Current Agreements

Dealdoc

Asset purchase and licensing agreement for stem cell technology

Novartis
Opexa Therapeutics

Aug 07 2009

Asset purchase and licensing agreement for stem cell technology

Companies:	Novartis Opexa Therapeutics
Announcement date:	Aug 07 2009
Deal value, US$m:	50.0 : sum of upfront, technology transfer and milestone payments

Details

Announcement date:	Aug 07 2009
Start date:	Aug 06 2009
Industry sectors:	Bigpharma Biotech Pharmaceutical
Technology types:	Regenerative medicine » Stem cells
Deal components:	Asset purchase Licensing Technology transfer
Stages of development:	Discovery Preclinical
Geographic focus:	Worldwide

Financials

Deal value, US$m:	50.0 : sum of upfront, technology transfer and milestone payments
Upfront, US$m:	3.0 : upfront payment 1.0 : technology access fee
Milestones, US$m:	0.5 : technology transfer milestone 45.5 : development and commercial milestone payments
Royalty rates, %:	n/d : from the sale of any products resulting from the use of the technology

Termsheet

Exclusive agreement with Novartis, one of the world’s largest pharmaceutical companies, for the further development of Opexa’s novel stem cell technology.

This technology, which has generated preliminary data showing the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells, was in early preclinical development at Opexa.

Novartis will acquire the stem cell technology from Opexa and Novartis will have full responsibility for funding and carrying out all research, development and commercialization activities.

Opexa will receive an upfront cash payment of $3 million, plus an additional $1 million as a technology transfer fee to be paid over the course of a six month period.

Total payments to Opexa, including the upfront payment, the technology transfer fee and development and commercial milestone payments could exceed $50 million not including royalties.

Opexa is also eligible to receive royalty payments from the sale of any products resulting from the use of the technology and retains an option on certain manufacturing rights.

Press Release

Opexa Announces Stem Cell Agreement with Leading Global Pharmaceutical Company

THE WOODLANDS, Texas--(BUSINESS WIRE)--Opexa Therapeutics, Inc. (NASDAQ:OPXA - News), a company developing a novel T-cell immunotherapy for multiple sclerosis (MS), today announced that it has entered into an exclusive agreement with Novartis, one of the world's largest pharmaceutical companies, for the further development of Opexa's novel stem cell technology. This technology, which has generated preliminary data showing the potential to generate monocyte derived islet cells from peripheral blood mononuclear cells, was in early preclinical development at Opexa.

Under the terms of the agreement, Novartis will acquire the stem cell technology from Opexa and Novartis will have full responsibility for funding and carrying out all research, development and commercialization activities. Opexa will receive an upfront cash payment of $3 million, plus an additional $1 million as a technology transfer fee to be paid over the course of a six month period. Total payments to Opexa, including the upfront payment, the technology transfer fee and development and commercial milestone payments could exceed $50 million not including royalties. Opexa is also eligible to receive royalty payments from the sale of any products resulting from the use of the technology and retains an option on certain manufacturing rights.

"This represents a great opportunity for Opexa," stated Neil K. Warma, Opexa's president and chief executive officer. "Novartis is one of the premier pharmaceutical companies and the expertise they bring to this program will undoubtedly advance the technology significantly. This agreement will also allow us to firmly focus our attention on our key clinical asset, Tovaxin®.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The Company's leading therapy, Tovaxin, is an individualized cellular immunotherapy treatment in Phase IIb clinical development for Multiple Sclerosis (MS). Tovaxin is derived from T-cells isolated from peripheral blood, expanded ex vivo, and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin and, thereby, reduces the risk of relapse over time. Data from the first Phase IIb clinical study showed compelling evidence that Relapsing Remitting MS patients treated with Tovaxin saw overall clinical, MRI, and immunological benefits over the placebo group, including statistical significance for decrease in the Annualized Relapse Rate (ARR), improvement in disability score (EDSS), and improvement in quality of life measures (MSQLI), as well as an excellent safety profile with no serious adverse events related to Tovaxin treatment.

