the rights and licenses granted to it under this Agreement to Affiliates or to Third Parties; and (b) subject to the OVAMED FALK License, FALK shall have the right to sublicense the rights and licenses granted to it under this Agreement to Affiliates or to Third Parties. A Party entering into any such sublicense shall advise the other Parties of such sublicense and any such sublicense shall be consistent with the terms and conditions of this Agreement and shall require the sublicensee to assume such Party's obligations under this Agreement to the extent applicable to the rights and territory covered by the sublicense.
- **9.6 Retention of Rights.** Except for the rights and licenses granted to another Party or as otherwise expressly set forth in this Agreement, each Party will retain their respective rights and responsibilities relating to Development and Commercialization in the FALK Territory and the CORONADO Territory, as applicable, pursuant to the OVAMED FALK License and the OVAMED CORONADO Agreements, as applicable.

Article 10. Safety Information; Pharmacovigilance

- 10.1 Safety Information. The Parties will promptly exchange with each other all relevant information that relates to the safety of Product, including all adverse drug experience reports, and 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 Territories. Each Party shall have the right to reference or use in any Regulatory Filing any safety information relating to Product provided to it by any other Party.
- **10.2 Pharmacovigilance Agreement.** As soon as reasonably practicable, the Parties shall enter into a separate agreement providing for the exchange and reporting of Pharmacovigilance Data related to the Product according to industry standards and applicable law.

Article 11. Consent and Rights and Obligations of OVAMED

- 11.1 Consent of OVAMED. OVAMED consents and agrees to all rights and licenses granted to FALK and to CORONADO as set forth in and contemplated by this Agreement.
- 11.2 Rights and Obligations of OVAMED. If not otherwise expressly provided for and subject to the rights and licenses granted to FALK and CORONADO in this Agreement, the rights and obligations of OVAMED with respect to FALK Pre-Clinical Know-How, FALK Patent Rights, Pre-Clinical Data, Clinical Data, Inventions, Development costs, and Pharmacovigilance Data shall be, as between OVAMED and FALK, subject to the OVAMED FALK License and, as between OVAMED and CORONADO, the OVAMED CORONADO Agreements.

Article 12.

Patent Prosecution and Maintenance, Third Party Infringements, Third Party Intellectual Property Rights

12.1 Patent Prosecution and Maintenance.

- (a) FALK Patent Rights. At its sole discretion, FALK shall have the initial right to file, prosecute, and maintain patent applications and patents for any and all FALK Patent Rights in such countries worldwide as it may determine. CORONADO shall reimburse FALK for Patent Costs for the FALK Patent Rights in the CORONADO Territory upon submission of appropriate invoices therefor. If FALK elects not to file, prosecute or maintain any FALK Patent Rights in any country of the CORONADO Territory, FALK shall so inform CORONADO with written advance notice sufficient to avoid any loss or forfeiture, and FALK shall enable CORONADO at CORONADO's request, and in that case CORONADO shall have the right, but not the obligation, to file, prosecute and maintain any such FALK Patent Rights in such country of the CORONADO Territory as it may determine at its own expense and discretion. In such event, at CORONADO's request, FALK shall assign such patent application or patent comprising such FALK Patent Right in such country.
- **(b) Review and Cooperation.** A Party having the initial right to prosecute and maintain patents and patent applications hereunder (including the Party that is determined by the Parties' representatives under *Article 8.5* to be initially responsible for filing in a particular country or jurisdiction a patent application claiming a Joint Invention) is referred to herein as the "**Prosecuting Party**". The Prosecuting Party agrees to keep the other concerned Party(ies) informed of the course of patent prosecution or other proceedings, including by providing such other Party(ies) 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. The Prosecuting Party shall also promptly furnish the other Party(ies) 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 or patent application 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(ies) of any patent issuing or granting from a patent application filed hereunder.

- (c) Joint Invention. If a Prosecuting Party elects not to file, prosecute or maintain a patent on a Joint Invention in any country (or not to pay or reimburse in accordance with *Article 8.5* the Patent Costs agreed to be paid by such Party), it shall provide the other Party(ies) owning such Joint Inventions with written advance notice sufficient to avoid any loss or forfeiture and, if such other Party includes either CORONADO or FALK, then CORONADO or FALK, as applicable, shall have the right, but not the obligation, at its expense, to file, prosecute or maintain such patent application or patent in such country. Thereafter, the Prosecuting Party shall transfer all its right, title and interest in such patent application or patent to either CORONADO or FALK, as applicable, and such Prosecuting Party shall no longer be a joint owner of such patent or patent application claiming a Joint Invention.
- 12.2 Third Party Infringements. In the event of an (alleged) infringement by a Third Party of Intellectual Property Rights owned or Controlled by one Party or more Parties regulated by the OVAMED CORONADO Agreements and/or the OVAMED FALK License, the rights and duties of the Parties concerned in such an event shall be governed by the OVAMED CORONADO Agreements and/or the OVAMED FALK License, respectively. In the event of an (alleged) infringement by a Third Party of Intellectual Property Rights owned or Controlled by one Party or more Parties regulated by this Agreement the following shall apply:
- (a) If a Party learns of any infringement or threatened (alleged) infringement by a Third Party of Intellectual Property Rights owned or Controlled by one Party or more Parties regulated by this Agreement, such Party shall promptly notify the other Parties in writing and shall provide the other Parties with all available evidence in its possession of such infringement.
- **(b)** If the infringement is in (i) the FALK Territory, FALK shall have the first right, but not the obligation, (ii) the CORONADO Territory, CORONADO shall have the first right, but not the obligation, (iii) neither the FALK nor the CORONADO Territory, the Party or Parties owning or Controlling such Intellectual Property Rights shall have the first right, but not the obligation, to institute, prosecute and control (collectively, "bring") any action or proceeding with respect to infringement by a Third Party of such Intellectual Property Right by counsel of its own choice, and the Party or the Parties not having such first right to bring such action shall have the right, but not the obligation, to be represented in any such action by counsel of its own choice. If the Party having such first right to bring such an action or proceeding within sixty (60) days of being notified of such infringement, then the Party not having such first right to bring such action shall have the right, but not the obligation, to bring such action. The Party or the Parties not bringing such action or proceeding agrees or agree to be joined as a party plaintiff if necessary to prosecute the action or proceeding and to give reasonable assistance and authority to file and prosecute the action or proceeding. The Party or the Parties that brings or bring such action to enforce a given Intellectual Property Right shall also have the right to control settlement of such claim; *provided, however*, that if one Party controls, no settlement shall be entered into without the express written consent of at least the Party in whose Respective Territory the action was brought, such consent not to be unreasonably delayed or withheld.

