



18-02357-E

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Office of
FOIA Services

FOIA / PA Officer John Livornese
U.S. Securities & Exchange Commission
FOIA Office
100 F Street NE, Mail Stop 5100
Washington, DC 20549

February 6, 2018

Dear Mr. Livornese:

I request pursuant to the Freedom of Information Act (FOIA) 5 U.S.C. § 552. As Amended by Public Law No. 104-231, 110 Stat. 3048, copies of the following agreement.

Exhibit 10.85 to Form 8-K/A filed on 07/03/2002 by Incara Pharmaceuticals Corp.

Exhibit Title: Development & Option Agreement

CIK: 936538

RoyaltyStat will pay up to \$61 for research, copies and review fees for all of the abovementioned agreements. Please forward all releasable material for copying. My daytime telephone number is 202-798-8809. Please call me or e-mail at accounts@royaltystat.com to discuss the total cost or estimated cost of this research/copies should the amount exceed the price indicated in this request.

Sincerely,

Marcia Coutinho
Manager
RoyaltyStat LLC
6931 Arlington Rd. # 580



UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
STATION PLACE
100 F STREET, NE
WASHINGTON, DC 20549-2465

Office of FOIA Services

February 12, 2018

Ms. Marcia Coutinho
RoyaltyStat, LLC
6931 Arlington Road, Suite 580
Bethesda, MD 20814

RE: Freedom of Information Act (FOIA), 5 U.S.C. § 552
Request No. 18-02357-E

Dear Ms. Coutinho:

This letter is in response to your request, dated and received in this office on February 06, 2018, for a copy of Exhibit 10.85, to the Form 8-K/A, filed by Incara Pharmaceuticals Corp. on July 3, 2002.

The search for responsive records has resulted in the retrieval of the above-requested exhibit, totaling 45 pages of records that may be responsive to your request. They are being provided to you with this letter.

If you have any questions, please contact me at wadeo@sec.gov or (202) 551-8323. You may also contact me at foiapa@sec.gov or (202) 551-7900. You also have the right to seek assistance from Ray J. McInerney as a FOIA Public Liaison or contact the Office of Government Information Services (OGIS) for dispute resolution services. OGIS can be reached at 1-877-684-6448 or Archives.gov or via e-mail at ogis@nara.gov.

Sincerely,

A handwritten signature in black ink that reads "Ollie R. Wade".

Ollie R. Wade
FOIA Research Specialist

Enclosures

Exhibit 10.85

Portions of this exhibit marked [] are requested to be treated confidentially.

Execution Copy

DEVELOPMENT AND OPTION AGREEMENT

BETWEEN

ELAN PHARMA INTERNATIONAL LIMITED

AND

INCARA PHARMACEUTICALS CORPORATION

AND

AEOLUS PHARMACEUTICALS, INC.

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THIS AGREEMENT dated May 2002

between:

- (1) **ELAN PHARMA INTERNATIONAL LIMITED**, a public limited company incorporated under the laws of Ireland, and having its registered office at WIL House, Shannon Business Park, Shannon, County Clare, Ireland ("EPIL");
- (2) **INCARA PHARMACEUTICALS CORPORATION**, a Delaware corporation, having its office at 79 T.W. Alexander Drive, 4401 Research Commons, Suite 200, Research Triangle Park, North Carolina 27709; and
- (3) **AEOLUS PHARMACEUTICALS, INC.**, a Delaware corporation, having its office at 79 T.W. Alexander Drive, 4401 Research Commons, Suite 200, Research Triangle Park, North Carolina 27709

RECITALS:

- A Incara and Aeolus are beneficially entitled to the use of various patents, which have been granted or are pending under the International Convention in relation to the development and production of drug specific dosage forms for pharmaceutical products and processes.
- B Incara, Aeolus and EPIL wish to cooperate in the research, development and commercialisation of a series of catalytic antioxidant compounds developed and licensed by Aeolus for a number of indications and routes of administration.
- C Incara and Aeolus have agreed to grant EPIL the option described in Clause 6.

NOW, IT IS HEREBY AGREED AS FOLLOWS in consideration of the mutual covenants contained herein:

1 DEFINITIONS

For the purposes of this Agreement, the following terms shall have the respective meanings set forth below:

"Aeolus" shall mean Aeolus Pharmaceuticals, Inc., a Delaware corporation.

"Affiliate" shall mean a corporation or entity controlling, controlled by, or under the common control with EPIL or Incara and Aeolus, as the case may be, excluding, in the case of EPIL, an Elan JV. For the purposes of this Agreement, "control" shall

mean the direct or indirect ownership of more than 50% of the issued voting shares or other voting rights of the subject entity to elect directors, or if not meeting the preceding criteria, any entity owned or controlled by or owning or controlling at the maximum control or ownership right permitted in the country where such entity exists.

"Albany" shall mean Albany Molecular Research, Inc.

"Albany Agreement" shall mean a research and manufacturing agreement between Aeolus Pharmaceuticals, Inc. and Albany dated 4 August 1995.

"cGCP, cGMP, cGLP" shall mean respectively current Good Clinical Practice, current Good Manufacturing Practice and current Good Laboratory Practice as defined in the Federal Food, Drug and Cosmetic Act and the regulations promulgated thereunder, as may be amended from time to time, and/or equivalent laws and regulations in other countries of the Territory, as applicable.

"Claims" shall mean all and any claims (whether successful or otherwise), loss, liability, damages and expenses, including reasonable attorneys' fees and expenses and legal costs.

"Commencement Date" shall have the meaning assigned thereto in Clause 2.2.

"Common Stock" shall have the same meaning as defined in the Securities Purchase Agreement.

"Compounds" shall mean AEOL [10113] and AEOL [10150] and any additional catalytic antioxidant compounds and/or related compounds that are described by the Developer Patents. * *

"Confidential Information" shall mean know-how, trade secrets, inventions (including patent applications covering such inventions), data, information, and any improvements, modifications, derivations, or compilations thereto that is owned, licensed by or controlled by the disclosing party, provided however, that Confidential Information shall not include any information which is:

- (i) already known to the receiving party at the time of disclosure, as evidenced by such party's written records, provided such information was not obtained directly or indirectly by the receiving party from the disclosing party pursuant to a confidentiality agreement;

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- (ii) publicly known prior to or after disclosure, through no default of the receiving party;
- (iii) disclosed in good faith to the receiving party by a third party, lawfully and contractually entitled to make such disclosure; or
- (iv) is independently discovered without the aid or application of the Confidential Information as shall be evidenced by the written records of the receiving party.

“Developer” shall mean Incara and Aeolus and any of their respective Affiliates.

“Developer Intellectual Property” shall mean the Developer Patents, Developer Know-How and Developer Improvements.

“Developer Improvements” shall mean any and all improvements to the Developer Patents, Developer Know-How and/or Compounds that have been conceived, created, developed and/or otherwise invented solely by, or by a third party on behalf of, the Developer in the course of the Development Plan.

In addition Developer Improvements shall include improvements to the Developer Patents, the Developer Know-How and/or the Compounds conceived, created, developed and/or otherwise invented by Developer outside the Development Plan, except as limited by agreements with third parties.

If the inclusion of any Developer Improvement in the EPIL Sub-Licence is restricted or limited by a third party agreement, Developer shall use reasonable commercial efforts to minimize any such restriction or limitation.

“Developer Know-How” shall mean any and all rights owned, licensed or controlled by the Developer to any scientific, pharmaceutical or technical information, data, discovery, invention (whether patentable or not), know-how, substances, techniques, processes, systems, formulations, designs and expertise relating to the Compounds which is not generally known to the public.

“Developer Patents” shall mean any and all rights under any and all patent applications and/or patents, now existing, currently pending or hereafter filed or obtained or licensed by Developer relating to the Compounds examples of which are as set forth in Schedule 1, and any foreign counterparts thereof and all divisionals, continuations, continuations-in-part, any foreign counterparts thereof and all patents issuing on any of the foregoing, and any foreign counterparts thereof, together with all registrations, reissues, re-examinations, supplemental protection certificates, or extensions thereof, and any foreign counterparts thereof.

“Development Plan” shall have the meaning set out in Clause 2.1

“Developer Licence Agreements” shall mean the First Duke Agreement, the Second Duke Agreement, the Third Duke Agreement, the National Jewish Agreement and the Albany Agreement.

