

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
WASHINGTON, D.C. 20549**

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**FORM 8-K**

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**CURRENT REPORT**

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

**Date of Report (Date of earliest event reported): December 19, 2011**

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**Coronado Biosciences, Inc.**

**(Exact name of registrant as specified in charter)**

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**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)**

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Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of registrant under any of the 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))

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**Item 1.01 Entry into a Material Definitive Agreement**

On December 22, 2011, Coronado Biosciences, Inc. (the “Company”) announced that it has entered into a binding Terms of Agreement (the “Agreement”) with OvaMed GmbH (“OvaMed”) and Dr. Falk Pharma GmbH (“Falk”). The purposes of the Agreement were to set forth the general agreements with respect to a collaboration by and among the Company, OvaMed and Falk and provide the framework for a collaboration agreement to be entered into by the parties. The Agreement and the press release are attached as Exhibits 10.32 and 99.1, respectively, to this Current Report on Form 8-K and are incorporated by reference herein.

**Item 5.02 Departure of Directors or Certain Officers; Election of Directors, Appointment of Certain Officers; Compensatory Arrangement of Certain Officers**

On December 19, 2011, the Company and its president and chief executive officer, Bobby W. Sandage, Jr., Ph.D., entered into an amendment to Dr. Sandage’s employment agreement which revised the terms of certain contingent payments to Dr. Sandage. This amendment is attached as Exhibit 10.33 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 8.01 Other Events**

On November 15, 2011, the Company entered into a Side Agreement with OvaMed and the University of Iowa Research Foundation (“UIRF”), pursuant to which the parties amended or restated certain provisions of the existing exclusive license agreement between UIRF and OvaMed and the exclusive sublicense agreement between OvaMed and the Company. The Side Agreement is attached as Exhibit 10.34 to this Current Report on Form 8-K and is incorporated by reference herein.

**Item 9.01 Financial Statements and Exhibits****(d) Exhibits**

10.32	Terms of Agreement among the Company, OvaMed and Falk effective as of December 22, 2011
10.33	Amendment to Employment Agreement between the Company and Bobby W. Sandage, Jr., Ph.D. effective as of December 19, 2011
10.34	Side Agreement among the Company, UIRF and OvaMed effective as of November 15, 2011
99.1	Press Release dated December 22, 2011

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**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: December 22, 2011

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Exhibit Index

<u>Exhibit No.</u>	<u>Description</u>
10.32	Terms of Agreement among the Company, OvaMed and Falk effective as of December 22, 2011
10.33	Amendment to Employment Agreement between the Company and Bobby W. Sandage, Jr., Ph.D. effective as of December 19, 2011
10.34	Side Agreement among the Company, UIRF and OvaMed effective as of November 15, 2011
99.1	Press Release dated December 22, 2011

## Execution Copy

## TERMS OF AGREEMENT

The purposes of this Terms of Agreement, effective as of December 22, 2011 (“Effective Date”) are to (i) set forth the general agreements with respect to a collaboration and associated transactions by and among Coronado Biosciences, Inc., having a principal place of business at 15 New England Executive Park, Burlington, MA 01803, USA (“Coronado”), OvaMed GmbH, having a principal place of business at Kiebitzhörn 31, 22885 Barsbüttel, Germany (“OvaMed”), and Dr. Falk Pharma GmbH, having a principal place of business at Leinenweberstrasse 5, Postfach 6529, 79108, Freiburg, Germany (“Falk”); and (ii) provide the framework for a collaboration agreement to be entered into by and among Coronado, OvaMed and Falk incorporating the agreements set forth in this Terms of Agreement and such other customary terms and conditions consistent with comparable agreements in the industry (the “Collaboration Agreement”). Each of Coronado, OvaMed and Falk may be referred to individually as a “Party” and collectively as the “Parties.” All capitalized terms not otherwise defined herein have the meanings set forth in **Appendix A** to this Terms of Agreement.

