# 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 of 1934

Date of report (Date of earliest event reported): February 10, 2015

# ADVAXIS, INC.

(Exact Name of Registrant as Specified in Charter)

Delaware

(State or Other Jurisdiction of Incorporation) 000-28489 (Commission

File Number)

02-0563870

(IRS Employer Identification No.)

305 College Road East Princeton, New Jersey, 08540

(Address of Principal Executive Offices)

(609) 452-9813

(Registrant's telephone number, including area code)

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

[] Written communications pursuant to Rule 425 under the Securities Act.

[] Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

[] Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act.

[] Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

# Item 1.01. Entry into a Material Definitive Agreement.

On February 10, 2015, Advaxis, Inc. (the "<u>Company</u>") entered into a Clinical Study Collaboration Agreement (the "Agreement") with Incyte Corporation ("<u>Incyte</u>") for the development and analysis of a combination therapy for the treatment of cervical cancer (the "<u>Study</u>"). The Company and Incyte have to date been independently developing their respective compounds, which treat certain types of tumors, respectively.

Under the terms of the Agreement, Incyte and the Company will contribute their respective compounds to be dosed in combination during the course of the Study, with Incyte acting as the sponsor of the Study and taking the lead role in its conduct. The Agreement is to continue in full force and effect until completion of the Final Study Report (as defined therein) or until earlier terminated by either Party. Costs for the Study are to be split between the parties, and Incyte will provide the Company with an invoice and supporting documents of the Company's share of the costs incurred through the end of each calendar quarter. A copy of the Agreement is being filed as Exhibit 10.1 and is incorporated herein by reference.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits.

The following exhibit is filed as a part of this report

10.1 Clinical Study Collaboration Agreement between Advaxis, Inc. and Incyte Corporation, dated February 10, 2015.

# SIGNATURES

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

# ADVAXIS, INC. (Registrant)

By /s/ Daniel J. O'Connor

Daniel J. O'Connor President and Chief Executive Officer

Date: February 12, 2015

Exhibit Number	Description
10.1	Clinical Study Collaboration Agreement between Advaxis, Inc. and Incyte Corporation, dated February 10, 2015.

#### CLINICAL STUDY COLLABORATION AGREEMENT

THIS CLINICAL STUDY COLLABORATION AGREEMENT (the "Agreement") is entered into as of February 10, 2015 (the "Effective Date"), by and between INCYTE CORPORATION, a Delaware corporation with its offices at 1801 Augustine Cut-Off, Wilmington, DE 19803 ("Incyte"), and ADVAXIS, INC., a New Jersey corporation having a place of business at 305 College Road East, Princeton, NJ ("Advaxis"). Incyte and Advaxis may each be referred to herein individually as a "Party" or collectively, as the "Parties."

#### RECITALS

- A. WHEREAS, Incyte is developing the Incyte Compound (as defined below) for the treatment of certain tumor types.
- B. WHEREAS, Advaxis is developing the Advaxis Compound (as defined below) for the treatment of certain tumor types.
- C. WHEREAS, Incyte desires to sponsor a clinical trial in which the Incyte Compound and the Advaxis Compound would be dosed in combination.
- D. WHEREAS, Advaxis and Incyte, consistent with the terms of this Agreement, desire to collaborate as more fully described herein, including by providing the Advaxis Compound and the Incyte Compound for the Study (as defined below).

NOW, THEREFORE, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

#### 1. Definitions

For all purposes of this Agreement, the capitalized terms defined in this Article 1 and throughout this Agreement shall have the meanings herein specified:

- 1.1. **"Advaxis"** has the meaning set forth in the preamble.
- 1.2. "Advaxis Compound" means ADXS11-001 (also known as ADXS-HPV) which is a live, attenuated *Listeria monocytogenes* (*Lm*) based vector bioengineered to secrete a fusion peptide of truncated Listeriolysin O (tLLO)-human papillomavirus type 16 E7.
- 1.3. "Affiliate" means, with respect to either Party, a firm, corporation or other entity which directly or indirectly owns or controls said Party, or is owned or controlled by said Party, or is under common ownership or control with said Party. The word "control" means (i) the direct or indirect ownership of fifty percent (50%) or more of the outstanding voting securities of a legal entity, or (ii) possession, directly or indirectly, of the power to direct the management or policies of a legal entity, whether through the ownership of voting securities, contract rights, voting rights, corporate governance or otherwise.
- 1.4. "Agreement" means this agreement, as amended by the Parties from time to time, and as set forth in the preamble.

- 1.5. "Applicable Law" means all federal, state, local, national and regional statutes, laws, rules, regulations and directives applicable to a particular activity hereunder, including performance of clinical trials, medical treatment and the processing and protection of personal and medical data, that may be in effect from time to time, including those promulgated by the United States Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA") and any successor agency to the FDA or EMA or any agency or authority performing some or all of the functions of the FDA or EMA in any jurisdiction outside the United States or the European Union (each a "Regulatory Authority" and collectively, "Regulatory Authorities"), and including without limitation cGMP and GCP (each as defined below); all data protection requirements such as those specified in the EU Data Protection Directive and the regulations issued under the United States Health Insurance Portability and Accountability Act of 1996 ("HIPAA"); export control and economic sanctions regulations which prohibit the shipment of United States-origin products and technology to certain restricted countries, entities and individuals; anti-bribery and anti-corruption laws pertaining to interactions with government agents, officials and representatives; laws and regulations governing payments to healthcare providers; and any United States or other country's or jurisdiction's successor or replacement statutes, laws, rules, regulations and directives relating to the foregoing.
- 1.6. **Background Intellectual Property**" means, individually and collectively, all Intellectual Property Rights of any of the Parties in existence at any time prior to the Effective Date and not generated through the use of the Incyte Compound in combination with the Advaxis Compound in the course of performing the Study, provided to the other Party for use in, or which is necessary or useful for performing the Study. In the case of Advaxis, Background Intellectual Property shall include but is not limited to, rights in and to the Advaxis Compound and in and to any INDs relating to the Advaxis Compound. In the case of Incyte, Background Intellectual Property shall include but is not limited to, the rights in and to the Incyte Compound and in and to any INDs relating to the Incyte Compound.
- 1.7. **"Business Day**" means any day other than a Saturday, Sunday or any public holiday in the country where the applicable obligations are to be performed.
- 1.8. "Calendar Quarter" means a three-month period beginning on January, April, July or October 1st.
- 1.9. "Calendar Year" means a one-year period beginning on January 1st and ending on December 31st.
- 1.10. "**cGMP**" means the current Good Manufacturing Practices officially published and interpreted by EMA, FDA and other applicable Regulatory Authorities that may be in effect from time to time and are applicable to the Manufacture of the Compounds.
- 1.11. "Clinical Data" means all data (including raw data), records and results generated under the Study including Sample Testing Results.
- 1.12. "Clinical Quality Agreement" means that certain clinical quality agreement being entered into by the Parties within sixty (60) days of the Effective Date.
- 1.13. **"Collaboration Know-How"** has the meaning set forth in Section 10.1.1.
- 1.14. **"Compounds**" means the Incyte Compound and the Advaxis Compound. A "**Compound**" means either the Incyte Compound or the Advaxis Compound, as applicable.

- 1.15. "Combination" means the use or method of using the Incyte Compound and the Advaxis Compound in concomitant or sequential administration.
- 1.16. **"Confidential Information**" means any information, Know-How or other proprietary information or materials furnished to one Party by the other Party pursuant to this Agreement, except to the extent that it can be established by the receiving Party that such information or materials: (a) was already known to the receiving Party, other than under an obligation of confidentiality, at the time of disclosure by the disclosing Party as demonstrated by competent business records; (b) was generally available to the public or otherwise part of the public domain at the time of its disclosure to the receiving Party; (c) became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party in breach of this Agreement; (d) was disclosed to the receiving Party by a Third Party who had no obligation to the disclosing Party not to disclose such information to others; or (e) was subsequently developed by the receiving Party without use of or reference to the Confidential Information as demonstrated by competent business records.
- 1.17. **"CTA**" means an application, including a clinical trial application, to a Regulatory Authority for purposes of requesting the ability to start or continue a clinical trial.
- 1.18. **Delivery** has the meaning set forth in Section 8.3.1 with respect to delivery of the Advaxis Compound, and Section 8.3.2 with respect to the Incyte Compound.
- 1.19. "**Disposition Package**" has the meaning set forth in Section 8.7.1.
- 1.20. "Dispute" has the meaning set forth in Section 21.1.
- 1.21. "Effective Date" has the meaning set forth in the preamble.
- 1.22. "EMA" has the meaning set forth in the definition of Applicable Law.
- 1.23. **"Field"** means the concomitant and/or sequenced administration of the Advaxis Compound and the Incyte Compound in patients with cervical cancer.
- 1.24. "First Site Ready" is when the first clinical site has all deliverables in place to support patient enrollment in the Study.
- 1.25. "FDA" has the meaning set forth in the definition of Applicable Law.
- 1.26. "**GCP**" means the Good Clinical Practices officially published by EMA, FDA and the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) that may be in effect from time to time and are applicable to the testing of the Compounds.
- 1.27. **"Government Official**" means: (a) any officer or employee of a government or any department, agency or instrument of a government; (b) any person acting in an official capacity for or on behalf of a government or any department, agency, or instrument of a government; (c) any officer or employee of a company or business owned in whole or part by a government; (d) any officer or employee of a public international organization such as the World Bank or United Nations; (e) any officer or employee of a political party or any person acting in an official capacity on behalf of a political party; and/or (f) any candidate for political office; who, when such Government Official is acting in an official capacity, or in an official decision-making role, has responsibility for performing regulatory inspections, government authorizations or licenses, or otherwise has the capacity to take decisions with the potential to affect the business of either of the Parties.