For more information visit the Opexa Therapeutics website at www.opexatherapeutics.com

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Opexa Triggers Milestone Payment Under Recently Announced Stem Cell Agreement THE WOODLANDS, Texas--(BUSINESS WIRE)--Opexa Therapeutics, Inc. (NASDAQ:OPXA), a company developing Tovaxin®, a personalized T-cell immunotherapy for multiple sclerosis (MS), today announced that it has achieved its first technology transfer milestone in connection with the company's recently announced exclusive stem cell agreement with Novartis, one of the world's largest healthcare companies. The milestone was completed on schedule and triggers a payment of $500,000 to Opexa.

Opexa recently announced that it entered into an exclusive agreement with Novartis for the further development of Opexa's novel stem cell technology. Under the terms of the agreement, Opexa received an upfront cash payment of $3 million and was entitled to an additional $1 million as a technology transfer fee to be paid over the course of a six month period. The $500,000 milestone is part of this $1 million technology transfer fee. Total payments to Opexa, including the upfront payment, the technology transfer fee and development and commercial milestone payments could exceed $50 million not including royalties. Opexa is also eligible to receive royalty payments from the sale of any products resulting from the use of the technology and retains an option on certain manufacturing rights.

In another positive development, Opexa recently received approximately $850,000 from the exercise of outstanding warrants. The five-year warrants were exercised at a $1.78 strike price. This, together with the milestone payment, has added over $1.3 million to Opexa's cash resources, providing the company with further flexibility as it pursues the preparation and planning for Tovaxin's ongoing clinical development program, as well as its ongoing partnership discussions.

About Opexa

Opexa Therapeutics, Inc. is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases. The Company's leading therapy, Tovaxin®, is an individualized cellular immunotherapy treatment in Phase IIb clinical development for multiple sclerosis (MS). Tovaxin is derived from T-cells isolated from peripheral blood, expanded ex vivo, and reintroduced into the patients via subcutaneous injections. This process triggers a potent immune response against specific subsets of autoreactive T-cells known to attack myelin, believed to be a primary cause of MS attacks and nervous system damage. For more information visit the Opexa Therapeutics website at www.opexatherapeutics.com.

Filing Data

Not available.

Contract

ASSET PURCHASE AGREEMENT

Dated as of August 6, 2009

By and Between

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.

and

OPEXA THERAPEUTICS, INC.

ASSET PURCHASE AGREEMENT

This ASSET PURCHASE AGREEMENT (this “Agreement”) is dated as of August 6, 2009 (the “Effective Date”), by and between Novartis Institutes for BioMedical Research, Inc., a Delaware corporation (“Novartis”) and Opexa Therapeutics, Inc., a Texas corporation (the “Company”).

RECITALS

WHEREAS, the Company is engaged in the research and development of the MDSC Program (as defined below);

WHEREAS, upon the terms and conditions set forth herein, Novartis desires to purchase, and the Company desires to assign to Novartis all of the Company Intellectual Property (as defined below);

WHEREAS, the Company and the University of Chicago have entered into the Chicago License, whereby the University of Chicago has licensed to the Company certain exclusive rights as set forth in the Chicago License; and

WHEREAS, the Company wishes to assign the Chicago License to Novartis, and Novartis wishes to assume the Chicago License from the Company, on the terms and conditions set forth herein;

NOW, THEREFORE, in consideration of the foregoing and the respective representations, warranties, covenants and agreements set forth herein, and intending to be legally bound hereby, the parties hereto agree as follows:

Article I

DEFINITIONS

1.1 Defined Terms. Defined terms used in this Agreement shall have the meanings ascribed to them as follows:

“Affiliate” shall mean, with respect to a party, any Person that controls, is controlled by, or is under common control with that party. For the purpose of this definition, “control” shall mean, direct or indirect, ownership of fifty percent (50%) or more of the shares of stock entitled to vote for the election of directors, in the case of a corporation, or fifty percent (50%) or more of the equity interest in the case of any other type of legal entity, status as a general partner in any partnership, or any other arrangement whereby the entity or Person controls or has the right to control the board of directors or equivalent governing body of a corporation or other entity, or the ability to cause the direction of the management or policies of a corporation or other entity. In the case of entities organized under the Laws of certain countries, the maximum percentage ownership permitted by Law for a foreign investor may be less than fifty percent (50%), and in such case such lower percentage shall be substituted in the preceding sentence, provided, that such foreign investor has the power to direct the management and policies of such entity. In the case of Novartis, “Affiliates” shall also expressly be deemed to include the Novartis Institute for Functional Genomics, Inc., the Friedrich Miescher Institute for Biomedical Research and their respective Affiliates.

“Allogeneic Generation Process” shall mean an in vitro process to generate MDSCs from a person’s blood, multiplying such MDSCs in number ex vivo, and converting them to a therapeutic for transplantation into a different person.

“Autologous Generation Process” shall mean an in vitro process to generate MDSCs from a person’s blood, multiplying such MDSCs in number ex vivo, and converting them to a therapeutic for transplantation back into the same person.

“Calendar Quarter” shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

“Calendar Year” shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.

“Change in Control” of the Company shall mean (i) the Company is involved in a merger, reorganization or consolidation in which its shareholders immediately prior to such transaction hold less than fifty percent (50%) of the voting securities or other voting interests representing the equity of the surviving entity immediately after such merger, reorganization or consolidation, where such surviving entity is or is an Affiliate of a Significant Pharmaceutical Company, (ii) there is a bona fide sale of all or substantially all of the Company’s assets or business relating to this Agreement to a Significant Pharmaceutical Company, or (iii) a Significant Pharmaceutical Company acquires effective control of the management and policies of the Company.

“Chicago License” shall mean that certain Second Amended and Restated License Agreement, dated July 31, 2007, between the Company and the University of Chicago, as amended as of August 5, 2009, attached hereto as Exhibit A.

“Company Intellectual Property” shall mean any Intellectual Property that is owned by or licensed to the Company in each case which is used in, held for use or intended for use in, or that arises out of or otherwise relates to the MDSC Program, excluding the Intellectual Property licensed to the Company under the Chicago License.

“Confidentiality Agreement” shall mean the Confidential Disclosure Agreement effective as of December 11, 2008, by and between the Company and Novartis International AG.

“dollars” or “$” shall mean United States dollars.

“EMEA” shall mean the European Medicines Evaluation Agency or any successor agency thereto.

“EU Regulatory Approval” shall mean (a) marketing authorization approval from the EMEA and pricing and reimbursement approval in any three Major EU Countries or (b) national marketing authorization approval and pricing and reimbursement approval in any three Major EU Countries.

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“FDA” shall mean the United States Food and Drug Administration, or any successor agency thereto.

“First Commercial Sale” shall mean the first sale of a Product or Method, by or under the authority of Novartis, an Affiliate of Novartis, or their licensees or sublicensees to a Third Party in a country following Regulatory Approval and reimbursement approval (if necessary) of such Product or Method in that country or, if no such Regulatory Approval or similar approval is required, the date upon which such Product or Method is first commercially launched in such country; provided that First Commercial Sale shall not include any distribution or other sale solely for so-called treatment investigational new drug sales, named patient sales, compassionate or emergency use sales or pre-license sales.

“FPFV” shall mean, with respect to a Product or Method, the administration of the first dose of such Product or first administration of such Method to the first patient at his first visit in a Phase III Clinical Study, as applicable.

“FTE” or “Full Time Equivalent” shall mean the equivalent of a full-time qualified employee’s work time (consisting of a total of [*] hours over a twelve-month period) for scientific work directly related to the technology transfer activities provided in the Technology Transfer Plan, excluding any managerial activities and travel time.