“Duke Consent” shall mean the consent of Duke University to the EPIL Sub-Licence and certain other matters pursuant to the First Duke Agreement and the Second Duke Agreement and the Third Duke Agreement by letter of consent of Duke University dated 14 May 2002, and the agreement by Duke University to certain amendments to the First Duke Agreement and the Second Duke Agreement by way of amendment agreements between Duke University and Aeolus each dated 14 May 2002 copies of which are attached at Schedule 4.

“Effective Date” shall mean the date of this Agreement.

“Elan JV” shall mean an entity that Elan Corporation, plc and a third party (i) establish or have established, (ii) take shareholdings in or have a right to take shareholdings in, and (iii) grant certain licenses in and to certain intellectual property rights for the purpose of implementing a strategic alliance.

“EPIL Improvements” shall mean any and all rights to any scientific, pharmaceutical or technical information, data, discovery, invention (whether patentable or not), know-how, substances, techniques, processes, systems, formulations, designs and expertise generated by, or by a third party on behalf of, EPIL or jointly by EPIL and Developer in the course of the Development Plan.

“EPIL Sub-Licence” shall have the meaning set out in Clause 6.1.

“EU” shall mean the Member States of the European Union, as same may change from time to time in terms of Member States.

“Field” shall mean prevention and treatment of radiation-induced and chemotherapy-induced tissue damage.

“First Duke Agreement” shall mean a licence agreement between Duke University and Aeolus dated 21 July 1995 and any amendments thereto.

“First Phase I Milestone” shall mean the completion of dosing of patients for a Phase I clinical trial for the Milestone Compound in the Field. Completion of dosing shall mean that an agreed number of patients have completed the dosing schedule as outlined in the Development Plan and the Steering Committee has approved in writing the completion of such dosing.

“First Phase II Milestone” shall mean the completion of the enrolment of the Phase II clinical trial for the Milestone Compound in the Field. Enrolment shall mean that an

agreed number of patients have been enrolled as outlined in the Development Plan and the Steering Committee has approved in writing such enrolment.

"IND" shall mean Investigational New Drug Application as set forth in the CFR Section 312 and/or its equivalent in the other countries of the Territory.

"IND Milestone" shall mean the occurrence and/or the achievement of all of the following:

- (i) US FDA acceptance of an IND filing with respect to the Milestone Compound; and,
- (ii) the approval by EPIL of the Phase I plan prepared by Developer with respect to the Milestone Compound; and
- (iii) an affirmative decision by the Steering Committee to proceed with initiation of dosing in the first Phase I clinical trial for the Milestone Compound in the Field in accordance with the Development Plan.

"IND Milestone Purchase" shall mean the purchase by EPIL following the occurrence of the IND Milestone of US\$[500,000] of shares of Series B Preferred Stock from Incara in accordance with and subject to the terms of the Securities Purchase Agreement. *

"In Market" shall mean the sale of the Compounds and/or Products in the Territory by the Developer or an Affiliate of the Developer, to an unaffiliated third party, such as a wholesaler, distributor, managed care organisation, hospital or pharmacy which effects the final commercial sale to the end-user consumer of the Compounds and/or Products, and shall exclude the transfer pricing of such Compounds and/or Products by one Developer Affiliate to another Developer Affiliate.

"Milestone" shall mean any of the IND Milestone, First Phase I Milestone, Second Phase I Milestone and Second Phase II Milestone.

"Milestone Compound" shall mean the first of the Compounds in respect of which the US FDA accept an IND filing. The Steering Committee may substitute another Compound as the Milestone Compound. Any required amendments to the Development Plan to accommodate such substitute Milestone Compound must be approved in writing in advance by the Steering Committee.

"National Jewish Agreement" shall mean a licence agreement between National Jewish Medical and Research Center and Aeolus dated 17 November 2000 and any amendment thereto.

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“National Jewish Consent” shall mean the consent of National Jewish Medical and Research Center to the EPIL Sub-Licence and certain other matters pursuant to the National Jewish Agreement by letter of consent of National Jewish Medical and Research Center dated 14 May 2002, and the agreement by National Jewish Medical and Research Center to certain amendments to the National Jewish Agreement by way of amendment agreement between National Jewish Medical and Research Center and Aeolus dated 14 May 2002, copies of which are attached at Schedule 5.

“Net Sales” shall mean in the case of Compounds and/or Products sold by Developer, the aggregate gross In Market sales proceeds billed for Compounds and/or Products by Developer in accordance with generally accepted accounting principles, less the following:-

- (i) customs and excise duties or other sales taxes (but (for the avoidance of doubt) not income or corporation tax), directly related to the sale of Compounds and/or Products in the Territory which are actually paid by Developer;
- (ii) such normal costs as are incurred by Developer in respect of industry standard transport, shipping and insurance costs; and industry standard or mandatory discounts or rebates directly related to the sale of the Compounds and/or Products in the Territory; and
- (iii) amounts repaid or credited by Developer, or by a permitted sub-licensee, as the case may be, consistent with its normal business practices for similar compounds and/or products, by reason of the rejection or return of goods.

“Net Revenues” shall mean all income received by the Developer in respect of the commercialisation of the Compounds and/or Products, including, but not limited to the following:

- (i) any royalties, license grant fees, sub-licence fees, milestone payments;
- (ii) any R&D funding payments [where such payments are made other than for reimbursement of direct expenses incurred by the Developer and other than on an FTE rate based on then current standard industry rates; where such payments are made other than on an FTE rate based on then current standard industry rates, the surplus over the current industry standard FTE rates shall be included in the calculation of Net Revenues];
- (iii) [any profits from manufacturing];

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- (iv) [any premium paid by a subscriber for stock over the average closing price of the Common Stock (or any other stock of the Developer) for the thirty (30) trading day period immediately prior to any such subscription].

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For the avoidance of doubt, "Net Revenues" shall exclude any funding provided by EPIL by way of capital contribution, subscription for share capital or otherwise.

"Phase I Report" shall mean a report detailing the results and conclusions of the Phase I clinical trials for the Milestone Compound in the Field and which report shall be referenced to the Development Plan and shall include, but shall not be limited to, those matters set out in Schedule 6.

"Phase II Report" shall mean a report detailing the results and conclusions of the Phase II clinical trials for the Milestone Compound in the Field and which report shall be referenced to the Development Plan and shall include, but shall not be limited to, those matters set out in Schedule 6.

"Preliminary Milestone" shall have the same meaning as that term is defined in the Securities Purchase Agreement.

"Products" shall mean any products that include the Compounds, and any formulations thereof.

"Second Duke Agreement" shall mean a licence agreement between Duke University and Aeolus dated 25 June 1998.

"Second Phase I Milestone" shall mean the occurrence and/or the achievement of all of the following:

- (i) the approval by the Steering Committee of the Phase I Report; and
- (ii) the approval by EPIL of the Phase II plan prepared by Developer with respect to the Milestone Compound; and
- (iii) the affirmative decision of the Steering Committee to proceed with a Phase II clinical trial for the Milestone Compound in the Field in accordance with the Development Plan.

"Second Phase I Milestone Purchase" shall mean the purchase by EPIL following the occurrence of the Second Phase I Milestone of US\$[1,000,000] of shares of Series B Preferred Stock from Incara in accordance with and subject to the terms of the Securities Purchase Agreement.

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"Second Phase II Milestone" shall mean the occurrence and/or the achievement of the following:

- (i) completion of a Phase II clinical trial for the Milestone Compound in the Field; and
- (ii) the approval by the Steering Committee of the Phase II Report.

"Second Phase II Milestone Purchase" shall mean the purchase by EPIL following the occurrence of the Second Phase II Milestone of US\$[1,000,000] of shares of Series B Preferred Stock from Incara in accordance with and subject to the terms of the Securities Purchase Agreement. *

"Securities Purchase Agreement" shall mean the Securities Purchase Agreement dated the date of this Agreement between EPIL, Incara and Aeolus.

"Series B Preferred Stock" shall have the same meaning as that term is defined in the Securities Purchase Agreement.

"Technological Competitor of EPIL" shall mean any of those entities listed on Schedule 3 attached hereto.

"Third Duke Agreement" shall mean a licence agreement between Duke University and Aeolus dated 7 May 2002.