- 1.28. "HIPAA" has the meaning set forth in the definition of Applicable Law.
- 1.29. "Incyte" has the meaning set forth in the preamble.
- 1.30. "Incyte Compound" means INCB024360, a Selective Inhibitor of IDO1 (indoleamine 2, 3 dioxygenase-1), as a freebase or pharmaceutical salt and any formulations thereof.
- 1.31. **"IND**" means the Investigational New Drug Application filed or to be filed with the FDA as described in Title 21 of the U.S. Code of Federal Regulations, Part 312, and the equivalent application in the jurisdictions outside the United States, including an "Investigational Medicinal Product Dossier" filed or to be filed with the EMA.
- 1.32. **"Intellectual Property Right(s)"** means any and all ideas, inventions, conceptions, discoveries, know-how, data, information, results, databases, documentation, reports, materials, writings, designs, computer software, processes, principles, methods, techniques and other information, including Patents, trade secrets, trade-marks, service marks, trade names, registered designs, design rights, copyrights (including rights in computer software and database rights), whether registered or not, and all legal means of establishing rights in and to and the aforesaid rights or property similar to any of the foregoing, in any part of the world, together with the right to apply for the registration of any such right.
- 1.33. **"Inventions**" means all inventions and discoveries which are (i) made developed, conceived, or first reduced to practice through the use of the Incyte Compound in combination with the Advaxis Compound in the performance of the Study, and/or (ii) made, developed, conceived, or first reduced to practice by a Party through the use of the Incyte Compound in combination with the Advaxis Compound through use of the Clinical Data.
- 1.34. "IRB" means an Institutional Review Board constituted and operating in accordance with FDA/HHS regulations.
- 1.35. "Jointly Owned Invention" has the meaning set forth in Section 10.1.1.
- 1.36. "Joint Patent Application" has the meaning set forth in Section 10.1.2.
- 1.37. "Joint Patent" means a patent that issues from a Joint Patent Application.
- 1.38. **"Know-How"** means any proprietary invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, including manufacturing, use, process, structural, operational and other data and information, whether or not written or otherwise fixed in any form or medium, regardless of the media on which contained and whether or not patentable or copyrightable, that is not generally known or otherwise in the public domain resulting from the use of the Incyte Compound in combination with the Advaxis Compound.
- 1.39. "Liability" has the meaning set forth in Section 14.2.1.



- 1.40. "*Lm*-LLO Immunotherapy" means the Advaxis proprietary platform technology in which live attenuated *Lm* are bioengineered to secrete an antigen-adjuvant fusion protein (antigen + LLO) consisting of a tumor associated antigen fused to a truncated fragment of the *Lm* protein listeriolysin (tLLO). This Agreement is specific to ADXS11-001 as described in 1.2.
- 1.41. **"Manufacture**," **"Manufactured**," or **"Manufacturing**" means all stages of the manufacture of a Compound, including planning, purchasing, manufacture, processing, compounding, storage, filling, packaging, waste disposal, labeling, leafleting, testing, quality assurance, sample retention, stability testing, release, dispatch and supply, as applicable.
- 1.42. "Manufacturer's Release" or "Release" has the meaning ascribed to such term in the Clinical Quality Agreement.
- 1.43. "Manufacturing Site" means the facilities where a Compound is Manufactured by or on behalf of a Party, as such Manufacturing Site may change from time to time in accordance with Section 8.6 (Changes to Manufacturing).
- 1.44. **"Non-Conformance**" means, with respect to a given unit of Compound, (i) an event that deviates from an approved cGMP requirement with respect to the applicable Compound, such as a procedure, Specification, or operating parameter, or that requires an investigation to assess impact to the quality of the applicable Compound or (ii) that such Compound failed to meet the applicable representations and warranties set forth in Section 2.3. Classification of the Non-Conformance is detailed in the Clinical Quality Agreement.
- 1.45. "**Party**" has the meaning set forth in the preamble.
- 1.46. **"Pharmacovigilance Agreement**" means that certain pharmacovigilance agreement being entered into by the Parties within sixty (60) days of the Effective Date regarding the Compounds.
- 1.47. **"Protocol**" means the written documentation that describes the Study and sets forth specific activities to be performed as part of the Study conduct, a synopsis of which is attached hereto as Appendix A.
- 1.48. **"Regulatory Approvals**" means, with respect to a Compound, any and all permissions (other than the Manufacturing approvals) required to be obtained from Regulatory Authorities and any other competent authority for the development, registration, importation and distribution of such Compound in the United States, Europe or other applicable jurisdictions for use in the Study.
- 1.49. "Regulatory Authorities" has the meaning set forth in the definition of Applicable Law.
- 1.50. "Samples" means the samples described in Appendix B.
- 1.51. "Sample Testing" means the studies to be performed by each Party using the applicable Samples, as set forth in Appendix B.
- 1.52. **"Sample Testing Results**" means those results arising from the Sample Testing which are to be shared between Advaxis and Incyte, as set forth in Appendix B.

- 1.53. **"Selective Inhibitor of IDO1"** means any compound that exhibits IDO1 inhibitory properties with average IC50  $\leq$  1 micromolar in either the HELA cellular assay or D-Trp enzyme assay, the methods for which are set forth in Appendix F. Average IC50 values will be calculated as the average of at least five separate IC50 determinations with values determined on at least three separate days. An average value will be acceptable if the %CV is 50 or less. If the %CV for the data is greater than 50, the average IC50 value will be calculated from at least ten IC50 measurements conducted on at least five separate days. Individual IC50 values that differ more than 10-fold from the average IC50 value will be excluded from the final IC50 average value calculation.
- 1.54. "Specifications" means, with respect to a Compound, the set of requirements for such Compound as set forth in the Clinical Quality Agreement.
- 1.55. **"Study**" means the clinical trial to be conducted under this Agreement for the concomitant or sequenced administration of the Advaxis Compound and the Incyte Compound (the **"Phase I/II Trial"**) as outlined in the protocol synopsis attached hereto as Appendix A.
- 1.56. "Study Completion" has the meaning set forth in Section 3.9.
- 1.57. "Third Party" means any person or entity other than Incyte, Advaxis or their respective Affiliates.

#### 2. Scope of the Agreement

- 2.1. Each Party shall contribute to the Study such resources as are necessary to fulfill its obligations set forth in this Agreement.
- 2.2. Each Party agrees to act in good faith in performing its obligations under this Agreement and shall notify the other Party as promptly as possible in the event of any delay (material supply or other delay) that is likely to adversely affect supply of its Compound as contemplated by this Agreement.
- 2.3. Incyte agrees to Manufacture and supply the Incyte Compound for purposes of the Study as set forth in Article 8, and Incyte hereby represents and warrants to Advaxis that, at the time of Delivery of the Incyte Compound, such Incyte Compound shall have been Manufactured and supplied in compliance with: (i) the Specifications for the Incyte Compound; (ii) the Clinical Quality Agreement; and (iii) all Applicable Law, including cGMP and health, safety and environmental protections. Advaxis agrees to Manufacture and supply the Advaxis Compound for purposes of the Study as set forth in Article 8, and Advaxis hereby represents and warrants to Incyte that, at the time of Delivery of the Advaxis Compound, such Advaxis Compound shall have been Manufactured and supplied in compliance with: (a) the Specifications for the Advaxis Compound; (b) the Clinical Quality Agreement; and (c) all Applicable Law, including cGMP and health, safety and environmental protections. Without limiting the foregoing, each Party is responsible for obtaining all regulatory approvals (including facility licenses) that are required to Manufacture its Compound in accordance with Applicable Law (provided that for clarity, Incyte shall be responsible for obtaining Regulatory Approvals for the Study as set forth in Section 3.3).
- 2.4. Each Party shall have the right to subcontract any portion of its obligations hereunder to subcontractors, provided that such Party shall remain solely and fully liable for the performance of such subcontractors. Each Party shall ensure that each of its subcontractors is appropriately qualified and that appropriate regulatory notification or approval is received for the activities selected. Each Party shall further ensure that each of its subcontractors performs its obligations pursuant to the terms of this Agreement, including the Appendices attached hereto. Each Party shall use reasonable efforts to obtain and maintain copies of documents relating to the obligations performed by such subcontractors that are held by or under the control of such subcontractors and that are required to be provided to the other Party under this Agreement.

- 2.5. This Agreement does not create any obligation on the part of Advaxis to provide the Advaxis Compound for any activities other than the Study, nor does it create any obligation on the part of Incyte to provide the Incyte Compound for any activities other than the Study.
- 2.6. Nothing in this Agreement shall (i) prohibit either Party from performing studies other than the Study relating to its own Compound, either individually or in combination with any other compound or product, in any therapeutic area, or (ii) create an exclusive relationship between the Parties with respect to any Compound.