- (c) All reasonable costs and expenses occurring from such actions shall be shared by the Parties in good faith contemplating the rights, duties, responsibilities, fields and territories of each Party concerned. 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 Part(ies) for the reasonable out-of pocket costs and expenses of the action or proceeding (which amount shall be allocated *pro rata* if insufficient to cover the totality of such costs and expenses), with the remainder to be paid to the Party (or shared equally among the Parties) owning the Intellectual Property Rights concerned.
- 12.3 Third Party Intellectual Property Rights. In the event of an (alleged) infringement of Intellectual Property Rights of a Third Party in the CORONADO Territory or the FALK Territory by the operations to be conducted by or on behalf of a Party under this Agreement or under the OVAMED CORONADO Agreements or under the OVAMED FALK License, the rights and duties of the Parties shall be governed as set forth herein and by the OVAMED CORONADO Agreements and/or the OVAMED FALK License, as applicable.

Article 13. Regulatory Filings and Post-Regulatory Approval Responsibilities

13.1 Responsibilities.

- (a) FALK Territory. In performing their respective obligations under this Agreement, as between CORONADO and FALK, FALK shall be responsible for Drug Approval Applications in the FALK Territory. As between OVAMED and FALK, Drug Approval Applications in the FALK Territory shall be governed by the OVAMED FALK License, except as otherwise set forth in this Agreement.
- **(b) CORONADO Territory.** In performing their respective obligations under this Agreement, as between CORONADO and FALK, CORONADO shall be responsible for Drug Approval Applications in the CORONADO Territory. As between OVAMED and CORONADO, Drug Approval Applications in the CORONADO Territory shall be governed by the OVAMED CORONADO Agreements, except as otherwise set forth in this Agreement.
- 13.2 External Responsibility. Each Party acknowledges that as between the Parties, each holder of a Regulatory Approval bears the ultimate responsibility *vis-à-vis* the competent Regulatory Authorities for complying with the regulatory requirements applicable to the manufacture, store, sale and supply of the Product, provided that in accordance with applicable law, the overall intents and purposes of the Development Collaboration, and the terms of this Agreement, the OVAMED FALK License and the OVAMED CORONADO Agreements, as applicable, the Parties shall cooperate with each other in providing any data owned or Controlled by the applicable Party in order for the other Parties to comply with such regulatory requirements.

Article 14. Commercialization and Manufacturing

14.1 Commercialization and Manufacturing related to the FALK Territory. As between CORONADO and FALK, FALK shall be responsible for Commercialization in the

Field in the FALK Territory. As between OVAMED and FALK, Commercialization and manufacturing (including supply) related to the Product in the FALK Territory shall be governed, to the extent applicable, by the OVAMED FALK License.

14.2 Commercialization and Manufacturing related to the CORONADO Territory. As between CORONADO and FALK, CORONADO shall be responsible for Commercialization in the Field in the CORONADO Territory. As between OVAMED and CORONADO, Commercialization and manufacturing (including supply) related to the Product in the CORONADO Territory shall be governed, to the extent applicable, by the OVAMED CORONADO Agreements.

Article 15. Confidentiality

- 15.1 Confidentiality. Except to the extent expressly authorized by this Agreement or otherwise agreed to, the Parties agree that, the receiving Party shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as permitted under this Agreement any confidential information or materials furnished to it and owned or Controlled by the other Party pursuant to this Agreement, including but not limited to any Know-How, Pre-clinical Data and/or Clinical Data, business plans, marketing plans, customer information, financial information or patent applications (unless and until such applications are published pursuant to applicable law) (collectively, "Confidential Information"), except to the extent that it can be established by the receiving Party that such Confidential Information:
- (a) 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;
- **(b)** is in the public domain or which 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;
- (c) 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;
- (d) 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
- (e) 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.
 - **15.2 Disclosure and Use of Confidential Information.** Except as contemplated by this Agreement or with the consent or agreement of the disclosing Party, the receiving Party agrees to hold the Confidential Information in confidence and not to use any Confidential Information for any purpose and not to disclose any Confidential Information to any Third Party other than in connection with the execution and performance of its rights, obligations

or responsibilities according to this Agreement, the OVAMED CORONADO Agreements or the OVAMED FALK License; provided, however, that the receiving Party may use and disclose such Confidential Information (a) in filing or prosecuting patent applications, Regulatory Filings, conducting Clinical Trials or seeking Regulatory Approvals, in accordance with the receiving party's rights and obligations under this Agreement, the OVAMED FALK License, and the OVAMED CORONADO Agreements, as applicable, prosecuting or defending litigation, in accordance with the publication provisions of Article 18, or complying with applicable laws or governmental regulations, and (b) 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 OVAMED CORONADO Agreements or the OVAMED FALK License.

15.3 Survival. This *Article 15* shall perpetually survive the termination or expiration of this Agreement with respect to specific Confidential Information as long as such Confidential Information is not in the public domain or not subject to any of the other exceptions referred to in this *Article 15*.

Article 16. Representations and Warranties

- **16.1 Representations and Warranties of FALK.** As a material inducement to CORONADO and OVAMED to enter into this Agreement and to consummate the transactions contemplated herein, FALK hereby represents and warrants to CORONADO and OVAMED, as of the Effective Date, as follows:
- (a) Organization. FALK is a corporation duly incorporated, validly existing and in good corporate standing under the Laws of Germany. FALK has full corporate power and authority to own and lease its properties and carry on its business and is duly qualified, registered or licensed as a corporation to do business and is in good standing in each jurisdiction in which the ownership or leasing of its properties or the character of its operations makes such qualification, registration or licensing necessary except where the failure to be so qualified, registered or licensed would not have a material adverse effect on the business of FALK;
- **(b) Authority.** FALK has the corporate right, power and authority to carry on its business and to execute and deliver this Agreement and to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly and validly authorized by all necessary corporate action on the part of FALK and no other corporate proceedings on the part of FALK are necessary to authorize this Agreement or consummate the transactions contemplated by this Agreement. This Agreement has been duly and validly executed and delivered by FALK and constitutes a legal, valid and binding obligation of FALK, enforceable against FALK except as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights;
- (c) No Conflict. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) violate, be in conflict with, constitute a default (or an event which, with notice or lapse of time or both, would constitute a default)

under, or result in the termination of, any material contract to which FALK is a party or by which any of its property is bound or subject, or (ii) violate any provision of any law, rule, regulation, judgment, injunction, or decree presently in effect having applicability to it; such that any such occurrence will have a material adverse effect on FALK or on FALK's ability to comply with its obligations under this Agreement;

- **(d) Litigation**. There is no existing litigation, arbitration, claim, action, or proceeding to which FALK is a party or, to the knowledge of FALK, which is pending or threatened against FALK, in either case which, if adversely determined, would have a material adverse effect on FALK's ability to perform in all material respects its obligations hereunder; and
- **(e) Right to Grant Licenses.** FALK has all necessary power and authority to grant to CORONADO in accordance with *Article 6.1* and *Article 9.1* the rights and licenses granted to CORONADO hereunder.