“Generation Process” shall mean, collectively, the Autologous Generation Process and the Allogeneic Generation Process.

“Governmental Authority” shall mean any federal, state, municipal, foreign or other governmental body, department, commission, board, bureau, agency, court or instrumentality, domestic or foreign, or other entity exercising any executive, legislative, judicial, quasi-judicial, regulatory or administrative function of government, including the FDA and all foreign equivalents thereof.

“Intellectual Property” shall mean any or all rights in, arising out of, or associated therewith: (a) all United States, international and foreign Patent Rights; (b) all Know-How; (c) all copyrights, copyright registrations and applications therefor, and all other rights corresponding thereto throughout the world; (d) all industrial designs and any registration and applications therefor throughout the world; (e) all trade names, brand names, model names and other source indicators, logos, domain names, URLs, common law trademarks and service marks, including all good will associated therewith, and all registration and applications therefor throughout the world; (f) all mask works and all applications, registrations, and renewals in connection therewith and (g) all databases and data collections and all rights therein throughout the world.

“Invoice” shall mean an invoice substantially in the form attached as Exhibit D.

“Know-How” shall mean all ideas, inventions (whether patentable or not), discoveries, concepts, formulae, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, technical information, designs, drawings, computer programs, skill, experience, documents, apparatus, results, data, specifications and materials, including all clinical and regulatory strategies, regulatory filings (and copies thereof), biological, chemical, biochemical, pharmacological, physical, toxicological and clinical data, analytical, safety, efficacy and quality control data, test data, manufacturing data and descriptions, patents and legal data, market data, financial data or descriptions, devices, assays, chemical formulations, specifications, compositions of matter, product samples and other samples, physical, chemical and biological materials and compounds, and the like, in written, electronic or other form.

“Law” shall mean any federal, state, local or foreign law, statute, common law, rule, regulation, code, directive, ordinance or other requirement of general application of any Governmental Authority.

“Liabilities” shall mean any direct or indirect liability, indebtedness, claim, loss, damage, deficiency, obligation or responsibility, fixed or unfixed, liquidated or unliquidated, secured or unsecured, accrued, absolute or contingent.

“Licensed Patents” shall have the meaning set forth in the Chicago License.

“LICENSEE” shall have the meaning set forth in the Chicago License.

“Lien” shall mean any lien, claim, charge, option, mortgage, pledge or security interest, rights of first refusal or rights of first offer, encumbrance or other similar right, whether arising by contract, operation of law or otherwise.

“Losses” of any Person shall mean any and all demands, claims, suits, actions, causes of action, proceedings, assessments, losses, damages, Liabilities, Taxes, costs and expenses, incurred by such Person, including settlement costs, costs of collection, interest, penalties and attorneys’ fees, Third Party expert and consultant fees and expenses, fines, judgments and awards.

“Major EU Country” shall mean France, Germany, Italy, Spain or the United Kingdom.

“MDSC” shall mean a monocyte-derived stem cell.

“MDSC Program” shall mean, in each instance as conducted by or on behalf of the Company up to and including the Effective Date: (i) the Generation Process; and (ii) any other use of MDSCs for any purpose.

“Method” shall mean any method, procedure or process where use or practice of such is covered by the scope of any Valid Claim.