#### 3. Conduct of the Study

- 3.1. Incyte shall act as the sponsor of the Study, shall take the lead role in conducting the Study and shall hold the IND relating to the Study. The IND held by Incyte will be filed with the Center for Biologics Evaluation and Research (CBER) at FDA.
- 3.2. Incyte shall ensure that the Study is performed in accordance with this Agreement, the Protocol and all Applicable Law, including GCP.
- 3.3. Incyte shall ensure all necessary regulatory approvals and IRB reviews and approvals are obtained prior to patient enrollment and shall be responsible for coordinating all ongoing IRB review, approval and monitoring, in compliance with 21 C.F.R. Part 56.
- 3.4. Incyte shall ensure that all directions from any Regulatory Authority and/or ethics committee with jurisdiction over the Study are followed. Further, Incyte shall ensure that all Regulatory Approvals from any Regulatory Authority and/or ethics committee with jurisdiction over the Study are obtained prior to commencing or initiating performance of the Study. Advaxis shall have the right (but no obligation) to participate in any discussions with a Regulatory Authority regarding matters related to the Advaxis Compound. Incyte shall notify Advaxis promptly upon receipt of Regulatory Authority request for any such discussions relating to the Advaxis Compound. Advaxis will authorize FDA and other applicable regulatory authorities to cross-reference the appropriate ADXS-HPV INDs and CTAs to support conduct of the Study, and shall execute any documents or instruments necessary to allow such cross-referencing. If Advaxis's CTA is not available in a given country, Advaxis will file its CMC data with the Regulatory Authority for such country, referencing Incyte's CTA as appropriate.
- 3.5. Each Party shall maintain reports and all related documentation in good scientific manner and in compliance with Applicable Law in connection with the Study. Incyte shall provide to Advaxis all Study information and documentation reasonably requested by Advaxis to enable Advaxis to comply with any of its legal, regulatory and/or contractual obligations, or any request by any Regulatory Authority, related to the Advaxis Compound.
- 3.6. Incyte shall provide to Advaxis copies of all Clinical Data (except the Sample Testing Results as set forth in Section 3.7), in electronic form or other mutually agreeable alternate form and on mutually agreeable timelines, provided, however, Clinical Data associated with pharmacokinetics of the Advaxis Compound shall be provided to Advaxis no less than once every three (3) months, if available. Incyte shall ensure that all patient authorizations and consents required under HIPAA, the EU Data Protection Directive or any other similar Applicable Law in connection with the Study permit such sharing of Clinical Data with Advaxis.

- 3.7. All Clinical Data, including raw data, records and results, generated under the Study, except for Sample Testing Results specific to the Incyte Compound or the Advaxis Compound, shall be jointly owned by Incyte and Advaxis. Clinical Data that is not Incyte Confidential Information may be used by Advaxis without restriction. Clinical Data that is not Advaxis Confidential Information. Each party shall bear the entire cost of any exploratory study it elects to do that is ; i) not part of the studies contemplated under this Agreement, and ii) expressly reviewed and approved by the JDC.
- 3.8. Each Party shall use the Samples only for the Sample Testing outlined in Appendix B. Advaxis shall pay for and own all Sample Testing Results arising from experiments conducted by or on behalf of Advaxis. Advaxis shall provide to Incyte those Sample Testing Results outlined in Appendix B for the Sample Testing conducted by or on behalf of Advaxis, in electronic form or other mutually agreeable alternate form and on the timelines specified in Appendix B. Likewise, Incyte shall pay for and own all Sample Testing Results arising from experiments conducted by or on behalf of Incyte. Incyte shall provide to Advaxis those Sample Testing Results outlined in Appendix B for the Sample Testing conducted by or on behalf of Incyte, in electronic form or other mutually agreeable alternate form and on the timelines specified in Appendix B. Each Party may use the other Party's Sample Testing Results only for the purposes of (i) seeking Regulatory Approval for the use of its respective Compound in the Combination or as monotherapy and/or for any companion diagnostic to any pharmaceutical product containing its respective Compound and (ii) filing and prosecuting patent applications for Joint Inventions and enforcing any resulting patents in accordance with Article 10; provided, however, that these restrictions shall no longer apply once the Sample Testing Results or portions thereof are available to the public.
- Joint Development Committee. The Parties shall form a joint development team (the "Joint Development Committee" or "JDC"), made up of an 3.9. equal number of representatives of Advaxis and Incyte (not to exceed three (3) each), which shall have responsibility for coordinating all regulatory and other activities under, and pursuant to, this Agreement. Each Party shall designate a project manager (the "Project Manager") who shall be responsible for ensuring clear and responsive communication between the Parties and the effective exchange of information, serving as the primary point of contact for any issues arising under this Agreement, implementing and coordinating activities, and facilitating the exchange of information between the Parties, with respect to the Study. Other JDC members will be agreed by both Parties. The JDC shall meet as soon as practicable after the Effective Date and then no less than once each Calendar Quarter, and more often as reasonably considered necessary at the request of either Party with reasonable notice, to provide an update on progress of the Study and make decisions regarding the conduct of the Study and any modifications to the Protocol and Budget. Five (5) business days prior to any such meeting, the Incyte Project Manager shall provide an update in writing to the Advaxis Project Manager, which update shall contain information about overall Study progress, recruitment status, interim analysis (if results are available), final analysis and other information relevant to the conduct of the Study. The JDC will attempt to reach decisions by consensus, except that Advaxis will determine in its sole discretion the dose and dosing regimen for the Advaxis Compound and Incyte will determine in its sole discretion the dose and dosing regimen for the Incyte Compound. When consensus is not achieved on any matter, the matter will be escalated to the Incyte CEO and the EVP CMO Advaxis or his/her nominee for resolution, provided however that (1) in the event that the matter relates solely to the Advaxis Compound, Advaxis shall have final decision-making authority and (2) in the event that the matter relates solely to the Incyte Compound, Incyte shall have final decision-making authority.

3.10. Incyte shall provide Advaxis with (i) an electronic draft of the Final Study Report, for Advaxis to provide comments to Incyte within thirty (30) days of Advaxis's receipt of the draft of the Final Study Report and (ii) a final version of the Final Study Report promptly following receipt of the Advaxis comments and Study Completion. Incyte shall consider in good faith all comments provided by Advaxis on the Final Study Report. "**Study Completion**" shall occur upon database lock of the Study results.

#### 4. Protocol, Budget and Related Documents

- 4.1. The Study will be conducted in accordance with the Protocol Synopsis that has been agreed to by the Parties dated January 30, 2015. The Protocol Synopsis of the Protocol for the Study is attached as Appendix A, with the full Protocol included herein by reference. The JDC shall have the authority to amend the Protocol and the corresponding Budget prior to Study initiation by unanimous approval. If the Parties are unable to agree after good faith discussions upon an amended Protocol, then the Study will proceed as outlined in the attached Protocol. Notwithstanding the above, Advaxis will determine the dose and dosing regimen for the Advaxis Compound and will have the final decision on all matters relating to the Advaxis Compound and any information regarding the Advaxis Compound included in the Protocol for the Study, and Incyte will determine the dose and dosing regimen for the Protocol for the Study. To the extent any changes need to be made to the Protocol, Incyte shall have the final decision regarding the contents of the Protocol after good faith consideration of any comments by Advaxis; provided that Incyte's changes will not exceed the Budget limitations set forth in Section 4.2 below and provided further that any changes relating specifically to the Advaxis Compound shall require Advaxis's prior written consent, not to be unreasonably withheld. Advaxis will provide such consent, or a written explanation for why such consent is being withheld, within ten (10) Business Days of receiving Incyte's request therefor.
- 4.2. A preliminary cost estimate for the Study ("Budget") is attached hereto as Appendix C which will be finalized upon completion of site and CRO selection. The JDC shall finalize a mutually agreed upon budget. Sample testing costs shall be borne by Party conducting the tests, unless otherwise agreed by the Parties. Excluding internal FTEs for both Parties, Advaxis and Incyte will share equally the cost of the budgeted activities for the Study as set forth in the Budget. Any increase in the cost of the Study that exceeds the final Budget by ten percent (10%) of the total cost of the Study as set forth in the Budget must be agreed upon in advance by the JDC. Otherwise, each Party shall be responsible for its own internal costs and expenses to support the Study. The Parties further agree that (i) Advaxis shall provide the Advaxis Compound for use in the Study, as described in Article 8 below; and (ii) Incyte shall provide the Incyte Compound for use in the Study, as described in Article 8 below.
- 4.3. Incyte shall prepare the patient informed consent form for the Study in consultation with Advaxis (it being understood that the portion of the informed consent form relating to the Advaxis Compound will be provided by Advaxis).