(f) Intellectual Property.

- (i) FALK Patent Rights. FALK owns or Controls the FALK Patent Rights as of the Effective Date. However, U.S. Patent Application No. 12/594,074 is jointly-owned by ParaTech, *provided*, *however*, that such joint ownership does not affect FALK's Control of such Patent Application with respect to the CORONADO Territory; and OVAMED has certain rights in the FALK Patent Rights in the future, *provided*, *further*, *however*, that OVAMED has consented under *Article 11.1* to FALK's grant to CORONADO of rights and licenses under the FALK Patent Rights. No claim has been asserted or threatened by any person regarding the manufacture, use or licensing by FALK of the FALK Patent Rights as of the Effective Date. To the best knowledge of FALK, the use of the FALK Patent Rights does not violate or infringe, the rights of, and are not subject to any claims by, any Third Party as of the Effective Date;
- (ii) FALK Pre-Clinical Know-How. Subject to the next sentence, FALK owns or Controls the FALK Pre-Clinical Know-How as of the Effective Date. OVAMED has certain rights in the FALK Pre-Clinical Know-How in the future, provided, however, that OVAMED has consented under Article 11.1 to FALK's grant to CORONADO of rights and licenses under the FALK Pre-Clinical Know-How. No claim has been asserted or threatened by any person regarding the use or licensing by FALK of the FALK Pre-Clinical Know-How in the CORONADO Territory as of the Effective Date. To the knowledge of FALK the FALK Pre-Clinical Know-How does not violate or infringe, and has not in the past violated or infringed the rights of any Third Party as of the Effective Date in the CORONADO Territory, and no claims have been asserted by FALK against any other person (other than OVAMED, which claim has been resolved or released) claiming infringement of the FALK Pre-Clinical Know-How as of the Effective Date in the CORONADO Territory;
- (iii) Limitation. Other warranties and representations with respect to FALK Patent Rights and FALK Pre-Clinical Know-How than those explicitly stated above shall be excluded to the extent legally possible.

- **16.2 Representations and Warranties of CORONADO.** As a material inducement to FALK and OVAMED to enter into this Agreement and to consummate the transactions contemplated herein, CORONADO hereby represents and warrants to FALK and OVAMED, as of the Effective Date, as follows:
- (a) Organization. CORONADO is a corporation duly incorporated, validly existing and in good corporate standing under the applicable laws of the State of Delaware, United States of America. CORONADO has full corporate power and authority to own and lease its properties and carry on its business and is duly qualified, registered or licensed as a foreign corporation to do business and is in good standing in each jurisdiction in which the ownership or leasing of its properties or the character of its operations makes such qualification, registration or licensing necessary except where the failure to be so qualified, registered or licensed would not have a material adverse effect on the business of CORONADO;
- **(b) Authority.** CORONADO has the corporate right, power and authority to carry on its business and to execute and deliver this Agreement and to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly and validly authorized by all necessary corporate action on the part of CORONADO and no other corporate proceedings on the part of CORONADO are necessary to authorize this Agreement or consummate the transactions contemplated by this Agreement. This Agreement has been duly and validly executed and delivered by CORONADO and constitutes a legal, valid and binding obligation of CORONADO, enforceable against CORONADO except as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights; and
- (c) No Conflict. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) violate, be in conflict with, constitute a default (or an event which, with notice or lapse of time or both, would constitute a default) under, result in the termination of, any material contract to which CORONADO is a party or by which any of its property is bound or subject, or (ii) violate any provision of any law, rule, regulation, judgment, injunction, or decree presently in effect having applicability to it; such that any such occurrence in (i) or (ii) will have a material adverse effect on CORONADO or on CORONADO's ability to comply with its obligations under this Agreement;
- **(d) Litigation**. There is no existing litigation, arbitration, claim, action, or proceeding to which CORONADO is a party or, to the knowledge of CORONADO, which is pending or threatened against CORONADO, in either case which, if adversely determined, would have a material adverse effect on CORONADO's ability to perform in all material respects its obligations hereunder; and
- **(e) Right to Grant Licenses.** CORONADO has all necessary power and authority to grant to FALK in accordance with *Article 9.2* the rights and licenses granted to FALK hereunder.
- **16.3 Representations and Warranties of OVAMED**. As a material inducement to CORONADO and FALK to enter into this Agreement and to consummate the transactions contemplated herein, OVAMED hereby represents and warrants to CORONADO and FALK, as of the Effective Date, as follows:
- (a) Organization. OVAMED is a corporation duly incorporated, validly existing and in good corporate standing under the Laws of Germany. OVAMED has full corporate power and authority to own and lease its properties and carry on its business and is duly qualified, registered or licensed as a corporation to do business and is in good standing in each jurisdiction

in which the ownership or leasing of its properties or the character of its operations makes such qualification, registration or licensing necessary except where the failure to be so qualified, registered or licensed would not have a material adverse effect on the business of OVAMED:

- (b) Authority. OVAMED has the corporate right, power and authority to carry on its business and to execute and deliver this Agreement and to consummate the transactions contemplated by this Agreement. The execution and delivery of this Agreement and the consummation of the transactions contemplated by this Agreement have been duly and validly authorized by all necessary corporate action on the part of OVAMED and no other corporate proceedings on the part of OVAMED are necessary to authorize this Agreement or consummate the transactions contemplated by this Agreement. This Agreement has been duly and validly executed and delivered by OVAMED and constitutes a legal, valid and binding obligation of OVAMED, enforceable against OVAMED except as limited by applicable bankruptcy, insolvency, reorganization, moratorium or other laws of general application affecting enforcement of creditors' rights;
- (c) No Conflict. Neither the execution and delivery of this Agreement nor the consummation of the transactions contemplated hereby will (i) violate, be in conflict with, constitute a default (or an event which, with notice or lapse of time or both, would constitute a default) under, or result in the termination of, any material contract to which OVAMED is a party or by which any of its property is bound or subject, or (ii) violate any provision of any law, rule, regulation, judgment, injunction, or decree presently in effect having applicability to it; such that any such occurrence in (i) or (ii) will have a material adverse effect on OVAMED or on OVAMED's ability to comply with its obligations under this Agreement; and
- **(d) Litigation**. There is no existing litigation, arbitration, claim, action, or proceeding to which OVAMED is a party or, to the knowledge of OVAMED, which is pending or threatened against OVAMED, in either case which, if adversely determined, would have a material adverse effect on OVAMED'S ability to perform in all material respects its obligations hereunder.