"Third Party Sub-Licensee" shall mean any sub-licensee appointed by the Developer (other than EPIL) to import, make, use, offer for sale, and sell the Compounds and/or Products in the Territory in the Field.

"Territory" shall mean all countries of the world.

"US FDA" shall mean the United States Food and Drug Administration or any other successor agency whose approval is necessary to market the Compounds and/or Product in the USA.

"US\$" shall mean U.S. dollars.

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2 RESEARCH AND DEVELOPMENT ACTIVITY

- 2.1 Within 60 days of the Effective Date, the Steering Committee (as defined in Clause 3.1) shall approve a development plan that shall contain, among other things, to the extent practicable, the research and development objectives, compound specifications, plans for preparation of IND filing, clinical indications, preliminary clinical trial designs (Phase I and Phase II), development timelines and budgeted costs with regard to the development of the Compounds in the Field in the Territory (the "**Development Plan**") and the relative responsibilities of Developer and EPIL as it relates to the implementation of the Development Plan.

Each of Developer and EPIL shall use commercially reasonable efforts to carry out their respective tasks under the Development Plan within the timeframe contained therein.

Developer shall perform the Development Plan in accordance with cGMP and cGLP.

- 2.2 The Steering Committee, shall agree in writing on a commencement date for the Developer's activities under the Development Plan ("**Commencement Date**"), which date shall not be later than July 30, 2002.
- 2.3 Developer shall promptly notify the Steering Committee and EPIL of any deviations from the Development Plan or delays in the performance of the Development Plan.
- 2.4 Within 5 business days of the Effective Date, the Developer shall designate one research employee as technical liaison to handle technical matters and communications relating to the Development Plan. Such research employee may be substituted by another research employee at any time upon written agreement of the Steering Committee.
- 2.5 The Development Plan to be conducted by Developer shall be completed when the Second Phase II Milestone has been achieved.
- 2.6 During the term of this Agreement:
- 2.6.1 each party shall co-operate with the other in good faith particularly with respect to unforeseen events or contingencies; and
- 2.6.2 save where the Developer has appointed a sub-contractor in accordance with Clause 15.4, the Developer shall furnish, maintain and preserve suitable and sufficient laboratory facilities, equipment and personnel for the work to be done by it; and
- 2.6.3 the Developer shall perform its obligations in good faith hereunder in a commercially reasonable, diligent and workmanlike manner.

- 2.7 Any amendments to the Development Plan shall require the prior written approval of the Steering Committee.
- 2.8 The Steering Committee shall review the Development Plan following the occurrence of each Milestone and make any amendments as the Steering Committee deems necessary.

3 STEERING COMMITTEE AND PROJECT MANAGEMENT

- 3.1 Within 30 days of the Effective Date, the parties will establish a steering committee ("Steering Committee"), which shall consist of personnel from each party who are appropriately skilled and knowledgeable in relation to the Development Plan and who are deemed necessary to accomplish and oversee the work of the Development Plan.

The Steering Committee shall have an equal number of members from each of the parties and the total size of the Steering Committee shall not exceed 6 people .

- 3.2 Unless otherwise agreed by the parties:
 - 3.2.1 the Steering Committee shall meet at least once every two months, such meetings to continue throughout the Term (as defined in Clause 12.1), at such location as the parties may agree or by telephone conference;
 - 3.2.2 at any such meeting, the presence of two EPIL members and two Developer members shall be required to constitute a quorum and, the unanimous vote of those members present at a meeting at which such a quorum is present shall constitute an action or approval of the Steering Committee;
 - 3.2.3 meetings shall be chaired alternately by representatives of the parties;
 - 3.2.4 each party shall be responsible for its own costs in respect of travel and accommodation expenses in attending meetings of the Steering Committee;
 - 3.2.5 at and between meetings of the Steering Committee, each party shall keep the other fully and regularly informed as to its progress with its respective tasks and obligations under the Development Plan.
 - 3.2.6 if the Steering Committee is unable to agree on a matter connected with the Development Plan it shall be referred to the CEO of the Developer and a senior executive of EPIL and thereafter, in the event of continued deadlock, the dispute shall be referred to an expert in pharmaceutical product development and marketing (including clinical development and regulatory affairs) jointly selected by the designated senior officers of each of EPIL and the Developer, provided that the decision of such expert will ultimately be non-binding on the parties.

- 3.3 Developer must submit to all members of the Steering Committee the Phase I Report and the Phase II Report as soon as each report becomes available. Without prejudice to EPIL's entitlement through its representatives on the Steering Committee to approve or not approve the Phase I Report or the Phase II Report, an EPIL representative on the Steering Committee shall use reasonable efforts to notify the Steering Committee within [45 days] of receipt of such reports if EPIL believe any issues or deficiencies arise in relation to such reports. *
- 3.4 The Steering Committee shall, by unanimous agreement, be responsible for determining Developer's strategy as regards the conduct of any clinical trials with respect to the development of the Compounds and/or Products in the Field. Any agreement between Developer and any independent third party relating to the conduct of any clinical trial in support of the development of the Compounds and/or Products in the Field shall require the prior approval of the Steering Committee, which approval shall not be unreasonably withheld or delayed.
- 3.5 Developer shall keep the Steering Committee promptly and fully advised of Developer's regulatory activities, progress and procedures. Developer shall inform Steering Committee of any dealings it shall have with a regulatory authority, and shall furnish EPIL with copies of all correspondence relating to the Compounds and/or Products.
- Developer shall provide Steering Committee with reasonable prior notice of all meetings between the Developer and any regulatory authority relating to the Compounds and/or the Products in the Field and an EPIL representative on the Steering Committee shall be entitled to attend any such meeting. The Developer shall make available to the Steering Committee the minutes of any such meetings.
- 3.6 The Steering Committee shall be responsible for ensuring that the Developer's regulatory activities in relation to the Compounds and/or Products in the Field comply in full with the Development Plan and the Steering Committee will inform Developer of any proposals it may have to ensure full compliance therewith. Developer shall use best efforts to comply with and implement any such proposals from the Steering Committee.

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4 NON-COMPETITION

- 4.1 During the Option Period (as defined in Clause 6.1) Developer shall not research, develop, market or otherwise commercialise the Compounds in the Field in the Territory other than in accordance with this Agreement.
- 4.2 Nothing in this Agreement shall prevent the Developer, either alone or in association with a co-development partner or sub-licensee, from licensing, developing or commercialising any of the Compounds or derivatives thereof or Products outside the Field.

However, in the event of such development or commercialisation, Developer shall to the extent that the Developer is not legally prohibited from doing so inform EPIL of any information discovered and of the progress of such development or commercialisation programmes which may have an impact on, or be capable of assisting in, the development of the Compounds in the Field.

Prior to providing any such information to EPIL, Developer shall notify EPIL so that it may consult with its patent attorneys prior to any such receipt of information to consider any issues that may arise.

5 PAYMENTS

- 5.1 EPIL shall make purchases of shares of Series B Preferred Stock from Incara in accordance with and subject to the terms set out in the Securities Purchase Agreement.
- 5.2 Any income or other taxes on any monies payable to Developer which EPIL is required by law to pay or withhold on behalf of Developer, shall be deducted by EPIL from such monies due. EPIL shall furnish Developer with proof of such payments. Any such tax required to be paid or withheld shall be an expense of and borne solely by Developer. EPIL shall promptly provide Developer with a certificate or other documentary evidence to enable Developer to support a claim for a refund or a foreign tax credit with respect to any such tax so withheld or deducted by EPIL. At Developer's request, EPIL reasonably cooperate to support any claim by Developer for such a refund or credit.

6. COMMERCIALIZATION OPTION

6.1 From the Effective Date until [180 days] after the occurrence of the Second Phase II Milestone Purchase (the "**Option Period**"), Developer shall grant EPIL an exclusive option (the "**Licence Option**") to conclude an exclusive, sub-licensable sub-licence and supply agreement whereby Developer would grant EPIL a sub-licence to the Developer Patents, the Developer Know-How and the Developer Improvements to import, make, use, offer for sale, and sell the Compounds and/or Products in the Territory in the Field on terms to be agreed in good faith on the basis of the [non-legally binding] heads of agreement set out in Schedule 2 (the "**EPIL Sub-Licence**").