#### 5. Adverse Event Reporting

- 5.1. Each Party will be responsible for compliance with all Applicable Law pertaining to safety reporting for the Study and related activities. The Parties will execute a Pharmacovigilance Agreement within sixty (60) days of the Effective Date to ensure the exchange of relevant safety data within appropriate timeframes and in appropriate format to enable the Parties to fulfill local and international regulatory reporting obligations and to facilitate appropriate safety reviews. The Pharmacovigilance Agreement will include safety data exchange procedures governing the coordination of collection, investigation, reporting, and exchange of information concerning any adverse experiences, pregnancy reports, and any other safety information arising from or related to the use of the Advaxis Compound and Incyte Compound in the Study, consistent with Applicable Law. Such guidelines and procedures shall be in accordance with, and enable the Parties and their Affiliates to fulfill local and international regulatory reporting obligations to Regulatory Authorities.
- 5.2. Incyte shall be responsible for all safety reporting requirements (submission of all Advaxis Compound and Incyte Compound SUSARs from all studies to FDA and the investigators in the Study) including the requirements set forth in 21 C.F.R. § 312.32. Each Party shall report to the other Party safety information related to its Compound that necessitates amendments to the protocols that are required to be implemented by Regulatory Authorities, or are implemented by the respective Party, in each case where, because of their severity, frequency or lack of reversibility, a Party reasonably needs to know such safety information in order to ensure patient safety and prevent unreasonable risks in the conduct of the Study. All such disclosures under this Section 5.2 are Confidential Information of the Party disclosing same

#### 6. Term and Termination

- 6.1. The term of this Agreement shall commence on the Effective Date and shall continue in full force and effect until completion of the Final Study Report or until terminated by either Party pursuant to this Article 6.
- 6.2. Either Party may terminate this Agreement if the other Party commits a material breach of this Agreement, and such material breach continues for thirty (30) days after receipt of written notice thereof from the non-breaching Party; provided that if such material breach cannot reasonably be cured within thirty (30) days, the breaching Party shall be given a reasonable period of time to cure such breach.
- 6.3. Either Party may terminate this Agreement immediately upon written notice to the other party if the terminating Party determines in good faith, based on a review of the Clinical Data or other Study-related Know-How or information, that the Study may unreasonably affect patient safety.
- 6.4. (a) Either Party may terminate this Agreement (in whole or in part on a country-by-country basis) immediately upon written notice to the other Party in the event that any Regulatory Authority takes any action, or raises any objection, that prevents the terminating Party from supplying its Compound for purposes of the Study. (b) Additionally, either Party shall have the right to terminate this Agreement immediately (in whole or in part) upon written notice to the other Party in the event that it determines in its sole discretion to discontinue all development of its Compound, for medical, scientific or legal reasons.
- 6.5. In the event that this Agreement is terminated, Incyte shall, at Advaxis's sole discretion, promptly either return or destroy all unused Advaxis Compound pursuant to Advaxis's instructions. If Advaxis requests that Incyte destroy the unused Advaxis Compound, Incyte shall provide written certification of such destruction. Likewise, if Incyte has provided Incyte Compound to Advaxis, Advaxis shall, at Incyte's sole discretion, promptly either return or destroy all unused Incyte Compound pursuant to Incyte's instructions. If Incyte arguests that Advaxis destroy any unused Incyte Compound, Advaxis shall provide written certification of such destruction.

- 6.6. The provisions of Sections 3.7, 3.8, 3.9, 3.10, 6.5, 6.6, 6.7, 6.8, 13.2, 13.3, 13.4, 14.2 (Indemnification), 14.3 (Limitation of Liability), and Articles 1 (Definitions), 4.2 (Costs of Study), 7(Payment Terms & Taxes), 9 (Confidentiality), 10 (Intellectual Property), 11 (Reprints; Rights of Cross-Reference), 12 (Publications), 15 (Use of Names), 18 (Assignment and Sub-Contracting), 20 (No Additional Obligations), 21 (Dispute Resolution and Jurisdiction), 22 (Notices), 23 (Relationship of the Parties) and 25 (Construction) shall survive the expiration or termination of this Agreement, provided that, in the event the Parties conduct any activities under Appendix B beyond the term of this Agreement, then the provisions of this Agreement governing ownership and data sharing of the Sample Testing Results shall remain in effect with respect to such activities.
- 6.7. Termination of this Agreement shall be without prejudice to any claim or right of action of either Party against the other Party for any prior breach of this Agreement.
- 6.8. Upon termination of this Agreement, each Party and its Affiliates shall promptly return to the other Party or destroy any Confidential Information of the other Party (other than Clinical Data and Inventions) furnished to the receiving Party by the other Party, except that the receiving Party shall have the right to retain one copy for record-keeping purposes.

### 7. Payment Terms & Taxes

- 7.1. Payment Terms: Incyte will provide Advaxis with an invoice sent to ap@advaxis.com and supporting documents of Advaxis's share of the costs incurred through the end of each calendar quarter. Such invoices are payable within sixty (60) days after Advaxis's receipt of Incyte's invoice. All payments by Advaxis to Incyte under this Agreement shall be made in U.S. Dollars to the following account via wire transfer:
- 7.2. Taxes: Incyte shall be liable for all income and other taxes (including interest) ("Taxes") imposed upon any payments made by Advaxis to Incyte under this Article 7. No payments made shall be subject to withholding unless required by Applicable Law.

#### 8. Supply and Use of Compounds

8.1. <u>Supply of the Compounds.</u> Incyte and Advaxis will each use commercially reasonable efforts to supply, or cause to be supplied, the quantities of its respective Compound as are set forth in Appendix D, on the timelines set forth in Appendix D, in each case, for use in the Study. In the event that the Party conducting the Study determines that the quantities of Compounds set forth on Appendix D are not sufficient to complete the Study, such Party shall so notify the other Party, and the Parties shall discuss in good faith regarding additional quantities of Compounds to be provided and the schedule on which such additional quantities shall be provided. Each Party shall also provide to the other Party a contact person for the supply of its Compound under this Agreement. Notwithstanding the foregoing, or anything to the contrary herein, in the event that either Party is not supplying its Compound in accordance with the terms of this Agreement, or is allocating under Section 8.10, then the other Party shall have no obligation to supply its Compound, or may allocate proportionally.

8.2. *Minimum Shelf Life Requirements*. Each Party shall provide the other Party with its Compound with shelf life as set forth in the Clinical Quality Agreement.

#### 8.3. Provision of Compounds.

- 8.3.1. Advaxis will deliver the Advaxis Compound DAP (INCOTERMS 2010) to Incyte's, or its designee's, location as specified by Incyte ("**Delivery**" with respect to the Advaxis Compound). Risk of Loss for the Advaxis Compound shall transfer from Advaxis to Incyte at Delivery. All costs associated with the subsequent transportation, warehousing and distribution of Advaxis Compound shall be shared equally by the Parties. Incyte will: (i) take delivery of the Advaxis Compound supplied hereunder; (ii) perform the acceptance (including testing) procedures allocated to it under the Clinical Quality Agreement; (iii) subsequently label and pack (in accordance with Section 8.5), and promptly ship the Advaxis Compound to the Study sites, in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement; and (iv) provide, from time to time at the reasonable request of Advaxis, the following information: any applicable chain of custody forms, in-transport temperature recorder(s), records and receipt verification documentation, such other transport or storage documentation as may be reasonably requested by Advaxis, and usage and inventory reconciliation documentation related to the Advaxis Compound.
- 8.3.2. Incyte is solely responsible for supplying (including all Manufacturing, acceptance and release testing) the Incyte Compound for the Study, and the subsequent handling, storage, transportation, warehousing and distribution of the Incyte Compound supplied hereunder. All costs associated with the subsequent transportation, warehousing and distribution of Incyte Compound shall be shared equally by the Parties. Incyte shall ensure that all such activities are conducted in compliance with cGMP, GCP and other Applicable Law and the Clinical Quality Agreement. For purposes of this Agreement, the "**Delivery**" of a given quantity of the Incyte Compound shall be deemed to occur when such quantity is packaged for shipment to a Study Site or other site as set forth herein.

#### 8.4. Labeling and Packaging; Use, Handling and Storage.

- 8.4.1. The Parties' obligations with respect to the labeling and packaging of the Compounds are as set forth in the Clinical Quality Agreement. Notwithstanding the foregoing or anything to the contrary contained herein, Advaxis shall provide the Advaxis Compound to Incyte in the form of bulk labeled vials, and Incyte shall be responsible for re-labeling, packaging and leafleting the Advaxis Compound in accordance with the terms and conditions of the Clinical Quality Agreement and otherwise in accordance with all Applicable Law, including cGMP, GCP, and health, safety and environmental protections.
- 8.4.2. Incyte shall (i) use the Advaxis Compound solely for purposes of performing the Study; (ii) not use the Advaxis Compound in any manner inconsistent with this Agreement or for any commercial purpose; and (iii) use, store, transport, handle and dispose of the Advaxis Compound in compliance with Applicable Law and the Clinical Quality Agreement, as well as all reasonable instructions of Advaxis. Incyte shall not reverse engineer, reverse compile, disassemble or otherwise attempt to derive the composition or underlying information, structure or ideas of the Advaxis Compound, and in particular shall not analyze the Advaxis Compound by physical, chemical or biochemical means except as necessary to perform its obligations under the Clinical Quality Agreement.



- 8.5. <u>Product Specifications</u>. A certificate of analysis shall accompany each shipment of the Advaxis Compound to Incyte and each shipment of the Incyte Compound to Advaxis. Incyte shall be responsible for any failure of the Advaxis Compound to meet the Specifications to the extent caused by shipping, storage or handling conditions after Delivery (and performance of the acceptance procedures) to Incyte hereunder.
- 8.6. <u>Changes to Manufacturing</u>. Each Party may make changes from time to time to its Compound or the Manufacturing Site without notice to the other Party; provided that such changes shall be in accordance with cGMP and the Clinical Quality Agreement.