Article 17. Indemnification and Release

- 17.1 Indemnification by FALK. If not otherwise provided for in this Agreement, FALK hereby agrees to indemnify and hold the other Parties harmless from and against any and all losses, damages, liabilities, settlements, penalties, fines, costs and expenses (including, without limitation, reasonable attorneys' fees and expenses) incurred by such Party(ies) (collectively, "Losses") resulting from any wilful or grossly negligent breach by FALK of any of FALK's duties or obligations, representations or warranties set forth in this Agreement. This indemnification provision shall include any reasonable attorney's fees incurred by the other Parties in connection with enforcing this indemnification.
- 17.2 Indemnification by CORONADO. If not otherwise provided for in this Agreement, CORONADO hereby agrees to indemnify and hold the other Parties harmless from and against any and all Losses resulting from any wilful or grossly negligent breach by CORONADO of any of CORONADO's duties or obligations, representations or warranties set forth in this Agreement. This indemnification provision shall include any reasonable attorney's fees incurred by the other Parties in connection with enforcing this indemnification.

- 17.3 Indemnification by OVAMED. If not otherwise provided for in this Agreement, OVAMED hereby agrees to indemnify and hold the other Parties harmless from and against any and all Losses resulting from any wilful or grossly negligent breach by OVAMED of any of OVAMED's duties or obligations, representations or warranties set forth in this Agreement. This indemnification provision shall include any reasonable attorney's fees incurred by the other Parties in connection with enforcing this indemnification.
- 17.4 Limitation of Liability. TO THE EXTENT LEGALLY POSSIBLE, NO PARTY SHALL BE LIABLE TO ANY OTHER PARTY OR ANY OF ITS AFFILIATES FOR ANY CONSEQUENTIAL, INCIDENTAL, INDIRECT, SPECIAL, PUNITIVE OR EXEMPLARY DAMAGES (INCLUDING LOST PROFITS, BUSINESS OR GOODWILL BUT EXCLUDING THE ROYALTY WHICH SHALL BE INCLUDED IN A CALCULATION AWARDING ACTUAL DAMAGES TO FALK) SUFFERED OR INCURRED BY SUCH OTHER PARTY OR ITS AFFILIATES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT.
- 17.5 Release. Each Party hereby irrevocably and completely releases and forever discharges each of the other Parties (and each of such other Parties' respective successors, assigns, affiliates, officers, employees, directors and agents) from any and all claims, causes of action, actions, duties, damages, liabilities, losses, and obligations of any kind and manner whatsoever, in law or equity, whether or not asserted or not asserted and whether known or unknown, accrued or arisen prior to the Effective Date and arising out of or related to the disclosure and/or use, as contemplated by this Agreement or the Terms of Agreement, or any refusal to such disclosure or refusal of such use, of the FALK Pre-Clinical Know-how and/or the Clinical Data to, by, on behalf of or in support of CORONADO, and/or any Regulatory Filing related to any Product planned by CORONADO.
- 17.6 Indemnification Conditions. In the event that a Party is seeking indemnification for Losses resulting from claims of Third Parties, it shall inform the indemnifying Party of a claim of a Third Party as soon as reasonably practicable after it receives notice of the claim, shall permit the indemnifying Party to assume direction and control of the defense of the claim (including the right to settle the claim solely for monetary consideration), shall cooperate as requested (at the expense of the indemnifying Party) in the defense of the claim, and shall not settle or compromise the claim without the express written consent of the indemnifying Party.
- 17.7 Insurance. Each Party agrees to maintain reasonable insurance coverage for general liability and product liability claims (including coverage for Clinical Trials conducted by such Party or, if such Party is OVAMED, for which such Party is providing Product) with respect to the Product in amounts as are reasonable and customary for pharmaceutical companies of size and activities comparable to those of such Party. Upon request, each Party shall furnish the other Party with a copy of such insurance policies.

Article 18. Publicity Review

18.1 Standard. The Parties acknowledge the importance of supporting each other's efforts to publicly disclose results and significant Developments regarding the Product. CORONADO shall be responsible for public disclosure for the CORONADO. Territory of results and significant Developments regarding the Product in the Field according to CORONADO's discretion at CORONADO's cost. FALK shall be responsible for public disclosure for the FALK Territory of results and significant Developments regarding the Product in the Field according to FALK's discretion at FALK's cost. However, the principles to be observed by CORONADO and FALK in such public disclosures shall be: a copy of any proposed public disclosure by either FALK or CORONADO describing results of a Clinical Trial for Crohn's disease, Clinical Data, or the filing for or receipt of Initial Regulatory Approval shall be provided to the other Party at least (a) one week prior to the disclosure in the event of a scientific publication or presentation (to be reasonably expedited in the event of a meeting abstract), or (b) two (2) Business Days prior to a general public disclosure (to be expedited in the event a shorter period for disclosure may be required by law); as well as, accuracy, the requirements for confidentiality under this Agreement, the advantage a competitor of CORONADO or FALK may gain from any public statements, and the standards and customs in the pharmaceutical industries for such disclosures by companies comparable to CORONADO and FALK, as applicable.

18.2 Exceptions.

- (a) The provisions of this *Article 18* shall not apply to subsequent publications or presentations of substantially the same subject matter that was previously reviewed under *Article 18*; and
- **(b)** CORONADO may make disclosure of this Agreement and the terms hereof in filings with the SEC or other documents as required by SEC or securities exchange rules, and file this Agreement as an exhibit to any such filing with the SEC.
- **18.3 OVAMED's Disclosure.** OVAMED shall not disclose to any Third Party results or Developments regarding the Product without CORONADO's and FALK's prior consent, except in accordance with the terms of the OVAMED FALK License and the OVAMED CORONADO Agreements.