“Net Sales” shall mean with respect to any Product or Method the gross amount invoiced by or on behalf of Novartis, its Affiliates and any licensees or sublicensees for that Product or Method sold to Third Parties, in bona fide, arm’s length transactions, less customary deductions, determined in accordance with Novartis’ usual and customary accounting methods, which are in accordance with International Financial Reporting Standards (IFRS) as consistently applied at Novartis, to the extent included in the gross invoiced sales price of any Product or Method or otherwise directly paid or incurred by Novartis, its Affiliates or licensees or sublicensees with respect to the sale of such Product or Method, such as:

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- [*];
- [*];
- [*];
- [*];
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• [*];

all as determined in accordance with Novartis' usual and customary accounting methods, which are in accordance with International Financial Reporting Standards (IFRS) as consistently applied at Novartis. Sales from Novartis to its Affiliates shall be disregarded for purposes of calculating Net Sales. Any of the items set forth above that would otherwise be deducted from the invoice price in the calculation of Net Sales but which are separately charged to Third Parties shall not be deducted from the invoice price in the calculation of Net Sales.

(a) In the case of any sale or other disposal of a Product or Method between or among Novartis, its Affiliates and licensees and sublicensees, for resale, Net Sales shall be calculated as above only on the value charged or invoiced on the first arm's length sale thereafter to a Third Party;

(b) In the case of any sale which is not invoiced or is delivered before invoice, Net Sales shall be calculated at the time of shipment or when the Product or Method is paid for, if paid for before shipment or invoice; and

(c) In the case of any sale or other disposal for value, such as barter or counter-trade, of any Product or Method, or part thereof, other than in an arm's length transaction exclusively for money, Net Sales shall be calculated as above on the value of the non-cash consideration received or the fair market price (if higher) of the Product or Method in the country of sale or disposal.

"Order" shall mean any order, writ, injunction, judgment, decree or ruling entered, issued, made or rendered by any court, administrative agency, arbitration tribunal or other Governmental Authority of competent jurisdiction.

"Patent Rights" shall mean all patents and patent applications, and any patents issuing therefrom, worldwide, including all divisionals, continuations, substitutions, continuations-in-part, re-examinations, reissues, additions, renewals, extensions (including patent term extensions and supplementary protection certificates), registrations, and the like of any of the foregoing.

"Permits" shall mean all licenses, permits, consents, applications, orders, waivers, clearances, franchises, certificates, variances, approvals, filings, notifications and other authorizations of any Governmental Authorities under applicable Law.

"Person" shall mean any individual, corporation, partnership, firm, limited liability company, joint venture, association, joint stock company, trust, unincorporated organization, Governmental Authority or other entity.

"Phase III Clinical Study" shall mean a pivotal human clinical study in any country that is conducted in accordance with cGCPs and is intended to establish efficacy and safety of a product for the purpose of preparing and submitting a Regulatory Filing to the competent Governmental Authority in such particular country.

"Proceeding" shall mean any action, suit, dispute, litigation, hearing, claim, grievance, arbitral action or other proceeding before any Governmental Authority, at law or in equity.

"Product" shall mean any product that is covered by the scope of any Valid Claim or made by a process, method or technique covered by the scope of any Valid Claim, or where a method of using such product is covered by the scope of any Valid Claim.

"Regulatory Approval" shall mean, with respect to a product in any country or jurisdiction, approval (including where required, pricing and reimbursement approvals), registration, license or authorization from a Governmental Authority in a country or other jurisdiction that is necessary to market and sell such product in such country or jurisdiction.

"Regulatory Filing" shall mean, with respect to a product, any submission to a Governmental Authority of any appropriate regulatory application to conduct clinical trials or market a product, and shall include any submission to a regulatory advisory board, marketing authorization application, and any supplement or amendment thereto. For the avoidance of doubt, Regulatory Filings shall include any Investigational New Drug Application, New Drug Application ("NDA"), Biologics License Application or the corresponding application in any other country or group of countries.

"Representative" shall mean any attorney, accountant, financial advisor or other authorized representative of any Person. "Sales Report" shall mean a written report or reports showing [*] the royalties payable, in United States Dollars, which shall have accrued hereunder with respect to

such Net Sales.

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“SEC” shall mean the United States Securities and Exchange Commission.

“Significant Pharmaceutical Company” shall mean a pharmaceutical company, biotechnology company, or group of such companies acting in concert which is a Third Party and with a market capitalization greater than [*] as of the effective date of a Change in Control.