**1. Pre-Clinical Know-How and Patent Rights License; Data Delivery**

- a. Falk will grant Coronado an exclusive license to use the Pre-Clinical Know-How and under the Patent Rights to develop, use, have made by OvaMed, and commercialize and sell Product in the Coronado Territory and, subject to Paragraph 1b below, will disclose to Coronado all Pre-Clinical Know-How as soon as such Pre-Clinical Know-How becomes available.
- b. Within ten (10) Business Days after execution of the Collaboration Agreement, Falk will deliver the Pre-Clinical Know-How set forth on **Appendix D** to Coronado. Falk shall permit Coronado to access and consents to Coronado’s reference and use of the Pre-Clinical Know-How in connection with any Regulatory Filing in the Coronado Territory.

**2. Consideration for Patent Rights and Pre-Clinical Know-How License:**

- a. Coronado will pay Falk a license fee aggregating five million euros (€5 million), payable as follows:
  1. One million euros (€1 million) payable five (5) Business Days after Coronado’s receipt of the Pre-Clinical Know-How in accordance with Paragraph 1b above;
  2. One million five hundred thousand euros (€1,500,000) payable five (5) Business Days after Coronado’s receipt of the recommendation of the independent data monitoring committee from the current FALK Phase 2 clinical trial evaluating Product in Crohn’s disease (the “Falk Phase 2 Trial”) based on the interim Clinical Data (blinded for Falk) independent from the results of the Falk Phase 2 Trial; and
  3. Two million five hundred thousand euros (€2,500,000) payable five (5) Business Days after Coronado’s receipt of the final written Clinical Study Report of the Falk Phase 2 Trial, independent from the results of the Falk Phase 2 Trial.

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- b. Coronado will pay Falk royalties equal to one percent (1%) of Net Sales of Product in the Coronado Territory.
  - c. 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 Terms of Agreement or the Collaboration Agreement.
3. **Cross-Licenses and Data Sharing:** Each of Falk and Coronado as sublicensees of OvaMed are obliged to use commercially reasonable efforts under the terms of the OvaMed/Falk License and the OvaMed/Coronado License, respectively, and (i) intend to develop and commercialize Product for Crohn's disease in the Falk Territory and the Coronado Territory, respectively; (ii) currently anticipate that Initial Regulatory Approval in each of Europe and the United States will require clinical testing of Product; and (iii) desire to collaborate and cooperate with each other in good faith in connection with such development, and to coordinate with OvaMed issues relating to Product manufacturing. To facilitate such collaboration and cooperation, the Parties agree as follows:
- a. Falk (i) will grant Coronado an exclusive license to and under Clinical Data owned or controlled by Falk to develop, have made by OvaMed, use, import, sell and commercialize Product for Crohn's disease in the Coronado Territory; and (ii) consents to Coronado's right of reference and use of Clinical Data owned or controlled by Falk in connection with Coronado's Regulatory Filings in the Coronado Territory.
  - b. Coronado (i) will grant Falk and OvaMed an exclusive license to and under Clinical Data owned or controlled by Coronado to develop, have made by OvaMed, use, import, sell and commercialize Product for Crohn's disease in the Falk Territory; and (ii) consents to Falk's right of reference and use of Clinical Data owned or controlled by Coronado in connection with Falk's Regulatory Filings in the Falk Territory.
  - c. Falk and Coronado will disclose to each other all Clinical Data, including interim Clinical Data, as soon as such Clinical Data becomes available.
  - d. The Parties will exchange 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, including a separate pharmacovigilance agreement among the Parties.
  - e. Each Party shall submit to each other Party all CMC information related to the Product as soon as such CMC data becomes available. Each of Falk and Coronado shall have the right to access, and each Party consents to Falk's and Coronado's reference and use of such CMC data, in connection with any Regulatory Filing in the Falk Territory or the Coronado Territory, as applicable.
  - f. The rights and obligations of OvaMed with respect to Pre-Clinical Know-How, Clinical Data, and Patent Rights shall be subject to the OvaMed/Falk License and the OvaMed/Coronado License. OvaMed consents and agrees to all rights and licenses granted to Falk and to Coronado as contemplated by this Terms of Agreement.
  - g. Except as otherwise specifically agreed, each of Falk and Coronado will retain their respective rights and responsibilities relating to the development and marketing of Product in the Falk Territory and the Coronado Territory, respectively.