#### 8.7. Product Testing; Noncompliance.

8.7.1. *After Manufacturer's Release*. After Manufacturer's Release of the Advaxis Compound but prior to shipment to Incyte, Advaxis shall provide Incyte with such certificates and documentation as are described in the Clinical Quality Agreement ("**Disposition Package**"). Incyte shall, upon receipt of the Advaxis Compound and within the time defined in the Clinical Quality Agreement, perform (i) with respect to the Advaxis Compound, the acceptance (including applicable testing) procedures allocated to it under the Clinical Quality Agreement, and (ii) with respect to the Incyte Compound, the testing and release procedures allocated to it under the Clinical Quality Agreement. Once Incyte has received and performed the acceptance procedures on the Advaxis Compound, Incyte shall be solely responsible for taking all steps necessary to determine that the Advaxis Compound or Incyte Compound, as applicable, is suitable for release before making such Advaxis Compound or Incyte Compound, as applicable for human use. For clarity, Incyte shall store and maintain the Advaxis Compound until it is released, which storage and maintenance shall be in compliance with (a) the Specifications for the Advaxis Compound, the Clinical Quality Agreement and Applicable Law, and (b) any specific storage and maintenance requirements as may be provided by Advaxis from time to time.

#### 8.7.2. Non-Conformance.

- 8.7.2.1. In the event that Incyte becomes aware that the Advaxis Compound may have a Non-Conformance, despite testing and quality assurance activities (including any activities conducted by the Parties under Sections 8.7.1 (*After Manufacturer's Release*)), Incyte shall immediately notify Advaxis in accordance with the procedures of the Clinical Quality Agreement. The Parties shall investigate any Non-Conformance in accordance with Section 8.9 (*Investigations*) and any discrepancy between them shall be resolved in accordance with Section 8.8 (*Resolution of Discrepancies*).
- 8.7.2.2. In the event that any proposed or actual shipment of the Advaxis Compound (or portion thereof) shall be agreed to have a Non-Conformance at the time of Delivery to Incyte, then unless otherwise agreed to by the Parties, Advaxis shall replace the non-conforming Advaxis Compound (with respect to Advaxis Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Incyte with respect to any Advaxis Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such Advaxis Compound as set forth in this Section 8.7.2.2, (ii) indemnification under Section 14.2 (to the extent applicable) and (iii) termination of this Agreement pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein); provided that, for clarity, Incyte shall not be deemed to be waiving any rights under Section 8.16. In the event Advaxis Compound is lost or damaged by Incyte after Delivery, Advaxis shall provide additional Advaxis Compound. Except as set forth in the foregoing sentence, Advaxis shall have no obligation to provide replacement Advaxis Compound for any Advaxis Compound supplied hereunder other than Advaxis Compound as has been agreed or determined to have a Non-Conformance at the time of Delivery to Incyte.

- 8.7.2.3. Incyte shall be responsible for, and Advaxis shall have no obligations or liability with respect to, any Incyte Compound supplied hereunder that is found to have a Non-Conformance. Incyte shall replace any Incyte Compound as is found to have a Non-Conformance (with respect to Incyte Compound that has not yet been administered in the course of performing the Study). Unless otherwise agreed to by the Parties in writing, the sole and exclusive remedies of Advaxis with respect to any Incyte Compound that is found to have a Non-Conformance at the time of Delivery shall be (i) replacement of such Incyte Compound as set forth in this Section 8.7.2.3, (ii) indemnification under Section 14.2 (to the extent applicable) and (iii) termination of this Agreement pursuant to Section 6.3 (to the extent applicable, but subject to the applicable cure periods set forth therein); provided that, for clarity, Advaxis shall not be deemed to be waiving any rights under Section 8.16.
- 8.8. <u>Resolution of Discrepancies</u>. If Advaxis disagrees with any determination of Non-Conformance by Incyte, such discrepancy shall be escalated to the head of quality of each Party (or such person's designee) for resolution.
- 8.9. *Investigations*. The process for investigations of any Non-Conformance shall be handled in accordance with the provisions set forth in the Clinical Quality Agreement.
- 8.10. Shortage; Allocation. In the event of a shortage of a Compound such that a Party reasonably believes that it will not be able to fulfill its supply obligations hereunder with respect to its Compound, such Party will provide prompt written notice to the other Party thereof (including the quantity of its Compound that such Party reasonably determines it will be able to supply) and, upon request, the Parties will promptly discuss such situation (including how the quantities of Compound that such Party is able to supply hereunder will be allocated within the Study). Notwithstanding anything to the contrary contained herein, in the event of a bona fide shortage of a Party's Compound, the Party experiencing such shortage shall have sole discretion, subject to Applicable Law, to determine the quantity of Compound it will be able to supply as a result of such shortage, and such Party shall not be deemed to be in breach of this Agreement for failure to supply any other quantities of such shortage. In case of one Party's shortage of its Compound, the other Party shall be proportionately relieved of its obligations under this Agreement as they directly relate to the shortage.
- 8.11. <u>Regulatory Responsibility</u>. The responsibilities of the Parties with respect to communication and filings with Regulatory Authorities related to the Compounds supplied hereunder in connection with the Study will be as set forth in the Pharmacovigilance Agreement and the Clinical Quality Agreement entered into by the Parties or their Affiliates in connection herewith, except that Advaxis will separately submit any CMC information with respect to the Advaxis Compound directly to any Regulatory Authorities as may be necessary.

#### 8.12. Records; Audit Rights.

- 8.12.1.Incyte will keep complete and accurate records pertaining to its use and disposition of Advaxis Compound (including its storage, shipping and chain of custody activities) and, upon reasonable request of Advaxis, will make such records open to review by Advaxis for the purpose of conducting investigations for the determination of Advaxis Compound safety and/or efficacy and Incyte's compliance with this Agreement with respect to the Advaxis Compound.
- 8.12.2.Each Party shall maintain complete and accurate records pertaining to its Manufacture of its Compound supplied hereunder, and, upon reasonable request of the other Party, will make such records open to review by such other Party in accordance with the Clinical Quality Agreement for the purpose of confirming such Party's compliance with this Agreement with respect to its Manufacturing obligations hereunder.
- 8.13. *Quality*. Quality matters related to the Manufacture of the Compounds shall be governed by the terms of the Clinical Quality Agreement in addition to the relevant quality terms of this Agreement.
- 8.14. *Quality Control*. Each Party shall implement and perform operating procedures and controls for sampling, stability and other testing of its Compound, and for validation, documentation and release of its Compound and such other quality assurance and quality control procedures as are required by the Specifications, cGMPs and the Clinical Quality Agreement.
- 8.15. Audits and Inspections. The Parties' audit and inspection rights are governed by the terms of the Clinical Quality Agreement.
- 8.16. Recalls. Recalls of the Compounds shall be governed by the terms of the Clinical Quality Agreement.

#### 9. Confidentiality

- 9.1. Prior to the Effective Date of this Agreement, Incyte and Advaxis entered into a certain Confidentiality Agreement dated September 2, 2014 ("CDA"). The CDA is hereby terminated and replaced by the terms of this Agreement. Any information previously disclosed by the Parties pursuant to the CDA shall now be Confidential Information for purposes of this Agreement and the Parties shall treat it as such in accordance with the terms hereof.
- 9.2. Incyte and Advaxis agree to hold in confidence any Confidential Information provided by the other Party, and neither Party shall use Confidential Information of the other Party except to fulfill such Party's obligations under this Agreement. Without limiting the foregoing, Advaxis may not use Confidential Information disclosed by or on behalf of Incyte relating to the Incyte Compound or the Incyte IDO1 program other than for purposes of the Study. Incyte may not use Confidential Information disclosed by or on behalf of Advaxis relating to the Advaxis Compound or the Advaxis Compound or the Advaxis LM-LLO program other than for purposes of the Study. Neither Party shall, without the prior written permission of the other Party, disclose any Confidential Information of the other Party to any Third Party except to the extent disclosure (i) is required by Applicable Law; (ii) is pursuant to the terms of this Agreement; or (iii) is necessary for the conduct of the Study, and in each case ((i) through (iii)) provided that the disclosing Party shall provide reasonable advance notice to the other Party before making such disclosure and further provided that the recipient of such Confidential Information shall be bound by an obligation of confidential Information to clinical trial sites and clinical trial investigators performing the Study, the data safety monitoring and advisory board relating to the Study, and regulatory agencies such as the FDA, EMA or other health authorities working with Incyte on the Study, in each case to the extent necessary for the performance of the Study and provided that such persons (other than governmental entities) are bound by an obligation of confidential Information to clinical trial sites and clinical trial such persons (other than governmental entities) are bound by an obligation of confidential formation to clinical trial sites and herein.

- 9.3. Notwithstanding the foregoing, (i) Inventions that constitute Confidential Information and are jointly owned by the Parties, shall constitute the Confidential Information of both Parties and each Party shall have the right to use such Confidential Information consistent with Articles 10, 11 and 12 and (ii) Inventions that constitute Confidential Information and are solely owned by one Party shall constitute the Confidential Information of that Party and each Party shall have the right to use such Confidential Information consistent with Articles 10, 11 and 12 and (iii) Inventions that constitute to use such Confidential Information consistent with Articles 10, 11 and 12 and (iii) Inventions that constitute to use such Confidential Information consistent with Articles 10, 11 and 12 and (iii) Inventions that constitute the right to use such Confidential Information consistent with Articles 10, 11 and 12.
- 9.4. All Confidential Information containing personal identifiable data shall be handled in accordance with all data protection and privacy laws, rules and regulations applicable to such Party.