*

*

6.2 If EPIL does not exercise the Licence Option, EPIL shall be entitled to elect to negotiate in good faith exclusively with the Developer during the Option Period an alternate form of collaboration or commercialisation agreement such as, but not limited to, a co-promotion or co-marketing arrangement for the further development of the Compounds in the Field in the Territory.

6.3 For the avoidance of doubt, during the Option Period, Developer will not negotiate in any form, directly or indirectly, with any other corporation, entity or person in relation to the subject matter of Clause 6.1 and Clause 6.2, nor provide any information relating thereto to third parties, save with the prior consent in writing of EPIL.

6.4 If, despite good faith negotiations, EPIL and Developer do not reach agreement within the Option Period, then Developer shall be free, for a period of [12 months], thereafter to enter into negotiations with a third party (other than a Technological Competitor of EPIL) to agree terms upon which the third party would commercialise the Compounds in the Field in the Territory, provided that such terms when taken as a whole, are not more favourable to the third party than the principal terms of the last written proposal offered by Developer to EPIL or by EPIL to Developer, as the case may be.

*

Prior to entering into any such agreement with the third party, Developer shall promptly notify EPIL in writing of the principal terms of such proposed agreement and shall certify that the third party with whom Developer intends to contract is not a Technological Competitor of EPIL.

6.5 If Developer has not entered into an agreement with a third party for the Compounds within the Field within the [12 month] period described above the Licence Option shall be deemed to have re-commenced upon the same terms as set forth herein, after which, if EPIL and Developer have not reached an agreement within such recommenced Option Period, the Developer shall again have the rights set forth in Clause 6.4.

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7. REPORTS

7.1 Developer shall issue the following full and complete reports to the satisfaction of EPIL:

- 7.1.1 the Phase I plan;
- 7.1.2 report on the completion of dosing of patients for a Phase I clinical trial of the Milestone Compound in the Field;
- 7.1.3 the Phase I Report;
- 7.1.4 the Phase II plan;
- 7.1.5 report on the completion of enrolment of a Phase II clinical trial of the Milestone Compound in the Field;
- 7.1.6 report on the completion of dosing of a Phase II clinical trial of the Milestone Compound in the Field;
- 7.1.7 the Phase II Report;
- 7.1.8 An annual report detailing progress related to all the Compounds in the Field

8 DEVELOPER LICENCE AGREEMENTS

8.1 Developer shall be responsible for payments related to the financial provisions and obligations of the Developer Licence Agreements and of any third party agreement with respect to the Developer Intellectual Property to which it is a party on the Effective Date (including amendments thereto) (the "**Developer Effective Date Agreements**"), including without limitation, any royalty or other compensation obligations triggered thereunder on the Effective Date, or triggered thereunder after the Effective Date.

For the avoidance of doubt, royalties, milestones or other payments which arise from the process of the commercialisation or exploitation of Compounds or products that include the Compounds under the Developer Effective Date Agreements (for example, a milestone payment payable upon successful completion of Phase I or II clinical trials shall be payments for which Developer will be responsible under this Clause 8.1.

8.2 If, after the Effective Date, Developer:

- 8.2.1 licenses or otherwise acquires from a third party know-how or patent rights relating to the Developer Intellectual Property in the Field in the Territory; or

8.2.2 acquires or merges with a third party entity that has know-how or patent rights relating to the Developer Intellectual Property in the Field in the Territory;

("After Acquired Technology")

then Developer shall offer to license the After Acquired Technology to EPIL (subject to existing contractual obligations) solely to import, make, use, offer for sale and sell the Compounds and/or Products in the Field in the Territory.

EPIL shall notify Developer in writing as to whether EPIL wishes to license the After Acquired Technology within [120 days] after the date upon which an offer is made by Developer to EPIL hereunder. *

If notice in writing has not been received by Developer from EPIL within such [120 day] period, EPIL shall be deemed to have rejected Developer's offer hereunder. *

If EPIL notifies Developer hereunder that it wishes to license the After Acquired Technology, the parties shall negotiate the terms of the license agreement in good faith on commercially reasonable terms.

If EPIL does not accept Developer's offer hereunder, Developer agrees that it shall not use the After Acquired Technology to research, develop, market or otherwise commercialise the Compounds and/or the Products in the Field in the Territory.

- 8.3 During the Term, Developer shall not in any way amend, modify, or waive any of its rights under the Developer Licence Agreements, without the prior written approval of the Steering Committee.

For the avoidance of doubt, Developer shall not terminate any of its rights under the Developer Licence Agreements without the prior written approval of the Steering Committee.

- 8.4 Developer shall indemnify and hold harmless EPIL against all costs, claims and liabilities in respect of any claims or proceedings which may be taken by Duke University or National Jewish Medical and Research Center or Albany and/or by a third party beneficiary under the Developer Licence Agreements against EPIL which arise from the performance or non-performance by Developer of any of its obligations under the Developer Licence Agreements.

- 8.5 Developer hereby confirms to EPIL as follows:

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- 8.5.1 EPIL will not require the consent of Developer, Duke University or National Jewish Medical and Research Center or Albany or any other third party in order to assign the EPIL Sub-Licence or to grant a sub-license to any third party under the EPIL Sub-Licence. EPIL will inform the relevant parties 30 days in advance of any such proposed assignment, licence or sub-licence.
- 8.5.2 In the event of the termination of the Developer Licence Agreements after the exercise by EPIL of the Licence Option, the EPIL Sub-Licence, and any assignment, license or sub-licence granted by EPIL to any third party as described in Clause 8.5.1 shall continue in accordance with the provisions of the Developer Licence Agreements.
- 8.5.3 In the event of termination of the Developer Licence Agreements following the grant by Developer of an exclusive, fully paid up (except as provided in Clause 13.1.1) sub-licensable sub-licence to EPIL pursuant to Clause 13.1.1, such sub-licence shall continue in accordance with the terms of the Developer Licence Agreements.
- 8.6 Without prejudice to the generality of Clause 9, Developer hereby further confirms to EPIL as follows:
 - 8.6.1 Developer has obtained the consent of Duke University to the replacement throughout the First Duke Agreement and the Second Duke Agreement of the term "best efforts" with the term "commercially reasonable efforts" as set out in the Duke Consent.
 - 8.6.2 Developer has obtained the consent of National Jewish Medical and Research Center to the replacement throughout the National Jewish Agreement of the term "best efforts" with the term "commercially reasonable efforts" as set out in the National Jewish Consent.
 - 8.6.3 Developer has obtained the consent of Duke University and National Jewish Medical and Research Center to amend Article 6.01 of each of the First Duke Agreement, Second Duke Agreement, Third Duke Agreement and National Jewish Agreement and Article 6.02 of each of the First Duke Agreement, Second Duke Agreement and National Jewish Agreement, as set out in the Duke Consent and the National Jewish Consent.

9 WARRANTIES

- 9.1 Developer (jointly and severally) represents and warrants to EPIL as of the Effective Date, as follows:
 - 9.1.1 Developer has the right to enter into this Agreement;

- 9.1.2 Developer has the right to grant the EPIL Sub-Licence and has obtained the Duke Consent and any other consents required including the consent of National Jewish Medical Center and Albany to the extent necessary to enter into this Development and Option Agreement and perform all its obligations set forth herein;
- 9.1.3 there are no agreements between Developer and any third party that conflict with this Agreement or with the Developer's right to grant the EPIL Sub-Licence, or that conflict with any rights granted by Developer to EPIL hereunder or any obligations undertaken by Developer to EPIL hereunder;
- 9.1.4 for the avoidance of doubt, the National Jewish Agreement does not contain any provisions that conflict with the Developer's right to grant the EPIL Sub-Licence;
- 9.1.5 there are no proceedings threatened or pending against Developer in connection with the Developer Intellectual Property in relation to the Field and that to the best of Developer's knowledge, Developer Patents are valid and enforceable or are likely to issue and be valid and enforceable or are likely to issue with regard to claims necessary for performance under this Agreement and such claims are likely to be valid and enforceable and be of sufficient scope to warrant investment in the development of the Compounds and/or Products in the Field as prescription pharmaceuticals;
- 9.1.6 to the best of Developer's knowledge, there is no patent or patent application of others which contains claims that dominate the Developer Patents.
- 9.2 Developer further agrees and represents and warrants to EPIL as follows:
 - 9.2.1 as of the Effective Date, the Developer Licence Agreements are valid and in full force and effect;
 - 9.2.2 as of the Effective Date, there are no existing or claimed defaults by Developer, and to Developer's best knowledge by Duke University or the National Jewish Medical and Research Center or Albany, under the Developer Licence Agreements and no event, act or omission has occurred which (with or without notice, lapse of time or the happening or occurrence of any other event) would result in a default under the Developer Licence Agreements by Developer, or to Developer's best knowledge by Duke University or the National Jewish Medical and Research Center or Albany;
 - 9.2.3 during the Term, Developer will fully comply with all of the terms and conditions of the Developer Licence Agreements. Developer, will enforce its rights under the Developer Licence Agreements and Developer will not assign its rights under the Developer Licence Agreements; and