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4. **Steering Committee.** The Parties will establish a Steering Committee comprised of three representatives of each Party, to function as a forum for the Parties to inform and consult with one another concerning development of Product for Crohn's disease. The responsibilities of the Steering Committee will include the following:
- a. Oversee development, including review of draft study protocols for clinical trials, with the goal of coordinating global development of Product for Crohn's disease such that Falk and Coronado are each responsible for clinical testing of Product on approximately 50% of the aggregate number of patients required for Initial Regulatory Approval in the United States and Europe;
  - b. Facilitate the exchange of Pre-Clinical Know-How, 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;
  - 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 related to the development of the Product in their respective territories, will retain final decision-making authority according to the OvaMed/Falk License and the OvaMed/Coronado License with respect to development of Product in the Falk Territory and the Coronado Territory, respectively.
5. **Release and Discharge.** Each Party shall release and forever discharge all 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 to date and arising out of or related to the disclosure and/or use, as contemplated by this Terms of Agreement, or any refusal to such disclosure or refusal of such use, of the 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.
6. **Binding Effect, Governing Law and Signatures**
- a. The Parties intend and agree to commence good faith negotiations to enter into the Collaboration Agreement as soon as practicable after the Effective Date and to execute the Collaboration Agreement on or before January 31, 2012. Notwithstanding the foregoing, the Parties intend and agree to memorialize in this Terms of Agreement the general agreements of the Parties with respect to the subject matter contained herein in view of the time required to finalize the Collaboration Agreement and desire to expedite development of Product. Accordingly, by execution hereof, each Party hereto acknowledges and agrees that this Terms of Agreement and the rights and obligations hereunder constitute valid and legally binding agreements of such Party in accordance with the terms hereof.
  - b. This Terms of Agreement shall be governed by the laws of the Republic of Germany, without regard to principles of conflicts of law.

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- c. This Terms of Agreement may be executed in counterparts, each of which shall be deemed an original, but each of which together shall constitute one and the same instrument. Signatures to this Terms of 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 Terms of Agreement shall have the same effect as physical delivery of the paper document bearing an original signature.

**Coronado Biosciences, Inc.**

By: /s/ Bobby W. Sandage, Jr.  
Name: Bobby W. Sandage, Jr., Ph.D  
Title: President and CEO

**OvaMed GmbH**

By: /s/ Alexander Beese  
Name: Alexander Beese  
Title: Managing Director

By: /s/ Detlev Goj  
Name: Detlev Goj  
Title: Director

**Dr. Falk Pharma GmbH**

By: /s/ Roland Greinwald  
Name: Roland Greinwald  
Title: Head R & D

By: /s/ Rolf-Dieter Stocklin  
Name: Rolf-Dieter Stocklin  
Title: Head Admin/CFO



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**Appendix A  
to Terms of Agreement  
Definitions**

**Clinical Data:** 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 case report forms, electronic databases, and clinical study reports or summaries.

**CMC:** chemistry, manufacturing and controls.

**Coronado Territory:** the countries and jurisdictions listed in **Appendix B**.

**Falk Territory:** Germany and the countries listed in **Appendix C**.

**Initial Regulatory Approval:** the first authorization or approval of a Marketing Authorization Application or New Drug Application, as applicable, for Product for Crohn's disease by the European Commission and the U.S. Food and Drug Administration ("FDA"), respectively.

**Net Sales:** Net Sales as defined in Section 1.6 of the OvaMed/Coronado License.

**OvaMed/Coronado License:** the Exclusive Sublicense Agreement dated December 12, 2005 by and between OvaMed and Coronado (as successor to Collingwood Pharmaceuticals, Inc.), as amended to date and from time to time during the term of the Collaboration Agreement.

**OvaMed/Falk License:** the Exclusive Sublicense Agreement dated January 9, 2004 by and between OvaMed and Falk, as amended to date and from time to time during the term of the Collaboration Agreement.

**Patent Rights:** Falk's rights in the following: (a) U.S. Patent Application Nos. 12/594,074 and 12/993,517 related to the Product; (b) patents issuing thereon or reissues thereof; (c) any divisional, continuation in part, continuation and reexamination applications, and extensions related to any of the foregoing; and (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, in each case in the Coronado Territory.