#### **10. Intellectual Property**

#### 10.1. Joint Ownership and Prosecution.

- 10.1.1. Subject to Sections 10.2 and 10.3, all rights to all Inventions embodying, claiming and/or covering the Combination (each a "Jointly Owned Invention"), and all Know-How that (i) is generated jointly by the Parties in the performance of the Study, which includes the Protocol, and (ii) is not a Jointly Owned Invention ("Collaboration Know-How"), shall be owned jointly by Incyte and Advaxis, and each Party hereby assigns to the other a joint ownership interest in all such Jointly Owned Inventions and Collaboration Know-How. Except as set forth in Section 10.1.3.2 below, Incyte and Advaxis shall each be entitled to use the Jointly Owned Inventions without accounting or financial payment to the other Party and without the consent of the other Party. For those countries where a specific license is required for a joint owner of a Jointly Owned Invention to practice such Jointly Owned Invention in such countries, (i) Advaxis hereby grants to Incyte a, non-exclusive, worldwide, royalty-free, fully paid-up license, transferable and sublicensable, under Advaxis's right, title and interest in and to all Jointly Owned Inventions and Collaboration Know-How to use such Inventions and Know-How without restriction and (ii) Incyte hereby grants to Advaxis a, non-exclusive, worldwide, royalty-free, fully paid-up license, fransferable and sublicensable and sublicensable, under Incyte's right, title and interest in and to all Jointly Owned Inventions and Collaboration Know-How to use such Inventions and Know-How without restriction. For clarity, the terms of this Agreement do not provide Incyte or Advaxis with any rights, title or interest or any license to the other Party's Background Intellectual Property except as necessary to conduct the Study.
- 10.1.2. Promptly following the Effective Date, patent representatives of each of the Parties shall meet (in person or by telephone) to discuss the patenting strategy for any Jointly Owned Inventions which may arise. In particular, the Parties shall discuss which Party will file a patent application (s) (the "Filing Party") (including any provisional, substitution, divisional, continuation, continuation in part, reissue, renewal, reexamination, extension, supplementary protection certificate and the like) and prosecution in respect of any Jointly Owned Invention (each, a "Joint Patent Application") and have final decision making authority with respect thereto. The Parties shall decide whether to appoint mutually acceptable joint patent counsel for filing and prosecution of applications. In the event that the Parties fail to agree on the filing strategy of a Jointly Owned Invention the matter will be referred to the JDC under Section 3.8. In any event, the Parties shall consult and reasonably cooperate with one another in, and shall equally share the expenses for, the preparation, filing, prosecution (including prosecution strategy) and maintenance of Joint Patent Applications and Joint Patents, including defense of any invalidity challenges thereto. The Filing Party shall provide the other Party with copies of draft Joint Patent Application and any Office Actions, communications, reporting letters, and proposed responses thereto, assignments, and related documents at least fifteen (15) days prior to any deadline for filing and will incorporate the reasonable comments of the Non-Prosecuting Party timely received ahead of such deadline. In the event that Filing Party wishes to file a patent application for a Jointly Owned Invention and the other Party (the "Non-filing Party") does not want to file any patent application for such Jointly Owned Invention or does not want to file in a particular country, the Non-filing Party shall execute such documents and perform such acts at the Filing Party's expense as may be reasonably necessary to effect an assignment of such Jointly Owned Invention to the Filing Party (in such country or all countries, as applicable) in a timely manner to allow the Filing Party to prosecute such patent application. Likewise, if a Party (the "Opting-out Party") wishes to discontinue the prosecution and maintenance of a Joint Patent Application, the other Party, at its sole option (the "Continuing Party"), may continue such prosecution and maintenance. In such event, the Opting-out Party shall execute such documents and perform such acts at the Continuing Party's expense as may be reasonably necessary to effect an assignment of such Joint Patent Application to the Continuing Party (in such country or all countries, as applicable) in a timely manner to allow the Continuing Party to prosecute and maintain such patent application. Any Joint Patent Application or Jointly Owned Invention so assigned shall thereafter be owned solely by the Continuing Party or Filing Party (as applicable), and the Opting-out Party or Non-filing Party (as applicable) shall have no right to practice under such Joint Patent Application or any patent claiming such Jointly Owned Invention in the applicable country or countries and, for the avoidance of doubt, any such patent, when issued, shall not be a Joint Patent.

#### 10.1.3.

- 10.1.3.1. Except as expressly provided in Section 10.1.2, each Party agrees not (a) to include or claim any data, compositions, information, methods and results; or (b) to file or prosecute any patent application, of or based on the other Party's Confidential Information, and to give no assistance to any Third Party for such application, without the other Party's prior written authorization.
- 10.1.3.2. Each Party covenants and agrees that it will not assign or license to any Third Party its rights to any claim in a Joint Patent Application or Joint Patent that specifically claims the Combination, except as necessary to research develop and/or commercialize its respective Compound for use in the Combination.
- 10.1.4. Each Party shall promptly provide the other Party with written notice reasonably detailing any known or alleged infringement or misappropriation by a Third Party of Joint Patents, as well as any declaratory judgment or similar actions alleging the invalidity, unenforceability or non-infringement of Joint Patents. Incyte shall have the first right to initiate legal action to enforce all Joint Patents against infringement or misappropriation by any Third Party that is manufacturing, developing, marketing, or seeking to market, a Selective IDO1 Inhibitor, and/or the Combination or to defend any declaratory judgment action relating thereto, at its sole expense. In the event such course of action includes litigation, Advaxis may choose, at its own expense, to be represented in such action by counsel of its own choice. If Advaxis is required as a necessary party to such action, each Party shall pay its respective expenses associated therewith. In the event that Incyte fails to initiate or defend such action within thirty (30) days after being first notified of such infringement, Advaxis shall have the right to do so at its sole expense. Advaxis shall have the first right to initiate legal action to enforce all Joint Patents against infringement or misappropriation by any Third Party that is manufacturing, developing, marketing, or seeking to market, an Advaxis Compound and, , or any other alleged infringement not solely related to the Incyte Compound or the Combination, or to defend any declaratory judgment action relating thereto, at its sole expense. In the event such course of action includes litigation, Incyte may choose, at its own expense, to be represented in such action by counsel of its own choice. If Incyte is required as a necessary party to such action, each Party shall pay its respective expenses associated therewith. In the event that Advaxis fails to initiate or defend such action within thirty (30) days after being first notified of such infringement, Incyte shall have the right to do so at its sole expense. Each Party shall keep the other Party reasonably informed as to any legal or commercial courses of action it pursues pursuant to this subsection. In connection with any proceeding, neither Party shall enter into any settlement without the prior written consent of the other Party.

- 10.1.5. If one Party brings any prosecution or enforcement action or proceeding against a Third Party with respect to any Joint Patent, the second Party agrees to be joined as a party plaintiff where necessary and to give the first Party reasonable assistance and authority to file and prosecute the suit, at the first Party's expense. The costs and expenses of the Party bringing suit under this Section 10.1.5 shall be borne by such Party, and any damages or other monetary awards recovered shall be shared as follows: (i) the amount of such recovery actually received by the Party controlling such action shall be first applied proportionately to the out-of-pocket costs of each Party in connection with such action; and then (ii) any remaining proceeds shall be divided evenly between Incyte and Advaxis. A settlement or consent judgment or other voluntary final disposition of a suit under this Section 10.1.5 may not be entered into without the consent of the Party not bringing the suit.
- 10.2. <u>Inventions Owned by Incyte</u>. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating solely to the Incyte Compound, or a Selective IDO1 Inhibitor, are the exclusive property of Incyte, and Advaxis hereby assigns any rights in such Inventions to Incyte. Incyte shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Incyte Compound (and not the Advaxis Compound) within its scope, even where the Incyte Compound is not disclosed per se, is the exclusive property of Incyte and Advaxis hereby assigns all of its rights in any such Invention to Incyte.
- 10.3. <u>Inventions Owned by Advaxis</u>. Notwithstanding Section 10.1, the Parties agree that all rights to Inventions relating solely to the Advaxis Compound are the exclusive property of Advaxis, and Incyte hereby assigns any rights in such Inventions to Advaxis. Advaxis shall be entitled to file in its own name relevant patent applications and to own resultant patent rights for any such Invention. For the avoidance of doubt, any Invention generically encompassing the Advaxis Compound (and not the Incyte Compound) within its scope, even where the Advaxis Compound is not disclosed per se, is the exclusive property of Advaxis and Incyte hereby assigns all of its rights in any such Invention to Advaxis.

#### 11. Reprints; Rights of Cross Reference

11.1. Consistent with applicable copyright and other laws, each Party may use, refer to, and disseminate reprints of scientific, medical and other published articles and materials from journals, conferences and/or symposia relating to the Study which disclose the name of the other Party, provided such use does not constitute an endorsement of any commercial product or service by the other Party. The Parties may not engage in the pre-approval promotion of the Compounds in conjunction with the usage, reference to, or dissemination of any such publications or materials.