- 9.2.4 during the Term, Developer will keep EPIL fully informed with respect to Developer's transactions, arrangements and business under the Developer Licence Agreements that relate to EPIL and/or the transactions contemplated hereunder, and Developer shall provide EPIL with any written notices delivered by Developer and/or Duke University or National Jewish Medical and Research Center or Albany thereunder that relate to EPIL and/or the transactions contemplated hereunder, or that may affect EPIL, including any proposals by Duke University or National Jewish Medical and Research Center to make any publications under the Developer Licence Agreements.

10 INDEMNIFICATION

- 10.1 In addition to any other indemnities provided for in this Agreement, Developer shall indemnify and hold harmless EPIL and its Affiliates and their respective employees, agents, officers and directors from and against any Claims incurred or sustained by EPIL arising out of or in connection with any:
- 10.1.1 breach of any representation, covenant, warranty or obligation by Developer hereunder; or
 - 10.1.2 negligent or wilful act or omission or failure to comply with applicable laws and regulations on the part of Developer or any of its respective employees, agents, officers and directors in the performance of this Agreement.
- 10.2 Developer shall further indemnify and hold harmless EPIL and its Affiliates and their respective employees, agents, officers and directors against all Claims made or brought against such a person to which the other party may become liable:
- 10.2.1 seeking damages for personal injury (including death) and/or for costs of medical treatment, caused or attributed to the Compounds;
 - 10.2.2 based upon an allegation that the manufacture, importation, use, offer for sale, sale or other commercialisation of the Compounds or Products infringe or misappropriate any third party's intellectual property rights; or
 - 10.2.3 caused by the use of the Compounds in humans in clinical trials or otherwise.
- 10.3 In addition to any other indemnities provided for herein, EPIL shall indemnify and hold harmless Developer and its Affiliates and their respective employees, agents, officers and directors from and against any Claims incurred or sustained by Developer arising out of or in connection with any:
- 10.3.1 breach of any representation, covenant, warranty or obligation by EPIL hereunder; or

10.3.2 negligent or wilful act or omission on the part of EPIL or any of its agents or employees in the performance of this Agreement;

in each case save to the relative extent that such Claim is attributable to Developer's negligence or wilful misconduct.

10.4 The party seeking an indemnity shall:

10.4.1 fully and promptly notify the other party of any claim or proceedings, or threatened claim or proceedings;

10.4.2 permit the indemnifying party to take full control of such claim or proceedings, with counsel of the indemnifying party's choice, provided that the indemnifying party shall reasonably and regularly consult with the indemnified party in relation to the progress and status of such claim or proceedings;

10.4.3 co-operate in the investigation and defence of such claim or proceedings; and

10.4.4 take all reasonable steps to mitigate any loss or liability in respect of any such claim or proceedings.

Save as aforesaid, neither the indemnifying party nor the party to be indemnified shall acknowledge the validity of, compromise or otherwise settle any Claim without the prior written consent of the other, which shall not be unreasonably withheld.

10.5 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, ELAN AND DEVELOPER SHALL NOT BE LIABLE TO THE OTHER BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE (WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE) AND WHETHER OCCASIONED BY THE NEGLIGENCE OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE.

10.6 Developer shall maintain product liability insurance in relation to the Compounds, Products and this Agreement of at least US\$[5,000,000] for the duration of this Agreement and for a period of [5 years] thereafter. Prior to commencing any clinical trials in relation to the Compounds and/or Products in the Field, Developer shall

*
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increase its product liability insurance (and any other insurances necessary in relation to clinical trials) in relation to the Compounds, Products and this Agreement and any clinical trials conducted by the Developer pursuant to this Agreement to US\$[10,000,000] for the remaining term of this Agreement and for a period of [5 * years] thereafter. *

Developer shall provide EPIL with a certificate from the insurance company verifying the above and shall notify the other party in writing at least 30 days prior to the expiration or termination of such coverage.

11 INTELLECTUAL PROPERTY

- 11.1 Developer shall remain the owner of the Developer Patents, the Developer Know-How and the Developer Improvements.
- 11.2 EPIL shall be the owner of any EPIL Improvements.
- 11.3 Each of the parties shall promptly notify the other party in writing of any claim or proceedings made against either of them alleging infringement or other unauthorised use of the proprietary rights of a third party arising from the manufacture, importation, use, offer for sale, sale or other commercialisation of the Compounds in the Territory.
- 11.4 The parties acknowledge the provisions of Clause 10.4.2.
- 11.5 Developer shall:
 - 11.5.1 secure the grant of any patent applications within the Developer Patents in major markets as agreed to by the Steering Committee but which shall not be less than the US, EU, Canada, Mexico, and Japan;
 - 11.5.2 file and prosecute patent applications on patentable inventions and discoveries relating to the same in such countries;
 - 11.5.3 defend all such applications against third party oppositions in such countries; and
 - 11.5.4 maintain in force any issued letters patent that relate to the same in such countries.

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- 11.6 Developer shall discuss the filing, defending, and prosecuting strategy for any proposed patents and patent application(s) with EPIL and shall co-ordinate the filing, defending, and prosecuting of such patent application(s) between the two parties in order to protect the intellectual property rights of both parties.
- 11.7 After the exercise of the Licence Option, in the event that Developer declines to file, prosecute or maintain an application or patent, EPIL shall upon thirty days written notice to the Developer have the right to file, prosecute, or maintain such application or patent at its own expense at which time such application or patent shall be assigned to EPIL.

Provided that the ownership rights of any party other than the Developer in respect of the subject matter of any such patent application shall not be assigned to EPIL but shall remain with the owner on record as of the Effective Date where contractual or other legally binding restrictions prohibit Developer from assigning such ownership rights to EPIL.

12 TERM AND TERMINATION

- 12.1 This Agreement shall come into force on the Effective Date and, subject to Clause 15.10, shall remain in effect until the expiry of the Option Period (the "Term"), unless EPIL has earlier terminated the agreement in accordance with Clause 12.2 below.

- 12.2 EPIL shall be entitled to terminate this Agreement at any time by serving [30 days] written notice on the Developer. *

- 12.3 In addition to the rights of termination provided for elsewhere in this Agreement, either party shall be entitled forthwith to terminate this Agreement by written notice to the other party if:

12.3.1 that other party commits any material breach of any of the provisions of this Agreement or of the Securities Purchase Agreement, and in the case of a breach capable of remedy, fails to cure the same within 60 days after receipt of a written notice giving full particulars of the breach and requiring it to be cured; or

12.3.2 that other party goes into liquidation (except for the purposes of amalgamation or reconstruction and in such manner that the company resulting therefrom effectively agrees to be bound by or assume the obligations imposed on that other party under this Agreement); or

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12.3.3 an encumbrancer takes possession or a receiver is appointed over any of the property or assets of that other party ; or

12.3.4 any proceedings are filed or commenced by that other party under bankruptcy, insolvency or debtor relief laws or anything analogous to any of the foregoing under the laws of any jurisdiction occurs in relation to that other party.

For the purposes of Clause 12.3.1, a breach will be considered capable of being cured if the party in breach can comply with the provision in question in all respects other than as to the time of performance (provided that time of performance is not of the essence).