**Pre-Clinical Know How:** all research data, pre-clinical data, including pharmacology and toxicology data, CMC data, stability and analytical testing data related to the Product and owned or controlled by Falk, including all data and documentation submitted to regulatory authorities in association with an IND or comparable application to conduct clinical trials with Product, including the Investigational Medicinal Product Dossier (IMPD) submitted by Falk to the German Federal Institute for Drugs and Medical Devices.

**Product:** any pharmaceutical composition containing *Trichuris suis* ova (TSO) incorporated into any formulation or delivery system.

**Regulatory Filing:** any submission, filing or application with any regulatory authority (including, in the U.S., the FDA, and in Europe, the European Medicines Agency (EMA) required to obtain authorization to conduct clinical trials with Product or authorization and approval to market Product in the Coronado Territory or the Falk Territory, as applicable.

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**Appendix B**  
**to Terms of Agreement**  
**Coronado Territory**

North America  
South America  
Japan

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**Appendix C**  
**to Terms of Agreement**  
**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

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+ 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.

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**Appendix D**  
**to Terms of Agreement**

Investigational Medicinal Product Dossier (IMPD) submitted by Falk to the German Federal Institute for Drugs and Medical Devices

Reports mentioned in the IMPD

Updates of such reports

## AMENDMENT NO. 1 TO AGREEMENT

**THIS AMENDMENT NO. 1 TO EMPLOYMENT AGREEMENT** (this “**Amendment**”), effective as of December 19, 2011 (the “**Amendment Effective Date**”), is entered into by and between Coronado Biosciences, Inc., a Delaware corporation with an office at 15 New England Executive Park, Burlington, MA 01803 (“**Company**”), and Bobby W. Sandage, Jr., Ph.D. (the “**Executive**”). Company and Executive are each sometimes referred to herein as a “**Party**” and collectively referred to herein as the “**Parties**”.

## WITNESSETH:

**WHEREAS**, the Parties entered into an Employment Agreement effective as of March 30, 2011 (the “**Agreement**”);

**WHEREAS**, the Parties mutually desire to amend the Agreement on the terms and conditions set forth in this Amendment.

**NOW, THEREFORE**, in consideration of the foregoing and the mutual agreements and covenants herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereby agree as follows:

1. **Definitions and References.** Except as set forth herein, capitalized terms not otherwise defined or amended in this Amendment shall have the meaning ascribed to them in the Agreement.

2. **Amendments to the Agreement.** Effective as of the Amendment Effective Date, Section 3.3 (i) of the Agreement is hereby amended and restated in its entirety to read as follows:

“(i) Subject to Executive’s continued employment, upon (or as soon as administratively practicable following) the Board’s (or a duly-authorized committee’s) determination that the Market Capitalization (as defined below) of the Company has, for the first time, exceeded One Hundred Twenty-Five Million Dollars (\$125,000,000) for a period of thirty (30) consecutive trading days during the Term and the average trading volume of the Company’s common stock (the “*Common Stock*”) during such period is at least Fifty Thousand (50,000) shares per trading day (the “*First Capitalization Milestone*”), then the Company shall pay to the Executive a one time cash bonus of One Hundred Thirty Seven Thousand, Five Hundred Dollars (\$137,500), subject to standard payroll deductions and withholdings.”

3. **Other.**

(a) **Effect of Amendment.** From and after the Amendment Effective Date, all references to the Agreement shall mean the Agreement as amended by this Amendment.

(b) **Counterparts.** This Amendment may be executed in two 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 Amendment 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 Amendment shall have the same effect as physical delivery of the paper document bearing original signature.

(c) **Entire Amendment.** This Amendment contains the entire understanding of the Parties with respect to the subject matter of this Amendment. All express or implied agreements and understandings, either oral or written, made on or before the Amendment Effective Date, with respect to the subject matter of this Amendment are expressly superseded by this Amendment. This Amendment may be amended, or any term hereof modified, only by a written instrument executed by all Parties.

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**IN WITNESS WHEREOF**, the Parties have executed this Amendment as of the Amendment Effective Date.

**Coronado Biosciences, Inc.**

By: /s/ Dale Ritter

Name: Dale Ritter

Title: Senior Vice President, Finance, Chief  
Accounting Officer

**Executive:**

/s/ Bobby W. Sandage, Jr.