#### 12. Publications

- 12.1. Incyte will register the Study with the Clinical Trials Registry located at www.clinicaltrials.gov no sooner than four (4) weeks prior to the date of First Site Ready (the "First Site Ready Date"), and no later than the First Site Ready Date, except to the extent required otherwise by Applicable Law and is committed to timely publication of the results following Study Completion, after the Parties have taken appropriate action to secure intellectual property rights (if any) arising from the Study. In addition, each Party shall provide the other Party with the opportunity to review and approve any proposed sponsored research involving the other Party's Compound under Section 3.10 and review any postings on www.clinicaltrials.gov prior to the First Site Ready Date posting to allow for the preservation of intellectual property rights (if any). Subject to Section 12.3, Incyte shall take the lead in drafting the first joint abstract, presentation or publication of the interim (as appropriate) and final results of the Study in each venue. Authorship of publications of the Clinical Data will be determined in accordance with appropriate scientific and academic standards and customs. Proper acknowledgement will be made for the contributions of each Party to the Clinical Data.
- 12.2. The Parties shall use reasonable efforts to jointly publish or present scientific papers dealing with the Study in accordance with accepted scientific practice and their internal policies and procedures.
- 12.3. The Parties agree that prior to submission of the results of the Study for publication or presentation or any other dissemination of results including oral dissemination, the publishing Party shall invite the other to comment on the content of the material to be published or presented according to the following procedure:
  - (i) At least thirty (30) days prior to submission for publication of any paper, letter or any other publication, or ten (10) days prior to submission for presentation of any abstract, poster, talk or any other presentation, the publishing Party shall provide to the other Party the details of the proposed publication or presentation in an electronic version (cd-rom or email attachment). Upon written request from the other Party, the publishing Party agrees not to submit data for publication/presentation for thirty (30) days in order to allow for actions to be taken to preserve rights for patent protection.
  - (ii) The publishing Party shall give reasonable consideration to any request by the other Party made within the periods mentioned in clause (i) above to modify the publication.
  - (iii) The publishing Party shall remove all Confidential Information of the other Party before finalizing the publication.
- 12.4. Except as outlined in Section 12.1 and except as required by judicial order or Applicable Law, neither Party shall make any public announcement concerning this Agreement without the prior written consent of the other Party. The Party preparing any such public announcement shall provide the other Party with a draft thereof at least three (3) Business Days prior to the date on which such Party would like to make the public announcement. Notwithstanding the foregoing, Advaxis shall issue a press release, in the form attached as Appendix E (including that the parties are co-funding the Study and the general design of the Study including the indications being evaluated), no later than two (2) days after the Effective Date to announce the execution of this Agreement. Future press releases may be made at mutually agreeable times if mutually agreed upon. Each Party agrees to identify the other Party and acknowledge its support in any publication or presentation of the Study.

#### 13. Representations and Warranties; Disclaimers

- 13.1. Each of Incyte and Advaxis represents and warrants to the other that it has the full right and authority to enter into this Agreement and to perform its obligations hereunder.
- 13.2. Incyte does not undertake that the Study shall lead to any particular result, nor is the success of the Study guaranteed. Neither Party accepts any responsibility for any use that the other Party may make of the Clinical Data nor for advice or information given in connection therewith.

#### 13.3. Anti-Corruption

13.3.1. In performing their respective obligations hereunder, the Parties acknowledge that the corporate policies of Incyte and Advaxis and their respective Affiliates require that each Party's business be conducted within the letter and spirit of the law. By signing this Agreement, each Party agrees to conduct the business contemplated herein in a manner which is consistent with all Applicable Law, including the U.S. Foreign Corrupt Practices Act, good business ethics, and its ethics and other corporate policies. In addition, Advaxis has provided Incyte with a copy of its Ethical Interactions Policy (http://www.advaxis.com/...), and Incyte has provided Advaxis with Incyte's Code of Business Conduct and Ethics, and each Party agrees to abide by the spirit of the other Party's guidelines, which may be updated from time to time by written notice.

Specifically, each Party agrees that it has not, and covenants that it, its Affiliates, and its and its Affiliates' directors, employees, officers, and anyone acting on its behalf, will not, in connection with the performance of this Agreement, directly or indirectly, make, promise, authorize, ratify or offer to make, or take any action in furtherance of, any payment or transfer of anything of value for the purpose of influencing, inducing or rewarding any act, omission or decision to secure an improper advantage; or improperly assisting it in obtaining or retaining business for it or the other Party, or in any way with the purpose or effect of public or commercial bribery.

- 13.3.2. Neither Party shall contact, nor otherwise knowingly meet with, any Government Official for the purpose of discussing activities arising out of or in connection with this Agreement, without the prior written approval of the other Party, except where such meeting is consistent with the purpose and terms of this Agreement and in compliance with Applicable Law. In such situations, the discussing party will promptly notify the other party of the Government official discussion.
- 13.3.3. Each Party represents that: (i) it is authorized and has no impediment to enter into the transaction contemplated in this Agreement; and (ii) it is not excluded, debarred, suspended, proposed for suspension or debarment, or otherwise ineligible for government programs.

- 13.3.4. Each Party represents and warrants that except as disclosed to the other in writing prior to the Effective Date of this Agreement: (1) it does not have any interest which directly or indirectly conflicts with its proper and ethical performance of this Agreement; (2) it shall maintain arm's length relations with all Third Parties with which it deals for or on behalf of the other in performance of this Agreement; and (3) it has provided, to the best of its knowledge, complete and accurate information and documentation to the other Party, the other Party's Affiliates and its and their personnel in the course of due diligence conducted by the other Party for this Agreement, including disclosure of any officers, employees, owners or persons directly or indirectly retained by such Party in relation to the performance of this Agreement who are Government Officials or relatives of Government Officials. Each Party shall make all further disclosures as necessary to the other Party to ensure the information provided remains complete and accurate throughout the term of this Agreement. Subject to the foregoing, each Party agrees that it shall not knowingly hire or retain any Government Official to assist in its performance of this Agreement, with the sole exception of conduct of or participation in clinical trials under this Agreement. Each Party further covenants that any future information and documentation submitted to the other Party as part of further due diligence or a certification shall be complete and accurate.
- 13.3.5. Each Party shall have the right during the term of this Agreement, and for a period of two (2) years following termination of this Agreement, to conduct, upon reasonable request, an investigation and audit of the other Party's activities, books and records, to the extent they relate to the other Party's performance under this Agreement and to verify compliance with the terms of this Section 13.3. Such other Party shall cooperate fully with such investigation or audit, the scope, method, nature and duration of which shall be at the sole reasonable discretion of the Party requesting such audit.
- 13.3.6. Each Party shall ensure that all transactions under the Agreement are properly and accurately recorded in all material respects on its books and records and that each document upon which entries in such books and records are based is complete and accurate in all material respects. Each Party further represents, warrants and covenants that all books, records, invoices and other documents relating to payments and expenses under this Agreement are and shall be complete and accurate and reflect in reasonable detail the character and amount of transactions and expenditures. Each Party must maintain a system of internal accounting controls reasonably designed to ensure that no off-the-books or similar funds or accounts will be maintained or used in connection with this Agreement.
- 13.3.7. Each Party shall comply with its own ethical business practices policy and shall conduct its Study-related activities in accordance with Applicable Law. Each Party agrees to ensure that all of its employees involved in performing its obligations under this Agreement are made specifically aware of the compliance requirements under this Section 13.3. In addition, each Party agrees to ensure that all such employees participate in and complete mandatory compliance training to be conducted by each Party, including specific training on anti-bribery and corruption, in accordance with such Party's standard operating procedures with respect to training. Each Party further agrees to certify its continuing compliance with the requirements under this Section 13.3 on a periodic basis during the term of this Agreement in such form as may be reasonably specified by the other Party.
- 13.4. EXCEPT AS EXPRESSLY PROVIDED HEREIN, ADVAXIS MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE ADVAXIS COMPOUND, AND INCYTE MAKES NO WARRANTIES, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, WITH RESPECT TO THE INCYTE COMPOUND. Incyte assumes no responsibility and shall have no liability for the nature, conduct or results of any research, testing or other work performed by or on behalf of Advaxis hereunder. Advaxis assumes no responsibility and shall have no liability for the nature, conduct or results of any research, testing or other work performed by or on behalf of Incyte hereunder.