13 CONSEQUENCES OF TERMINATION

13.1 If EPIL terminates this Agreement pursuant to Clause 12.3 the following shall occur:

13.1.1 upon EPIL's election, the Developer shall grant to EPIL an exclusive, fully paid up (except as provided below), sub-licensable sub-licence to the Developer Patents, the Developer Know-How and the Developer Improvements to import, make, use, offer for sale, and sell the Compounds and/or Products in the Territory in the Field;

[in this event, EPIL] shall be liable to Duke University and National Jewish Medical and Research Center and Albany for any and all royalty and milestone obligations under the Developer Licence Agreements which may become due to such parties [following the date upon which the sublicense described herein is granted to EPIL by the Developer provided that, for the avoidance of doubt], the Developer shall be liable for all accrued obligations under the Developer Licence Agreements [up to such date pursuant to Clause 8.4. EPIL] shall remit any such royalties to Duke University and National Jewish Medical and Research Center and Albany as the case may be;

13.1.2 in addition to the grant of the sub-licence under clause 13.1.1, if the Developer has appointed a Third Party Sub-Licensee outside the Field the following shall occur:

13.1.2.1 if EPIL terminates prior to making the IND Milestone Purchase, Developer shall be obliged to pay to EPIL [1.25]% of Net Revenues outside the Field;

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- 13.1.2.2 if EPIL terminates after making the IND Milestone Purchase but prior to making the Second Phase I Milestone Purchase, Developer shall be obliged to pay to EPIL [3]% of Net Revenues outside the Field; *
- 13.1.2.3 if EPIL terminates after making the Second Phase I Milestone Purchase but prior to making the Second Phase II Milestone Purchase, Developer shall be obliged to pay to EPIL [7.5]% of Net Revenues outside the Field. *
- 13.1.3 in addition to the grant of the sub-licence under clause 13.1.1, if the Developer has not appointed a Third Party Sub-Licensee outside the Field the following shall occur:
 - 13.1.3.1 if EPIL terminates prior to making the IND Milestone Purchase, Developer shall be obliged to pay to EPIL [0.2]% of Net Sales outside the Field; *
 - 13.1.3.2 if EPIL terminates after making the IND Milestone Purchase but prior to making the Second Phase I Milestone Purchase, Developer shall be obliged to pay to EPIL [0.6]% of Net Sales outside the Field; *
 - 13.1.3.3 if EPIL terminates after making the Second Phase I Milestone Purchase but prior to making the Second Phase II Milestone Purchase, Developer shall be obliged to pay to EPIL [1]% of Net Sales outside the Field. *
- 13.2 If EPIL terminates this Agreement pursuant to Clause 12.2 and the Developer has appointed a Third Party Sub-Licensee, the following shall occur:
 - 13.2.1 if EPIL terminates prior to making the IND Milestone Purchase, Developer shall be obliged to pay to EPIL [1.25]% of Net Revenues inside the Field; *
 - 13.2.2 if EPIL terminates after making the IND Milestone Purchase but prior to making the Second Phase I Milestone Purchase, Developer shall be obliged to pay to EPIL [3]% of Net Revenues inside the Field; *
 - 13.2.3 if EPIL terminates after making the Second Phase I Milestone Purchase but prior to making the Second Phase II Milestone Purchase, Developer shall be obliged to pay to EPIL [7.5]% of Net Revenues inside the Field. *

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13.3 If EPIL terminates this Agreement pursuant to Clause 12.2 and the Developer has not appointed a Third Party Sub-Licensee, the following shall occur:

13.3.1 if EPIL terminates prior to making the IND Milestone Purchase, Developer shall be obliged to pay to EPIL [0.5]% of Net Sales inside the Field; *

13.3.2 if EPIL terminates after making the IND Milestone Purchase but prior to making the Second Phase I Milestone Purchase, Developer shall be obliged to pay to EPIL [1]% of Net Sales inside the Field; *

13.3.3 if EPIL terminates after making the Second Phase I Milestone Purchase but prior to making the Second Phase II Milestone Purchase, Developer shall be obliged to pay to EPIL [1.5]% of Net Sales inside the Field. *

13.4 If Developer terminates this Agreement pursuant to Clause 12.3, the Licence Option shall terminate.

14 CONFIDENTIAL INFORMATION/ANNOUNCEMENTS

14.1 Upon execution of this Agreement, and thereafter during the term hereof, at such times as the parties shall mutually agree, each party may disclose to the others, in confidence Confidential Information necessary or useful to the activities contemplated by this Agreement.

Except as specifically authorised or permitted by this Agreement, each party shall, for the term of this Agreement and for [seven 7 years] after its expiration or termination keep confidential and not disclose to others (except its Affiliates), and use only as permitted hereunder, all of the Confidential Information owned by the other parties. *

14.2 Save as otherwise specifically provided herein, each party shall disclose Confidential Information of the other parties only to those employees, representatives and agents requiring knowledge thereof in connection with fulfilling the party's obligations under this Agreement. Each party further agrees to (i) inform all such employees, representatives and agents of the terms and provisions of this Agreement relating to Confidential Information and their duties hereunder, and (ii) obtain their agreement hereto as a condition of receiving Confidential Information, provided that such agreement shall be deemed given in respect of such employees, representatives and agents that, at the time of disclosure, are under existing obligations of confidentiality no less onerous than those contained herein covering such disclosure. Each party shall exercise the same standard of care as it would itself exercise in relation to its own confidential information (but in no event less than a reasonable standard of care) to protect and preserve the proprietary and confidential nature of the Confidential Information disclosed to it by the other parties.

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- 14.3 Notwithstanding the provisions of this Clause 14, Confidential Information may be:
- 14.3.1 published if and to the extent such publication has been approved in writing by each of the parties; or
 - 14.3.2 disclosed to the extent required by applicable laws or regulations or as ordered by a court or other regulatory body having competent jurisdiction, provided that if a party becomes legally required to disclose any Confidential Information of the other party hereunder, the receiving party shall give the disclosing party prompt notice of such requirement to enable the disclosing party to seek a protective order or other appropriate remedy concerning any such disclosure. The receiving party shall fully co-operate with the disclosing party in connection with the disclosing party's efforts to obtain any such order or other remedy. If any such order or other remedy does not fully preclude disclosure, the receiving party shall make such disclosure only to the extent that such disclosure is legally required.
- 14.4 The parties agree that the obligations of this Clause 14 are necessary and reasonable in order to protect the parties' respective businesses, and each party agrees that monetary damages would be inadequate to compensate a party for any breach by the other party of its covenants and agreements set forth herein.
- The parties agree that any such violation or threatened violation shall cause irreparable injury to a party and that, in addition to any other remedies that may be available, in law and equity or otherwise, each party shall be entitled to seek injunctive relief against the threatened breach of the provisions of this Clause 14, or a continuation of any such breach by the other party, specific performance and other equitable relief to redress such breach together with damages and reasonable counsel fees and expenses to enforce its rights hereunder.
- 14.5 Subject to Clause 14.2 and Clause 14.3.2, neither party shall have the right to disclose to third parties the existence of this Agreement or any of the terms and conditions hereof without the prior written consent of the other party. In the event that either party wishes to make an announcement concerning the Agreement, that party will seek the consent of the other party, which consent shall not be unreasonably withheld or delayed. The terms of any such announcement shall be agreed in good faith.

15 MISCELLANEOUS

- 15.1 This Agreement shall be governed by and construed in accordance with the laws of the State of New York and the parties submit to the non-exclusive jurisdiction of the Federal and State courts located in New York.

- 15.2 No waiver of any right under this Agreement shall be deemed effective unless contained in a written document signed by the party charged with such waiver, and no waiver of any breach or failure to perform shall be deemed to be a waiver of any future breach or failure to perform or of any other right arising under this Agreement.
- 15.3 Neither party to this Agreement shall be liable for delay or failure in the performance of any of its obligations hereunder to the extent such delay or failure results from causes beyond its reasonable control, including, without limitation, acts of God, fires, strikes, acts of war, or intervention of a government authority, non-availability of raw materials, but any such delay or failure shall be remedied by such party as soon as practicable.
- 15.4 This Agreement and, except as otherwise provided for in this Agreement, the rights and obligations hereunder, shall not be assigned by any party without the prior written consent of the other parties save that:
- 15.4.1 any party may assign this Agreement in whole or in part and delegate its duties hereunder to its Affiliate or Affiliates without such consent provided that such assignment or delegation has no material adverse tax implications for the other parties; and
- 15.4.2 in the event of a proposed assignment of this Agreement by any party to a third party, such consent shall not be unreasonably withheld or delayed provided that, without prejudice to the generality of the foregoing, the parties acknowledge that it will not be unreasonable for EPIL to withhold consent hereunder in the event of a proposed assignment of this Agreement by Developer to a Technological Competitor of EPIL.