Bobby W. Sandage, Jr., Ph.D

## Execution Copy

**SIDE AGREEMENT**

Reference is made to the (i) Exclusive License Agreement dated December 8, 2005 (the “**License Agreement**”) by and between the University of Iowa Research Foundation (“**UIRF**”) and OvaMed GmbH (“**OvaMed**” or “**LICENSEE**”), and (ii) exclusive Sublicense Agreement dated December 12, 2005, as amended (the “**Sublicense Agreement**”) by and between OvaMed and Coronado Biosciences, Inc., as successor to Asphelia Pharmaceuticals, Inc. (“**Asphelia**”) and Collingwood Pharmaceuticals, Inc. (“**Coronado**”).

WHEREAS, in connection with Coronado’s acquisition of certain assets of Asphelia in January 2011, Asphelia assigned to Coronado and Coronado assumed certain rights and obligations of Asphelia under the Sublicense Agreement and the Manufacturing and Supply Agreement effective March 29, 2006, as amended, between OvaMed and Asphelia (the “**MSA**”); and

WHEREAS, UIRF, OvaMed and Coronado (sometimes collectively referred to herein as the “**Parties**”) desire to clarify, amend or restate certain provisions of the License Agreement to reflect the current intentions of the Parties with respect to such agreement and to avoid any potential disputes under the License Agreement, and to provide for certain additional agreements of the Parties related to certain matters under the License Agreement and the Sublicense Agreement.

In view of the foregoing and for other good and valuable consideration, the adequacy and receipt of which are hereby acknowledged, effective as of November 15, 2011 (the “**Effective Date**”) the Parties hereby agree as follows:

1. **Definitions and References.** Except as set forth or amended herein, (a) capitalized terms used herein shall have the meaning ascribed to them in the License Agreement; and (b) references herein to Sections or Articles are to the same with all their subparts as they appear in the License Agreement.

2. **Coronado as Sublicensee.** Effective as of the Effective Date, the License Agreement is hereby amended as follows: all references therein to “Collingwood Pharmaceuticals, Inc.” “Collingwood”, “Asphelia Pharmaceuticals, Inc.” and/or “Asphelia” shall be changed to and construed as “Coronado Biosciences, Inc.” or “Coronado”, respectively, *mutatis mutandis*. The Parties acknowledge and confirm Coronado’s designation as SUBLICENSEE under the License Agreement.

3. **Amendments to License Agreement.** Effective as of the Effective Date, the License Agreement is hereby amended as set forth in this Paragraph 3:

(a) To clarify the definition of PATENT RIGHTS, the last sentence of Section 1.1 is hereby deleted in its entirety.

(b) To clarify the exclusive nature of the license granted under the License Agreement, the first sentence of Section 2.1 is hereby amended to delete the words “a license” and to replace such words with the words “an exclusive license”.



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(c) To amend, clarify and conform certain diligence and reporting obligations:

(i) The first paragraph of Section 2.3(e) is hereby amended and restated to read in its entirety as follows:

“(e) LICENSEE shall use commercially reasonable efforts to (i) submit an IND to the FDA before July 31, 2012; (ii) commence a Phase 1 clinical trial with respect to a Licensed Product by January 1, 2013; (iii) commence a Phase 2 clinical trial with respect to a LICENSED PRODUCT by June 30, 2014; and (iv) submit an application for regulatory approval of LICENSED PRODUCT to the FDA within 16 months after successful completion of all testing and studies required by the FDA as a condition to or in connection with obtaining regulatory approval of LICENSED PRODUCT in the United States (each, an “Article 2.3 Milestone”); *provided, however*, that an Article 2.3 Milestone may be achieved or satisfied by SUBLICENSEE”.

(ii) The second paragraph of Section 2.3(e) is hereby amended to delete therefrom in each instance the words “Article 2.4 Milestone” and replace such words with the words “Article 2.3 Milestone”.

(iii) Section 4.1 is hereby amended to (A) insert the following sentence immediately prior to the last sentence thereof: “Notwithstanding the foregoing, subsequent to the filing of an IND, such annual reports may instead be provided within sixty (60) days after the submission to the FDA of the annual report in connection with the periodic reporting requirement for the IND and may be in form and substance similar to development plans employed by LICENSEE in the ordinary course of its business” and (B) delete therefrom in each instance the words “Section 2.4 (e)” and replace such words with the words “Section 2.3 (e)”.