#### 14. Insurance; Indemnification; Limitation of Liability

- 14.1. <u>Insurance</u>. Each Party warrants that it maintains a policy or program of insurance or self-insurance at levels sufficient to support the indemnification obligations assumed herein. Upon written request, a Party shall provide evidence of such insurance.
- 14.2. Indemnification.
  - 14.2.1. Indemnification by Incyte. Incyte agrees to defend, indemnify and hold harmless Advaxis, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any loss, damage, reasonable costs and expenses (including reasonable attorneys' fees and expenses) incurred in connection with any claim, proceeding, or investigation by a Third Party arising out of this Agreement or the Study (a "Liability"), to the extent that such Liability (A) was directly caused by (i) negligence or willful misconduct on the part of Incyte (or any of its Affiliates, or its or their employees, directors, subcontractors or agents); (ii) a breach on the part of Incyte of any of its representations and warranties or any other covenants or obligations of Incyte under this Agreement; or (iii) a breach of Applicable Law by Incyte, or (B) is determined to be attributable to the Incyte Compound except to the extent any such claims arise from the gross negligence or intentional misconduct of Advaxis.
  - 14.2.2. Indemnification by Advaxis. Advaxis agrees to defend, indemnify and hold harmless Incyte, its Affiliates, and its and their employees, directors, subcontractors and agents from and against any Liability to the extent such Liability (A) was directly caused by (i) negligence or willful misconduct on the part of Advaxis (or any of its Affiliates, or its and their employees, directors, subcontractors or agents); (ii) a breach on the part of Advaxis of any of its representations and warranties or any other covenants or obligations of Advaxis under this Agreement; or (iii) a breach of Applicable Law by Advaxis; or (B) is determined to be attributable to the Advaxis Compound except to the extent any such claims arise from the gross negligence or intentional misconduct of Incyte.
  - 14.2.3. Other Liability. Any Liability contemplated by this agreement which is not indemnifiable under either Section 14.2.1 or 14.2.2. shall be shared equally by the Parties.
  - 14.2.4. Procedure. The obligations of Advaxis and Incyte under this Section 14.2 are conditioned upon the delivery of written notice to Advaxis or Incyte, as the case might be, of any potential Liability within a reasonable time after the indemnified Party becomes aware of such potential Liability. The indemnifying Party will have the right to assume the defense of any suit or claim related to the Liability if it has assumed responsibility for the suit or claim in writing. The indemnified Party may participate in (but not control) the defense thereof at its sole cost and expense.
  - 14.2.5. Study Subjects. Incyte shall not offer compensation on behalf of Advaxis to any Study subject or bind Advaxis to any indemnification obligations in favor of any Study subject.

14.3. <u>LIMITATION OF LIABILITY</u>. OTHER THAN WITH RESPECT TO THE OBLIGATIONS OF EACH PARTY UNDER ARTICLE 9, IN NO EVENT SHALL EITHER PARTY (OR ANY OF ITS AFFILIATES OR SUBCONTRACTORS) BE LIABLE TO THE OTHER PARTY FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING LOST PROFITS OR DAMAGES FOR LOST OPPORTUNITIES), WHETHER IN CONTRACT, WARRANTY, NEGLIGENCE, TORT, STRICT LIABILITY OR OTHERWISE, ARISING OUT OF (x) THE MANUFACTURE OR USE OF ANY COMPOUND SUPPLIED HEREUNDER OR (y) ANY BREACH OF OR FAILURE TO PERFORM ANY OF THE PROVISIONS OF THIS AGREEMENT OR ANY REPRESENTATION, WARRANTY OR COVENANT CONTAINED IN OR MADE PURSUANT TO THIS AGREEMENT, EXCEPT THAT SUCH LIMITATION SHALL NOT APPLY TO DAMAGES PAID OR PAYABLE TO A THIRD PARTY BY AN INDEMNIFIED PARTY FOR WHICH THE INDEMNIFIED PARTY IS ENTITLED TO INDEMNIFICATION HEREUNDER.

#### 15. Use of Names

15.1. Except as otherwise provided herein, neither Party shall have any right, express or implied, to use in any manner the name or other designation of the other Party or any other trade name, trademark or logo of the other Party for any purpose in connection with the performance of this Agreement.

#### **16. Force Majeure**

16.1. If in the performance of this Agreement, one of the Parties is prevented, hindered or delayed by reason of any cause beyond such Party's reasonable control (*e.g.*, war, riots, fire, strike, governmental laws), such Party shall be excused from performance to the extent that it is necessarily prevented, hindered or delayed ("**Force Majeure**"). The non-performing Party will notify the other Party of such Force Majeure within ten (10) days after such occurrence by giving written notice to the other Party stating the nature of the event, its anticipated duration, and any action being taken to avoid or minimize its effect. The suspension of performance will be of no greater scope and no longer duration than is necessary and the non-performing Party will use commercially reasonable efforts to remedy its inability to perform.

#### 17. Entire Agreement; Modification

17.1. The Parties agree to the full and complete performance of the mutual covenants contained in this Agreement. This Agreement, together with the Clinical Quality Agreement and the Pharmacovigilance Agreement, constitutes the sole, full and complete agreement by and between the Parties with respect to the subject matter of this Agreement, and all prior agreements, understandings, promises and representations, whether written or oral, with respect thereto are superseded by this Agreement. No amendments, changes, additions, deletions or modifications to or of this Agreement shall be valid unless reduced to writing and signed by the Parties hereto.

#### 18. Assignment and Sub-Contracting

18.1. Neither Party shall assign or transfer this Agreement without the prior written consent of the other Party, which consent shall not be unreasonably withheld; provided, however, that either Party may assign this Agreement to one or more of its Affiliates without the other Party's consent, and any and all rights and obligations of either Party may be exercised or performed by its Affiliates, provided that such Affiliates agree to be bound by this Agreement. Notwithstanding the foregoing, either Party may assign this Agreement to a Third Party successor to all or substantially all of its business relating to its respective Compound, whether by merger, sale of stock, sale of assets or otherwise.

#### **19. Invalid Provision**

19.1. If any provision of this Agreement is held to be illegal, invalid or unenforceable, the remaining provisions shall remain in full force and effect and will not be affected by the illegal, invalid or unenforceable provision. In lieu of the illegal, invalid or unenforceable provision, the Parties shall negotiate in good faith to agree upon a reasonable provision that is legal, valid and enforceable to carry out as nearly as practicable the original intention of the entire Agreement.

#### 20. No Additional Obligations

20.1. Incyte and Advaxis have no obligation to renew this Agreement or apply this Agreement to any clinical trial other than the Study. Neither Party is under any obligation to enter into another type of agreement at this time or in the future.

#### 21. Dispute Resolution and Jurisdiction

- 21.1. The Parties shall attempt in good faith to settle all disputes arising out of or in connection with this Agreement in an amicable manner. Any claim, dispute or controversy arising out of or relating to this Agreement, including the breach, termination or validity hereof or thereof (each, a "**Dispute**"), shall be governed by and construed in accordance with the substantive laws of the State of Delaware, without giving effect to its choice of law principles.
- 21.2. Nothing contained in this Agreement shall deny either Party the right to seek injunctive or other equitable relief from a court of competent jurisdiction in the context of a bona fide emergency or prospective irreparable harm, and such an action may be filed or maintained notwithstanding any ongoing discussions between the Parties.

#### 22. Notices

22.1. All notices or other communications that are required or permitted hereunder shall be in writing and delivered personally, sent by facsimile (and promptly confirmed by personal delivery or overnight courier), or sent by internationally-recognized overnight courier addressed as follows:

If to Incyte, to:

1801 Augustine Cut-Off Wilmington, DE 19803 Attn: Executive Vice President, Business Development

With a copy to:

1801 Augustine Cut-Off Wilmington, DE 19803 Attn: General Counsel

If to Advaxis, to:

305 College Road East Princeton, NJ Attn: Executive Vice President, Chief Operating Officer

With a copy to:

Pearl Cohen Zedek Latzer Baratz, LLP 1500 Broadway, 12th Floor New York, New York 10036 Email: <u>mcohen@pearlcohen.com</u> Facsimile: 646 878 0801 Attn: Mark Cohen

#### 23. Relationship of the Parties

23.1. The relationship between the Parties is and shall be that of independent contractors, and does not and shall not constitute a partnership, joint venture, agency or fiduciary relationship. Neither Party shall have the authority to make any statements, representations or commitments of any kind, or take any actions, which are binding on the other Party, except with the prior written consent of the other Party to do so. All persons employed by a Party will be the employees of such Party and not of the other Party and all costs and obligations incurred by reason of any such employment shall be for the account and expense of such Party.

#### 24. Counterparts and Due Execution

24.1. This Agreement and any amendment may be executed in two (2) or more counterparts (including by way of facsimile or electronic transmission), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. When executed by the Parties, this Agreement shall constitute an original instrument, notwithstanding any electronic transmission, storage and printing of copies of this Agreement from computers or printers. For clarity, facsimile signatures and signatures transmitted via PDF shall be treated as original signatures.

#### 25. Construction

25.1. Except where the context otherwise requires, wherever used, the singular will include the plural, the plural the singular, the use of any gender will be applicable to all genders, and the word "or" is used in the inclusive sense (and/or). Whenever this Agreement refers to a number of days, unless otherwise specified, such number refers to calendar days. The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The term "including" as used herein shall be deemed to be followed by the phrase "without limitation" or like expression. The term "will" as used herein means shall. References to "Article," "Section" or "Appendix" are references to the numbered sections of this Agreement and the appendices attached to this Agreement, unless expressly stated otherwise. Except where the context otherwise requires, references to this "Agreement" shall include the appendices attached to this Agreement. The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction will be applied against either Party hereto.

[Remainder of page intentionally left blank.]

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

# **Incyte Corporation**

By: February 10, 2015

/s/ Barry Flannelly

Barry Flannelly

Executive Vice President, Business Development and Strategic Planning

## Advaxis, Inc.

By: February 10, 2015

/s/ Gregory T. Mayes Gregory T. Mayes

Executive Vice President, Chief Operating Officer