Article 19. Term

- **19.1 Term**. This Agreement shall commence as of the Effective Date. Unless sooner terminated by notice (provided in accordance with *Article 22.5*) and as expressly provided in this Agreement, this Agreement shall continue in force and effect:
- (a) with respect to the Development Collaboration until the completion of the Development Collaboration and the grant of the Initial Regulatory Approvals;
 - (b) with respect to the FALK Pre-Clinical Know-How License as long as the Pre-Clinical Know-How qualifies as Know-How;

- (c) with respect to the FALK Patent Rights License on a country by country basis until the date of expiration of the last of the FALK Patent Rights or the final abandonment of the last application for the FALK Patent Rights;
- (d) with respect to the Royalty on a country by country basis until the later of (i) the date of expiration of the last of the FALK Patent Rights in such country; (ii) 10 years from the Launch Date in such country; or (iii) the date on which there is a Competing Product in such country (the "Royalty Term");
- (e) with respect to licenses regarding Joint Inventions on a country by country basis until the date of expiration of the last patent resulting from the Joint Invention concerned or the date of the final failure of the last application for a patent resulting from the Joint Invention concerned or, in case of unpatented Joint Inventions, as long as the Joint Invention concerned qualifies as Know-How;
- (f) with respect to licenses regarding Pre-Clinical Data and Clinical Data as long as the Pre-Clinical Data or Clinical Data concerned qualify as Know-How;
- (g) with respect to safety information and Pharmacovigilance Data on a Party by Party basis until the date where the Party concerned completely terminates the Development (prior to or in the absence of any Commercialization) or Commercialization, except to the extent required by law; and
 - (h) with respect to Confidential Information, subject to the terms of Article 15.
- 19.2 Right to Use Upon Expiration. Upon expiration of this Agreement with respect to FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data or unpatented Joint Inventions, as applicable, CORONADO and FALK shall each thereafter be entitled to Develop, manufacture, Commercialize and exploit in any other respect on a non-exclusive basis, either by themselves or through their Affiliates or sublicensees, under such FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data or unpatented Joint Inventions free of any further payment or obligation to each other, as applicable, subject, to the extent then in effect and applicable, to each Parties' rights and obligations under the OVAMED CORONADO Agreements and the OVAMED FALK License, respectively.

Article 20. Termination

20.1 Termination of the Development Collaboration.

(a) Development Termination by CORONADO. CORONADO may terminate the Development Collaboration with FALK in the event CORONADO completely terminates its Development prior to any Commercialization. If CORONADO terminates the Development Collaboration with FALK in accordance with this paragraph, effective on the termination date the rights and obligations of CORONADO and FALK provided for in this Agreement with respect to further Development under the Development Collaboration shall cease. However, notwithstanding the foregoing, the licenses granted to FALK and/or OVAMED by CORONADO with respect to Pre-Clinical Data, Clinical Data, Pharmacovigilance Data and Inventions shall remain in effect. Furthermore, the licenses granted to CORONADO by FALK with respect

to FALK Pre-Clinical Know-How, FALK Patent Rights, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, and Inventions shall cease and CORONADO shall cease to use the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, or Inventions licensed to it by FALK, and shall cease to Develop, use, have made by OVAMED, Commercialize and sell Product, in each case except as required by law or to the extent required for an orderly transition. Without further request, CORONADO shall promptly send or return all documents, copies of documents and electronically memorised data referencing the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, and Inventions licensed to it by FALK, and FALK's Confidential Information. As far as it is not possible to return electronically processed information, CORONADO is obliged to use commercially reasonable efforts to delete or erase it immediately. In any case CORONADO is not allowed to retain any of the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, or Inventions licensed to it by FALK, and any of FALK's Confidential Information in any form. Exempted from this obligation is the retaining of documents which have to be kept according to the applicable law.

(b) Development Termination by FALK. FALK may terminate the Development Collaboration with CORONADO in the event FALK completely terminates its Development prior to any Commercialization. If FALK terminates the Development Collaboration with CORONADO in accordance with this paragraph, effective on the termination date the rights and obligations of CORONADO and FALK provided for in this Agreement with respect to further Development under the Development Collaboration shall cease. Notwithstanding the foregoing, the licenses granted to CORONADO by FALK with respect to FALK Pre-Clinical Know-How, FALK Patent Rights, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, and Inventions, including FALK's right to the Royalty and FALK's rights connected to such Royalty, shall remain in effect. However, the licenses granted to FALK by CORONADO with respect to Pre-Clinical Data, Clinical Data, Pharmacovigilance Data and Inventions shall cease and FALK shall cease to use the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, or Inventions licensed to it by CORONADO, and shall cease to Develop, use, have made by OVAMED, Commercialize and sell Product, in each case except except as required by law or to the extent required for an orderly transition. Without further request, FALK shall promptly send or return to CORONADO all documents, copies of documents and electronically memorised data referencing Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, and Inventions licensed to it by CORONADO, and CORONADO's Confidential Information. As far as it is not possible to return electronically processed information, FALK is obliged to use commercially reasonable efforts to delete or erase it immediately. In any case FALK is not allowed to retain any of the Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, or Inventions licensed to it by CORONADO, and any of CORONADO's Confidential Information in any form. Exempted from this obligation is the retaining of documents which have to be kept according to the applicable law.

20.2 Termination for Non-Payment or Other Material Breach.

(a) Termination for Non-Payment. If CORONADO or FALK (the "Breaching Party") fails to make any of the payments required under this Agreement within [*******] days after such payment becomes payable and such failure is not remedied within [*******] days after the Breaching Party's receipt of written notice from the other Party (the "Non-Breaching

Party") of such breach, then the Non-Breaching Party shall have the right, without prejudice to any other rights to compensation for damages or any other remedies available to it under this Agreement or at law or in equity, to terminate this Agreement; provided, however, that the Non-Breaching Party shall not be entitled to terminate the Agreement for the Breaching Party's failure to make any payments following the first instance of such failure to make payments and to timely remedy the failure (provided that the Breaching Party has made the required payments within a reasonable time after the end of the [*******] day cure period), or if (i) CORONADO and FALK have a bona fide disagreement as to any event that would trigger such payment or the amount of such payment to be made to the Non-Breaching Party, and (ii) the Breaching Party has paid the Non-Breaching Party any undisputed amounts.

(b) Termination for Material Breach (Other Than Non-Payment). In the event there shall have occurred a material adverse breach of this Agreement or a material adverse default in the observance or performance of any provision of this Agreement (other than for non-payment of non-disputed monies due) by a Party (the "Defaulting Party"), the Party claiming the same (the "Non Defaulting Party") shall promptly provide detailed notice thereof to the Defaulting Party. The Defaulting Party shall have [******] days from the date of receipt of such notice to cure the material adverse breach or material adverse default detailed in such notice and, if the same is timely cured within such [*******] day period the provisions of this Agreement shall remain in full force and effect. In the event that the material adverse breach or material adverse default detailed in such notice (other than on account of nonpayment of monies owed) cannot with due diligence be cured within such [*******] day period and the Defaulting Party promptly notifies the Non Defaulting Party of the period (not exceeding [*******] days) in which it anticipates that it can be cured, the time to cure such material adverse breach or material adverse default shall be extended for such period (up to a maximum of [*******] days) as may be necessary to cure the same with all due diligence. Without prejudice to any other remedies available to it under this Agreement or at law or in equity, this Agreement may be terminated forthwith by service of notice in writing by the Non Defaulting Party in the event that the Defaulting Party shall fail to cure such material adverse breach or material adverse default within such initial or extended period.