Any permitted assignee shall assume all obligations of its assignor under this Agreement.

[Developer shall also have the right to subcontract all or any portion of the Development Plan to a third party with the prior written consent of EPIL, such consent not being unreasonably withheld or delayed. In such circumstances, Developer shall procure that the terms of the subcontract are not inconsistent with the terms of this Agreement. Furthermore, Developer shall procure that the confidentiality provisions of the subcontract are no less onerous than the confidentiality provisions set forth herein. Any breach of such obligations of confidentiality by any such third party shall be regarded a breach of confidentiality by Developer and Developer shall be responsible to and shall indemnify and hold harmless EPIL for such breach in accordance with the terms of this Agreement. Developer shall be responsible for supervising all activities that may be undertaken by a third party. No subcontract permitted hereunder shall negate or reduce Developer's obligations to EPIL hereunder.]

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- 15.5 Nothing contained in this Agreement is intended or is to be construed to constitute Developer and EPIL as partners or members of a joint venture or any party as an employee of the other. None of the parties hereto shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other parties or to bind the other parties to any contract, agreement or undertaking with any third party.
- 15.6 No amendment, modification or addition hereto shall be effective or binding on any party unless set forth in writing and executed by a duly authorised representative of each of the parties.
- 15.7 Any notice to be given under this Agreement shall be sent in writing in English by overnight courier, registered airmail or telecopied to:

EPIL at:

Elan Pharma International Limited
C/o Elan International Services Ltd.
102 St James Court
Flatts
Smiths FL04
Bermuda

Attention: Secretary
Telefax : +1 441 292 2224

Incara at:

Incara Pharmaceuticals Corporation,
P.O. Box 14287
79 T.W. Alexander Drive
4401 Research Commons, Suite 200
Research Triangle Park, North Carolina 27709

Attention: Chief Executive Officer
Telephone: (919) 558 8688
Telefax: (919) 544 1245

Aoelus at:

Aeolus Pharmaceuticals Inc
P.O. Box 14287
79 T.W. Alexander Drive,

4401 Research Commons, Suite 200
Research Triangle Park, North Carolina 27709

Attention: Chief Executive Officer
Telephone: (919) 588-8688
Telefax: (919) 544 1245

or to such other address(es) and telecopier numbers as may from time to time be notified by any of the parties to the others hereunder.

Any notice sent by overnight courier, registered mail or telecopier shall be deemed to have been delivered upon receipt by the addressee.

- 15.8 If any provision in this Agreement is agreed by the parties to be, or is deemed to be, or becomes invalid, illegal, void or unenforceable under any law that is applicable hereto:-
- 15.8.1 such provision will be deemed amended to conform to applicable laws so as to be valid and enforceable or, if it cannot be so amended without materially altering the intention of the parties, it will be deleted, with effect from the date of such agreement or such earlier date as the parties may agree; and
- 15.8.2 the validity, legality and enforceability of the remaining provisions of this Agreement shall not be impaired or affected in any way.
- 15.9 This Agreement sets forth all of the agreements and understandings between the parties with respect to the subject matter hereof, and supersedes and terminates all prior agreements and understandings between the parties with respect to the subject matter hereof. There are no agreements or understandings with respect to the subject matter hereof, either oral or written, between the parties other than as set forth in this Agreement.
- 15.10 The provisions of Clauses 1, 8.1, 8.3, 9, 10, 11, 13, 14, and 15 shall survive the termination for any reason of this Agreement.
- 15.11 At the request of any of the party, the other parties shall (and shall use reasonable efforts to procure that any other necessary third parties shall) execute and do all such documents, acts and things as may reasonably be required subsequent to the signing of this Agreement for assuring to or vesting in the requesting party the full benefit of the terms hereof.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement.

SIGNED

for and on behalf of

Elan Pharma International Limited

Date

SIGNED

For and on behalf of

Incara Pharmaceuticals Corporation

Date

SIGNED

For and on behalf of

Aeolus Pharmaceuticals, Inc.

Date

Schedule 1

Developer Patents

1) ["Substituted Porphyrins"]

Serial Nos.: U.S. application [09/880,124]
PCT application [US98/23287]

Docket Numbers: U.S. #[1579-246, #1579-580]
PCT #[1579-314]
From Nixon & Vanderhye P.C.
Arlington, VA

INVENTORS:

[Irwin Fridovich]
[Ines Batinic-Haberle]
[James Crapo]
[Brian Day]

2) ["Substituted Porphyrins"]

Serial Nos.: U.S. Application #: [09/490,537]
International application #: [PCT/US00/02062]

Foreign equivalents in [EPO, Australia, Canada, Japan, Brazil, China,
Israel, South Korea, Mexico, New Zealand, and
South Africa]

Docket Numbers: U.S. #: [2661-2]
International #s: [2661-5, 2661-10 through 20]
From Nixon & Vanderhye P.C.
Arlington, VA

INVENTORS:

[Irwin Fridovich]
[Ines Batinic-Haberle]
[James Crapo]
[Brian Day]

[] Confidential treatment requested.

[Michael Trova]
[Polivini Jolicia Gauuan]
[Douglas Kitchen]

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3) ["Cancer Therapy"]

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Serial Nos.: U.S. application [10/051,367]
PCT application [TBA, filed 1/22/02]

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*

Docket Numbers: U.S. #[2661-4; #2661-22]
PCT #[2661-23]
From Nixon & Vanderhye P.C.
Arlington, VA

*
*

INVENTORS:

[Ines Batinic-Haberle]
[Zeljko Vujaskovic]
[James Crapo]
[Brian Day]
[Richard Gammans]

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[] Confidential treatment requested.

Schedule 2

[Non-legally binding] Heads of Agreement for the EPIL Sub-Licence

1. Right granted	[Exclusive, sub-licensable sub-licence to the Developer Intellectual Property to import, make, use, offer for sale, and sell the Compounds and/or Products in the Field in the Territory.]	* * * *
2. Territory	[World-wide]	
3. Development Work	[Developer will carry out additional development work as required by EPIL after the execution of the EPIL Sub-Licence. Payment for such subsequent development work will be charged at an FTE rate to be agreed between the parties taking account of the then current standard industry rates. A development agreement will be negotiated at the time of the EPIL Sub-Licence.]	* * * * * *
4. Licence Fees	[Upon execution of the EPIL Sub-Licence EPIL will pay to the Developer a licence fee of US\$3,000,000.]	* * *
5. Royalties	[EPIL shall pay a royalty to Developer which the parties estimate will be in the region of 5-15% on in market net sales (to be defined in the EPIL Sub-Licence). Developer shall be responsible for any royalties due to Duke University or National Jewish Medical and Research Center or Albany.] [On a country by country basis during any period where there are no Developer Patents covering the Compounds or Products, a 1% royalty on in market net sales in the relevant country will apply.]	* * * * * * * * * *
6. Intellectual Property	[The Developer shall be responsible for the filing, defence, and enforcement of the Developer Patents in consultation with EPIL.]	* * *

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	[The Developer shall fully indemnify EPIL against any Claims based on an allegation that the manufacture, importation, use, offer for sale, sale or other commercialisation of the Compounds or Products infringe or misappropriate any third party's intellectual property rights.]	* * * * *
7. Term and termination	[The agreement will terminate on a country by country basis on:]	* *
	(i) [The 15 th anniversary of the date of the launch of the product in the country concerned; or]	* * *
	(ii) [in any country upon the expiry of the life of the last to expire patent included in the Developer Intellectual Property in that country]	* * * *
	[whichever date is the later to occur.]	*
	[The EPIL Sub-Licence will contain customary provisions regarding termination for breach or insolvency.]	* * * *
	[In the event of termination of the Developer Licence Agreements, the EPIL Sub-Licence (and any assignment, licence or sub-licence thereof) shall continue in accordance with the terms of the Developer Licence Agreements.]	* * * *
8. Consequences of Termination	[If EPIL terminates the EPIL Sub-Licence for breach by Developer, Developer shall grant to EPIL an exclusive, fully paid up sub-licensable sub-licence to the Developer Intellectual Property to import, make, use, offer for sale, and sell the Compounds for use in the Field in the Territory;]	* * * * *
9. Applicable law	The Agreement will be subject to [New York] law.	*

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10. Warranties

[The Developer will provide customary warranties to EPIL similar to those in the Development and Option Agreement in relation to the Compounds and/or Products.]