(d) A new Section 4.3 is hereby added immediately following Section 4.2 to read in its entirety as follows:

“4.3 Purposely Omitted”

(e) The following new Section 9.11 is hereby added immediately following Section 9.10:

“9.11 In the event of a breach or default by LICENSEE in a particular country or jurisdiction in the TERRITORY which breach or default would give UIRF the right, pursuant to the provisions of this Agreement, to terminate this Agreement, such right shall, notwithstanding such provisions, be limited to a right to terminate this Agreement solely with respect to the particular country or jurisdiction to which the breach or default relates. In the event of a breach or default or termination of this Agreement in a particular country or jurisdiction in accordance with the foregoing sentence, the rights and obligations relating to or arising from such breach, default or termination shall be applicable to the country or jurisdiction to which the breach, default or termination relates.”

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#### 4. Additional Agreements among the Parties.

(a) Coronado and OvaMed hereby agree that, provided OvaMed has not breached its obligations under the Sublicense Agreement or the MSA, Coronado agrees to be bound by the terms of Section 2.3(e) of the License Agreement, as amended by this Amendment, to the extent applicable to the Territory (as defined in the Sublicense Agreement) and Coronado's rights under the Sublicense Agreement.

(b) In satisfaction of and in accordance with the provisions of Section 9.5, the License Agreement shall be assigned to Coronado as SUBLICENSEE upon termination of the License Agreement and UIRF shall accept and honor such assignment.

(c) Subject to the provisions of this Paragraph 4(), in the event of any breach or default by LICENSEE under the License Agreement which breach or default gives UIRF the right to terminate the License Agreement (in its entirety or, in accordance with Section 9.11, in a particular country or jurisdiction), the following shall be applicable:

(i) UIRF shall provide Coronado with written notice of such breach (and, as applicable, failure to cure such breach or intent to terminate), in addition to any notice thereof provided to LICENSEE, which notice shall disclose the nature and amount of the breach;

(ii) If the breach is of a curable obligation, Coronado shall have the right, but not the obligation, to cure such breach within sixty (60) days after receiving such written notice if the breach relates to a payment obligation or within ninety (90) days after receiving such written notice if the breach relates to any other material obligation; provided that if Coronado cures such breach within the applicable periods, (A) any payments by Coronado to UIRF to cure such breach shall discharge the related payment obligation LICENSEE may have had to UIRF; (B) Coronado may, but shall not be obligated to, make future payments required to be made by LICENSEE to UIRF under the License Agreement directly to UIRF; (C) OvaMed shall reimburse Coronado for any such payments made by Coronado to UIRF and any other costs associated with curing such breach (or, at Coronado's option, Coronado shall be permitted to set off such payments and costs against amounts payable by Coronado to OvaMed under the Sublicense Agreement or the Supply Agreement); and (D) UIRF shall not have the right to terminate the License Agreement as a result of such breach; and

(iii) If the breach is of a non-curable obligation, and Coronado has not caused such LICENSEE breach (it being understood that Coronado will not be deemed to have caused such breach if OvaMed has breached its obligations to Coronado under the Sublicense Agreement or the MSA), Coronado shall have the right, but not the obligation, to have the License Agreement survive, provided that from and after any such election by Coronado, (A) LICENSEE's rights, licenses and obligations in the License Agreement shall be deemed assigned to and assumed by Coronado on the same terms and conditions as set forth in the License Agreement; (B) all references to LICENSEE in the License Agreement shall be construed as Coronado; and (C) UIRF shall not have the right to terminate the License Agreement as a result of such breach.

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**5. Validity of License Agreement.** The License Agreement is valid and in full force and effect in accordance with its terms and there are no breaches, defaults in the performance of any obligation thereunder, or other acts or events which would (with or without notice, the passage of time, or both) constitute a breach or default or otherwise give rise to any right by UIRF to terminate or render non-exclusive the License Agreement. From and after the Effective Date, all references to the License Agreement shall mean the License Agreement as amended or supplemented by this Side Agreement.