20.3 Effect of Termination for Non-Payment or Other Material Breach.

(a) Termination by CORONADO for Non-Payment or Material Breach of FALK. If CORONADO terminates this Agreement for non-payment or material breach by FALK in accordance with *Article 20.2(a)* or *20.2(b)*, the licenses granted to CORONADO by FALK with respect to FALK Pre-Clinical Know-How, FALK Patent Rights, Pre-Clinical Data, Clinical Data, Pharmacovigilance Data, and Inventions, shall remain in effect. However, effective on the termination date, (i) the licenses granted to FALK and/or OVAMED by CORONADO with respect to Pre-Clinical Data, Clinical Data, and Inventions shall cease, and FALK and OVAMED shall cease to use Pre-Clinical Data, Clinical Data, or Inventions licensed to it by CORONADO except as required by law or to the extent required for an orderly transition, and (ii) in the event such termination results from a FALK breach of its compensation obligations under *Article 9.4*, FALK's right to a Royalty on Net Sales of Product in the Field and FALK's rights connected to such Royalty shall terminate. Without further request, FALK and OVAMED shall promptly send or return all documents, copies of documents and electronically memorised data referencing the Pre-Clinical Data, Clinical Data, or Inventions licensed to it by

CORONADO, and CORONADO's Confidential Information. As far as it is not possible to return electronically processed information, FALK and OVAMED are obliged to use commercially reasonable efforts delete or erase it immediately. In any case FALK and OVAMED are not allowed to retain any of the Pre-Clinical Data, Clinical Data, or Inventions licensed to it by CORONADO, and any of CORONADO's Confidential Information in any form. Exempted from this obligation is the retaining of documents which have to be kept according to the applicable law.

(b) Termination by FALK for Non-Payment or Material Breach of CORONADO. If FALK effectively terminates this Agreement for non-payment or material breach by CORONADO in accordance with *Article 20.2(a)* or 20.2(b), the licenses granted to FALK and/or OVAMED by CORONADO with respect to Pre-Clinical Data, Clinical Data, Pharmacovigilance Data and Inventions shall remain in effect. However, effective on the termination date, the licenses granted to CORONADO by FALK with respect to FALK Pre-Clinical Know-How, FALK Patent Rights, Pre-Clinical Data, Clinical Data, and Inventions shall cease and CORONADO shall cease to use the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, or Inventions licensed to it by FALK, and shall cease to Develop, use, have made by OVAMED, Commercialize and sell Product under the FALK Patent Rights, except as required by law or to the extent required for an orderly transition. Without further request, CORONADO shall promptly send or return all documents, copies of documents and electronically memorised data referencing the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, or Inventions licensed to it by FALK, and FALK's Confidential Information. As far as it is not possible to return electronically processed information, CORONADO is obliged to use commercially reasonable efforts to delete or erase it immediately. In any case CORONADO is not allowed to retain any of the FALK Pre-Clinical Know-How, Pre-Clinical Data, Clinical Data, or Inventions licensed to it by FALK, and any of FALK's Confidential Information in any form. Exempted from this obligation is the retaining of documents which have to be kept according to the applicable law.

20.4 Bankruptcy.

- (a) Termination for Bankruptcy of FALK. CORONADO may, in addition to any other rights or remedies available to it by law or in equity or according to this Agreement, terminate this Agreement, in whole or in part as CORONADO may determine, by written notice to the other Parties in the event FALK shall have become bankrupt, or shall have made an assignment for the benefit of its creditors or there shall have been appointed a trustee or receiver of FALK or for all or a substantial part of its property or any case or proceeding shall have been commenced or other action taken by or against FALK in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for [*******] days undismissed, unbonded and undischarged. However, the licenses granted to CORONADO by FALK with respect to FALK Pre-Clinical Know-How, FALK Patent Rights, Pre-Clinical Data, Clinical Data, and Inventions, including FALK's right to the Royalty and FALK's rights connected to such Royalty, shall remain in effect.
- **(b) Termination for Bankruptcy of CORONADO.** FALK may, in addition to any other rights or remedies available to it by law or in equity or according to this Agreement, terminate

this Agreement, in whole or in part as FALK may determine, by written notice to the other Parties in the event CORONADO shall have become bankrupt, or shall have made an assignment for the benefit of its creditors or there shall have been appointed a trustee or receiver of CORONADO or for all or a substantial part of its property or any case or proceeding shall have been commenced or other action taken by or against CORONADO in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency, reorganization or other similar act or law of any jurisdiction now or hereafter in effect and any such event shall have continued for [*******] days undismissed, unbonded and undischarged. However, the licenses granted to FALK and/or OVAMED by CORONADO with respect to Pre-Clinical Data, Clinical Data, and Inventions shall remain in effect.

Article 21. General Effects of Expiration or Termination.

- **21.1 Surviving Rights and Obligations**. Except as specifically provided herein, upon termination or expiration of this Agreement, obligations and rights of a Party that expressly or by nature shall survive any termination or expiration of this Agreement will survive any termination or expiration of this Agreement.
- **21.2 Accrued Rights.** Except as specifically provided in this Agreement, termination or expiration of the Agreement for any reason shall be without prejudice to any rights which shall have accrued to the benefit of either Party prior to such termination or expiration, including payments due prior to termination or expiration of the Agreement or damages arising from any breach hereunder.

Article 22. Miscellaneous

22.1 Assignment. This Agreement and the rights, obligations and interests related to Inventions or Joint Inventions may not be assigned by any Party without the consent of the other Parties, which consent will not be unreasonably withheld, except that each Party may, without such consent, assign this Agreement and the rights, obligations and interests related to Inventions or Joint Inventions of such Party, (a) in whole or in part, to any of its Affiliates (*provided, however*, that any assignment in part to an Affiliate shall be subject to the foregoing consent requirement with respect to any further assignment by such Affiliate to a Third Party), or (b) in its entirety, to any purchaser of all or substantially all of its assets in the line of business to which this Agreement pertains, or of all of its capital stock, or to any successor corporation resulting from any merger or consolidation of such Party with or into such corporation (each, a "**Successor**") where such Affiliate or other Successor to a Party could reasonably be expected to satisfy that Party's obligations hereunder; *provided, however*, that in the case of an assignment the assigning Party shall remain fully responsible for all of its obligations hereunder and shall provide notice to the other Parties of such assignment. This Agreement shall be binding upon and inure to the benefit of the Successors and permitted assigns of the Parties. Any attempt to assign any portion of this Agreement in violation of this paragraph shall be void. Subject to the foregoing, any references to CORONADO, OVAMED and FALK hereunder shall be deemed to include the Successors and permitted assigns thereof.