11. Marketing and Promotion

[EPIL will use reasonable efforts to commercialise the Compounds and/or Products in the Field in the Territory.]



12. Regulatory Matters

[Developer shall transfer all regulatory approvals relating to the Compounds and/or Products to EPIL upon execution of the EPIL Sub-Licence. EPIL will be entitled to control all subsequent regulatory matters relating to the Compounds and/or Products and EPIL shall own all regulatory approvals obtained.]



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Schedule 3

Technological Competitors of EPIL

[3M Pharmaceuticals]
[Aerogen, Inc.]
[Alkermes, Inc.]
[Alza Corporation]
[Andrx Corporation]
[Aradigm Corporation]
[Battelle Pulmonary Therapeutics Inc.]
[Biovail Corporation International]
[Cardinal Health/RP Scherer]
[Celltech/Medeva]
[Cima Labs, Inc.]
[Elite Pharm]
[Emisphere Technologies Inc.]
[Ethypharm]
[Eurand]
[Fauldings]
[Fournier]
[Inhale Therapeutic Systems Inc.]
[Johnson & Johnson]
[Kos Pharmaceuticals]
[K-V Pharmaceutical Company]
[Labopharm]
[Lohmann Therapies/LTS]
[Penwest Pharmaceuticals Co.]
[PowderJect Pharmaceuticals plc.]
[RTP Pharma]
[The West Company]
[Shire Pharmaceuticals]
[SkyePharma plc]
[Unigene Laboratories Inc.]
[Weston Medical Ltd]
[Yamanouchi Pharmaceutical Co., Ltd.]



[] Confidential treatment requested.

Schedule 4

Duke Consent

May __, 2002

Robert Taber
Office of Science & Technology
Duke University
PO Box 90083
2020 West Main Street, Suite 10
Durham, NC 27705

Dear Mr. Taber:

As you know, we are in the final stages of negotiating a Development and Option Agreement among Elan Corporation, plc (including its affiliates) ("Elan"), Incara Pharmaceuticals Corporation and Aeolus Pharmaceuticals, Inc. ("Aeolus") (the "Elan Agreement") to develop and eventually commercialize in the Field (as defined in the Elan Agreement) the catalytic antioxidant technology licensed by Aeolus from Duke University ("Duke").

Under the Agreement, Elan has an option to obtain a sublicensable sublicense (the "Option Sublicense") of certain of Aeolus' rights under the License Agreements dated July 21, 1995, June 25, 1998 and May __, 2002 between Duke and Aeolus (the "License Agreements"), and may be granted such a sublicense under certain other circumstances described in the Elan Agreement (the "Default Sublicense" together with the Option Sublicense are collectively the "Elan Sublicense").

We hereby request: (i) [Duke's consent to any Elan Sublicense granted in connection with the Elan Agreement; (ii) Duke's agreement that its consent will not be required for (a) Elan to grant sublicenses under the Elan Sublicense or (b) Elan to assign its rights to the Elan Sublicense; (iii) that in the event of the termination of the License Agreements, Duke agrees, at such time as Elan receives an Elan Sublicense, to license to Elan the technology licensed to Aeolus under the License Agreement on substantially the same terms and conditions set forth in the License Agreements, except that Elan's use shall be limited to the Field (as defined in the Elan Agreement), so that Elan may continue to avail itself of its rights under such Elan Sublicense; and (iv) Duke's agreement that the last sentence of Section 6.01 of the License Agreements shall not apply during the term of the Elan Agreement and an Elan Sublicense, if any.] Your timely consent and agreement by designation below is greatly appreciated.

Sincerely,

Clayton I. Duncan
President and CEO
Aeolus Pharmaceuticals, Inc.

[] Confidential treatment requested.

Acknowledged and Agreed:

Duke University

By: _____

Name: _____

Title: _____

Date: _____

Schedule 5

National Jewish Consent

May __, 2002

Mr. Verne Singleton
Chief Operating Officer
National Jewish Medical and Research Center
1400 Jackson Street
Denver, CO 80206

Dear Mr. Singleton:

As you know, we are in the final stages of negotiating a Development and Option Agreement among Elan Corporation, plc (including its affiliates) ("Elan"), Incara Pharmaceuticals Corporation and Aeolus Pharmaceuticals, Inc. ("Aeolus") (the "Elan Agreement") to develop and eventually commercialize in the Field (as defined in the Elan Agreement) the catalytic antioxidant technology licensed from National Jewish Medical and Research Center ("National Jewish").

Under the Agreement, Elan has an option to obtain a sublicense (the "Option Sublicense") of certain of Aeolus' rights under the License Agreement dated November 17, 2000 between National Jewish and Aeolus (the "License Agreement"), and may be granted such a sublicense under certain other circumstances described in the Elan Agreement (the "Default Sublicense" together with the Option Sublicense, the "Elan Sublicense").

Specifically, but without prejudice to the generality of the rights to be granted by Aeolus to Elan under the Elan Agreement, we hereby request [(i) National Jewish's waiver of any requirement of Aeolus to assign sub-licenses to National Jewish in the event of the termination of the License Agreement; (ii) that in the event of the termination of the License Agreement, National Jewish agrees, at such time as Elan receives an Elan Sublicense, to license to Elan the technology licensed to Aeolus under the License Agreement on substantially the same terms and conditions set forth in the License Agreement, except that Elan's use shall be limited to the Field (as defined in the Elan Agreement), so that Elan may continue to avail itself of its rights under such Elan Sublicense; and (iii) National Jewish's agreement that the last sentence of Section 6.01 of the License Agreement shall not apply during the term of the Elan Agreement and an Elan Sublicense, if any and Section 6.01 will not apply only if Aeolus cancels the Agreement.] Your timely consent and agreement by designation below is greatly appreciated.

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Sincerely,

Clayton I. Duncan
President and CEO
Aeolus Pharmaceuticals, Inc.

[] Confidential treatment requested.

Acknowledged and Agreed:

National Jewish Medical and Research Center

By: _____

Name: _____

Title: _____

Date: _____

Schedule 6

Phase I Report and Phase II Report

The information to be included in each of the Phase I Report and the Phase II Report will be set out in the Development Plan.

Phase I Report

At a minimum, the Phase I Report should contain the following information relating to the Phase I clinical trial:

- 1) [A brief synopsis, one to two pages in length, describing the study population, critical design features, and effectiveness and safety results, including critical numerical data.] *
- 2) [The protocol (a plan for the study prepared prior to its conduct), including a sample of the case report form(s) used to carry out the study, and any protocol amendments made during the study.] *
- 3) [Any publication that reports on or analyzes all, or any portion of, the data in the study. If there are significant discrepancies between the data or analyses in the application and those in the published report, they should be explained.] *
- 4) [A list of all investigators and other persons whose participation materially affected the conduct of the study and a brief description of their training (physician, psychologist, etc.) and of the role of each in the study, such as the particular observations or decisions for which each was responsible, should be provided as an appendix to the report. If there was an external (to the applicant) data monitoring group, its members should be included.] *
- 5) [Summary of effectiveness data.] *

Phase II Report

At a minimum the Phase II Report should contain the following information relating to the Phase II clinical trial:

- 1) [A brief synopsis, one to two pages in length, describing the study population, critical design features, and effectiveness and safety results, including critical numerical data.] *

[] Confidential treatment requested.

- 2) [The protocol (a plan for the study prepared prior to its conduct), including a sample of the case report form(s) used to carry out the study, and any protocol amendments made during the study.] *
- 3) [Any publication that reports on or analyzes all, or any portion of, the data in the study. If there are significant discrepancies between the data or analyses in the application and those in the published report, they should be explained.] *
- 4) [A list of all investigators and other persons whose participation materially affected the conduct of the study and a brief description of their training (physician, psychologist, etc.) and of the role of each in the study, such as the particular observations or decisions for which each was responsible, should be provided as an appendix to the report. If there was an external (to the applicant) data monitoring group, its members should be included.] *
- 5) [Summary of effectiveness data.] *

[] Confidential treatment requested.