**6. Miscellaneous.**

(a) Notices provided hereunder to be given by a Party to any other Party shall be in writing and shall be sent by fax or email (and confirmed by personal delivery, registered or certified mail or overnight courier), or delivered by recognized overnight delivery service or sent by government mail service (certified or registered air mail) to the following respective addresses or to such other addresses as the Parties may hereafter communicate to each other in writing:

If to Coronado:

Coronado Biosciences, Inc.  
15 New England Executive Park  
Burlington, MA 01803, USA  
Attention: Chief Executive Officer  
Fax No.: 781-459-7788

If to OvaMed:

OvaMed GmbH.  
Kiebitzhörn 31  
22885 Barsbüttel, Germany  
Attention: Chief Executive Officer  
Fax No.: +49 40 675 095 58

If to UIRF:

University of Iowa Research Foundation  
214 Technology Innovation Center  
Iowa City, Iowa 52242-5000, USA  
Attention: Executive Director  
Fax No: 319-335-4486

(b) This Side Agreement may be executed in two 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 Side 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 Side Agreement shall have the same effect as physical delivery of the paper document bearing an original signature.

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IN WITNESS WHEREOF, the Parties have executed this Side Agreement as of the Effective Date.

UNIVERSITY OF IOWA RESEARCH  
FOUNDATION

BY: /s/ Zev Sunleaf

NAME: Zev Sunleaf

TITLE: Interim Executive Director

CORONADO BIOSCIENCES, INC.

BY: /s/ Bobby W. Sandage, Jr., Ph.D

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

TITLE: President and Chief Executive Officer

OVAMED GMBH

BY: /s/ Detlev Goj

NAME: Detlev Goj

TITLE: Director

BY: /s/ Alexander Beese

NAME: Alexander Beese

TITLE: Director

**Coronado Biosciences Signs Binding Terms of Agreement to enter into Collaboration for Development of CNDO-201 for Crohn's disease with Dr. Falk Pharma and OvaMed**

Burlington, MA – December 22, 2011 – 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 a binding Terms of Agreement with Dr. Falk Pharma GmbH and OvaMed GmbH to collaborate in the development of CNDO-201, or *Trichuris suis ova* (TSO), for Crohn's disease.

Under the Terms of Agreement, Coronado, Falk and OvaMed have agreed to enter into a Collaboration Agreement under which Falk will grant 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 II clinical trial, for use in North America, South America and Japan. Coronado will grant Falk exclusive rights and licenses to Company data from planned clinical trials of TSO in Crohn's disease for use in Europe. Under the agreement, Coronado will pay Falk a total of €5 million during 2012 and a royalty of 1% of net sales of TSO.

Coronado and Falk have each licensed TSO, a novel, orally administered, natural immunomodulator that regulates T-Cells and inflammatory cytokines, from OvaMed, the manufacturer of the product, in their respective territories. A Steering Committee comprised of Coronado, Falk and OvaMed representatives will oversee the development program, 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. Coronado expects to finalize the Collaboration Agreement in the first quarter of 2012.

"We are very pleased to have signed this binding Terms of Agreement and we look forward to working together in the development of TSO for Crohn's disease, an area of high unmet medical need," said Bobby W. Sandage, Jr., Ph.D., Coronado's President and CEO. "This collaboration will significantly accelerate the development and reduce the overall costs to Coronado of the TSO development program for Crohn's disease. Further, we are very pleased to be working with Dr. Falk Pharma, a company with substantial expertise in the development and marketing of products used in hepatology and gastroenterology, and continuing our collaboration with OvaMed, the manufacturer of TSO. As a result of this collaboration, Coronado will advance to a mid-Phase II company, as we expect to have Phase II clinical data before the end of 2012 from Falk's ongoing European trial and expect to commence our Phase II clinical trial in Crohn's disease in the first half of 2012."

Dr. Falk Pharma is currently conducting a Phase II 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 and results are expected in the second half of 2012.

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#### About CNDO-201

CNDO-201 is Coronado Biosciences' designation for our immunomodulator, *Trichuris suis* ova (TSO), the microscopic eggs of a parasitic helminth also known as the pig whipworm. The use of TSO as a therapeutic immunomodulator 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.

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 clinical trials for inflammatory bowel disease, one in Crohn's disease and a second trial in ulcerative colitis. In an open-label clinical trial 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 *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: 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](http://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

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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.

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