- **22.2 Legal Compliance**. Each Party shall comply in all material respects with all laws, rules and regulations applicable to the conduct of its business pursuant to this Agreement.
- 22.3 Force Majeure. Neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by government action, war, terrorism, fire, explosion, flood, strike, lockout, embargo, act of God, or any other cause beyond the control and without the fault or negligence of the defaulting Party, provided that the Party claiming force majeure has exerted all reasonable efforts to avoid or remedy such force majeure; provided, however, that in no event shall a Party be required to settle any labor dispute or disturbance. Such excuse shall continue as long as the condition preventing the performance continues. Upon cessation of such condition, the affected Party shall promptly resume performance hereunder. Each Party agrees to give the other Party prompt written notice of the occurrence of any such condition, the nature thereof, and the extent to which the affected Party will be unable to perform its obligations hereunder. Each Party further agrees to use all reasonable efforts to correct the condition as quickly as possible and to give the other Party prompt written notice when it is again fully able to perform its obligations.
- **22.4 Further Actions**. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be reasonably necessary or appropriate in order to carry out the purposes and intent of this Agreement.

22.5 Notices. All notices hereunder shall be in writing (including telecopy) and shall be deemed given if delivered personally or by registered or certified mail (return receipt requested), postage prepaid, or sent by express courier service with tracking service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided, that notices of a change of address shall be effective only upon receipt thereof), in case of a telecopy/fax at the following number (or at such other number for a Party as shall be specified by like notice):

If to CORONADO to: CORONADO BIOSCIENCES, INC.

15 New England Executive Park

Burlington, MA 01803

USA

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

President and CEO

Telecopy/Fax: +[******]

If to OVAMED to: OVAMED GMBH

Kiebitzhörn 31 22885 Barsbüttel

Germany

Attention: Mr. Alexander Beese and Mr. Detlev Goj,

Managing Directors

Telecopy/Fax: +[******]

If to FALK to: DR. FALK PHARMA GMBH

Leinenweberstraße 5 Postfach 6529 79041 Freiburg Germany

Attention: Mrs. Ursula Falk, Managing Director

Telecopy/Fax: +[******]

22.6 Waiver. Except as specifically provided for herein, the waiver from time to time by either of the Parties of any of their rights or their failure to exercise any remedy shall not operate or be construed as a continuing waiver of same or of any other of such Party's rights or remedies provided in this Agreement.

22.7 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable including but not limited to competition laws, then (a) the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition of this Agreement shall be valid and be enforced to the fullest extent permitted by law; and (b) the Parties hereto covenant and agree to renegotiate any such term, covenant or application thereof in good faith in order to provide a reasonably acceptable alternative to the term, covenant or condition of this Agreement or the application thereof that is invalid or unenforceable, it being the intent of the Parties that the basic purposes of this Agreement are to be effectuated.

22.8 Governing Law. This Agreement shall as far as legally possible be governed by and construed in accordance with the laws of Germany, without regard to principles of conflicts of law; *provided, however*, that The United Nations Convention on Contracts for the International Sale of Goods shall not apply in any action, suit or proceeding arising out of or relating to this Agreement.

- 22.9 Dispute Resolution and Jurisdiction.
- (a) The Parties recognize that disputes, controversies or claims arising out of or relating to this Agreement (each a "Dispute") may from time to time occur during the Term. It is the objective of the Parties to establish procedures to facilitate the resolution of Disputes in an expedient manner by mutual cooperation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this *Article 22.9* if and when a Dispute occurs. Disputes shall be first referred to the Steering Committee. If the Steering Committee is unable to resolve such Dispute within [*******] days of being requested by a Party to resolve the Dispute, the matter shall be presented to the Chief Executive Officers ("CEOs") of the concerned Parties for resolution. In the event that the CEOs cannot resolve the Dispute within [*******] days after it has been presented to them, the provisions of *Article 22.9(b)* shall be applicable.
- **(b)** Subject to the foregoing provisions of *Article 22.9(a)*, the Parties agree to the exclusive jurisdiction and venue of any court located in Frankfurt am Main, Germany, for purposes of any action arising out of or relating to this Agreement and agree that service of process in any such action may be made in the manner provided for in this Agreement for the delivery of notices.
- **22.10 Ambiguities**. Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- **22.11 Headings; References.** All headings are for reference purposes only and shall not in any way affect the meaning or interpretation of this Agreement. Any reference in this Agreement to an Article or Exhibit shall, unless otherwise specifically provided, be to an Article or Exhibit of this Agreement.
- **22.12 Counterparts.** This Agreement may be executed in three (3) or more counterparts, each of which shall be deemed an original, but all 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.
- 22.13 Entire Agreement and other Agreements. This Agreement, including all Exhibits attached hereto, which are hereby incorporated herein by reference, sets forth all the covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the subject matter hereof and all prior or contemporaneous understandings or agreements, whether written or oral, between the Parties with respect to such subject matter, including but not limited to the Mutual Non-Disclosure Agreement and Terms of Agreement, are hereby superseded in their entirety from and after the Effective Date. However, the OVAMED FALK License and the OVAMED CORONADO Agreements and all other agreements entered into between only two of the Parties of this Agreement or between Parties of this Agreement and Third Parties shall remain unaffected and, except as specifically set forth herein, no term of this Agreement shall alter any term of such other agreements.

- **22.14 Modifications.** This Agreement may not be amended except by a separate written instrument specifically referencing this Agreement which is executed by all Parties. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties.
- **22.15 No Third Party Beneficiary**. Except as expressly provided herein, this Agreement shall not confer any rights or remedies upon any Third Party other than the Parties and their respective successors and permitted assigns.
- **22.16 Independent Contractors.** It is expressly agreed that except as specifically set forth herein, the Parties shall be independent contractors and that the relationship among the Parties shall not constitute a partnership, joint venture or agency. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on another Party, without the prior consent of such other Party.

[This space is intentionally left blank.]

IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the date and year first above written.

CORONADO BIOSCIENCES, INC.

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

Name: Bobby W. Sandage, Jr.

Title: President & CEO

OVAMED GMBH

 Name:
 Alexander Beese
 Name:
 Detlev Goj

 Title:
 Managing Director
 Title:
 Managing Director

/s/ Detlev Goj

By:

DR. FALK PHARMA GMBH

/s/ Ursula Falk

/s/ Alexander Beese

By:

By:

Name: Ursula Falk
Title: Managing Director

$\frac{Exhibit\ 1}{\text{to the Collaboration Agreement between Coronado, Ovamed and Falk}}$ to the Collaboration Agreement between Coronado, Ovamed and Falk - FALK Territory -

Austria

Belarus

Belgium

Czech Republic

Denmark

Estonia

Finland

France

Greece

Hungary

Iceland

Ireland

Italy

Latvia

Lithuania

Luxembourg

Republic of Macedonia

Netherlands

Norway

Poland

Portugal

Romania

Russia

Slovak Republic

Slovenia

Spain

Sweden

Switzerland

Turkey

Ukraine

United Kingdom

+ Germany and FALK's right of first refusal in the Territory II as defined in Art. 19 of the OVAMED FALK License, with the exception of the CORONADO Territory.

End of Exhibit 1

$\frac{Exhibit\ 2}{\text{to the Collaboration Agreement between Coronado, Ovamed and Falk}}$ - CORONADO Territory -

North America South America Japan

End of Exhibit 2

Exhibit 3

to the Collaboration Agreement between Coronado, Ovamed and Falk - Initial Steering Committee Members -

Steering Committee Members of CORONADO

(1)	[******
	[******]
(3)	[******

Steering Committee Members of OVAMED

(1) [******] (2) [******] (3) [******]

Steering Committee Members of FALK

(1) [******] (2) [******] (3) [******]

End of Exhibit 3

Coronado Biosciences Signs Collaboration Agreement with Dr. Falk Pharma and OvaMed for the Development of TSO for Crohn's Disease

Burlington, MA – March 22, 2012 – Coronado Biosciences, Inc. (NASDAQ: CNDO), a biopharmaceutical company focused on the development of novel immunotherapy agents for the treatment of autoimmune diseases and cancer, today announced that the Company signed a Collaboration Agreement with Dr. Falk Pharma GmbH (Falk) and OvaMed GmbH (OvaMed) for the development of TSO (*Trichuris suis* ova or CNDO-201) for Crohn's disease. On December 22, 2011, Coronado announced the execution of a binding Terms of Agreement with respect to this collaboration.

Under the Collaboration Agreement, Falk granted Coronado exclusive rights and licenses under certain Falk patent rights, pre-clinical data and clinical data from Falk's clinical trials of TSO in Crohn's disease, including an ongoing Phase 2 clinical trial, for use in North America, South America and Japan. Coronado granted Falk exclusive rights and licenses to data from Coronado's clinical trials of TSO in Crohn's disease for use in Europe. Under the agreement, Coronado agreed to pay Falk a total of €5 million after receipt of certain pre-clinical and clinical data, all of which is estimated to be paid within 12 months, and a royalty of 1% of net sales of TSO.

Coronado has licensed TSO, a novel, orally administered, natural immunomodulator that regulates T-Cells and inflammatory cytokines, from OvaMed, the manufacturer of the product, in North America, South America and Japan. Falk has licensed TSO from OvaMed for gastroenterology indications in Europe. A Steering Committee comprised of Coronado, Falk and OvaMed representatives is overseeing the clinical development program for Crohn's disease, under which Coronado and Falk will each be responsible for clinical testing on approximately 50% of the total number of patients required for regulatory approval of TSO for Crohn's disease in the United States and Europe and will share in certain pre-clinical development costs.

Falk is currently conducting a Phase 2 double-blind, randomized, placebo-controlled, multi-center trial in Europe evaluating the efficacy and safety of three different dosages of TSO in Crohn's disease. This trial is expected to enroll over 200 patients. An independent data safety monitoring committee will conduct an interim analysis of clinical data early in the second quarter of 2012 and will communicate their findings to Falk in the form of a blinded recommendation regarding the study. Coronado expects to commence its Phase 2 clinical trial in Crohn's disease in the second quarter of 2012.

About TSO

TSO, the microscopic eggs of the porcine whipworm, is a novel, orally administered, natural immunomodulator that regulates T-Cells and inflammatory cytokines. The use of TSO as a therapeutic is based on the "hygiene hypothesis" and numerous animal and human studies. TSO was chosen as the biological agent of choice because it is not a human pathogen and is spontaneously eliminated from the body within several weeks after dosing.

The Company recently reported positive results from a Phase 1 clinical study of TSO in patients with Crohn's disease, where TSO was shown to be safe and well tolerated. The Phase 1 trial was a multi-center, sequential dose, dose-escalation, double-blind, placebo-controlled study of 36 patients with Crohn's disease.

Multiple investigator-sponsored clinical trials of TSO for the treatment of Crohn's disease, ulcerative colitis and multiple sclerosis have been completed in which TSO demonstrated benefit with regard to accepted outcome measurements of remission of disease and was shown to be well tolerated. TSO has demonstrated efficacy in two investigator initiated clinical trials for inflammatory bowel disease, one in Crohn's disease and one in ulcerative colitis. In an open-label clinical trial with 29 patients reported in *GUT* in January 2005, TSO was shown to induce clinical remission in over 72% of patients with Crohn's disease after 24 weeks of treatment using the Crohn's Disease Activity Index as the primary outcome variable. As reported in the *American Journal of Gastroenterology* in April 2005, in a double-blind, randomized placebo-controlled trial in 54 patients with ulcerative colitis, TSO was shown to produce statistically significantly more responders than those treated with placebo (43.3% vs. 16.7%, p=.04).

About Coronado Biosciences

Coronado Biosciences is engaged in the development of novel immunotherapy biologic agents. The Company's two principal pharmaceutical product candidates in clinical development are: TSO (*Trichuris suis* ova or CNDO-201), a biologic for the treatment of autoimmune diseases, such as Crohn's disease, ulcerative colitis and multiple sclerosis; and CNDO-109, a biologic that activates natural killer (NK) cells, for the treatment of acute myeloid leukemia (AML) and solid tumors. For more information, please visit www.coronadobiosciences.com.

Forward-Looking Statements

This press release may contain "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. Such statements include, but are not limited to, any statements relating to the Company's product development programs and any other statements that are not historical facts. Forward-looking statements are based on management's current expectations and are subject to risks and uncertainties that could negatively affect our business, operating results, financial condition and stock price. Factors that could cause actual results to differ materially from those currently anticipated risks relating to the results of research and development activities, uncertainties relating to preclinical and clinical testing, financing and strategic agreements and relationships, the early stage of products under development, our need for substantial additional funds, government regulation, patent and intellectual property matters; our dependence on third party suppliers and competition, as well as other risks described in our SEC filings. We expressly

disclaim any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in our expectations or any changes in events, conditions or circumstances on which any such statement is based, except as required by law.

Contact Information:

Investor Relations

Lucy Lu, MD, Executive Vice President & Chief Financial Officer Coronado Biosciences, Inc. 781-238-6619; ir@coronadobio.com

Marcy Nanus, Vice President The Trout Group, LLC. 646-378-2927; mnanus@troutgroup.com

Media Relations

Dennis S. Dobson Jr., CEO Dobson Media Group 203-258-0159; dobsonpr@erols.com