“Tax” or “Taxes” shall mean any taxes of any kind, including those measured on, measured by or referred to as, income, alternative or add-on minimum, gross receipts, escheat, capital, capital gains, sales, use, ad valorem, franchise, profits, license, privilege, transfer, withholding, payroll, employment, social, excise, severance, stamp, occupation, premium, value added, property, environmental or windfall profits taxes, customs, duties or similar fees, assessments or charges of any kind whatsoever, together with any interest and any penalties, additions to tax or additional amounts (including any interest thereon) imposed by any Governmental Authority.

“Third Party” shall mean any Person other than a party to this Agreement or an Affiliate of such Party.

“Valid Claim” shall mean: (i) an issued claim of any unexpired patent within the Acquired Patents or Licensed Patents which has not been (x) held unenforceable, unpatentable or invalid by a decision of a court or governmental body of competent jurisdiction, in a ruling that is unappealable or unappealed within the time allowed for appeal; (y) rendered unenforceable through disclaimer or otherwise; or (z) lost through an interference proceeding or irrecoverable failure, prior to the Effective Date, to pay a maintenance fee; or (ii) a claim of any patent application within the Acquired Patents or Licensed Patents so long as such patent application has not been pending for more than [*] following the filing date for such application.

1.2 Other Defined Terms. The following capitalized terms are defined in this Agreement in the Section indicated below:

Defined Term	Section
Acquired Patents	2.1(a)(i)
Agreement	Preamble
Assumed Liabilities	2.2
Claim	7.2(a)
Company	Preamble
Confidential Information	6.4
Direct Claim	7.2(b)
Effective Date	Preamble
Indemnification Claim Notice	7.2(a)
Indemnified Party	7.2(a)
Indemnifying Party	7.2(a)
MDIs	Schedule 2.1(a)(ii)
Milestone	3.2(a)

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Defined Term	Section

Milestone Payment 3.2(a)

Negotiation Period 6.2

Novartis Preamble

Personal Information 8.16

Retained Liabilities 2.2

Technology Transfer Plan 6.1(a)

Third Party Claim 7.2(a)(i)

Transaction Documents 5.1(b)

Violation 5.1(c)

1.3 Rules of Construction. References in this Agreement to gender include references to all genders, and references to the singular include references to the plural and vice versa. The words “include,” “includes” and “including” when used in this Agreement shall be deemed to be followed by the phrase “without limitation.” Unless the context otherwise requires, references in this Agreement to Articles, Sections, Exhibits and Schedules shall be deemed references to Articles and Sections of, and Exhibits and Schedules to, this Agreement. Unless the context otherwise requires, the words “hereof,” “hereby” and “herein” and words of similar meaning when used in this Agreement refer to this Agreement in its entirety and not to any particular Article, Section or provision of this Agreement. The table of contents and headings contained in this Agreement are for reference purposes only and shall not affect in any way the meaning or interpretation of this Agreement.

Article II

PURCHASE AND SALE OF THE COMPANY INTELLECTUAL PROPERTY;

TRANSFER OF LICENSE

2.1 Purchase and Sale of the Company Intellectual Property

(a) On the terms and conditions set forth in this Agreement, the Company shall (and shall cause its Affiliates to) and hereby does, as of the Effective Date, sell, transfer, convey, assign and deliver to Novartis, and Novartis shall and hereby does, as of the Effective Date, purchase and acquire all of the Company’s (and its Affiliates’) right, title and interest in, to and under all of the Company Intellectual Property, including but not limited to:

(i) the patent applications set forth on Schedule 2.1(a)(i) attached hereto and all Patent Rights therein (the “Acquired Patents”);

(ii) all data, results, research and development plans, experiments, laboratory notebooks, biological materials and other information relating to the research conducted by, or on behalf of, the Company and/or its Affiliates with respect to the MDSC Program, including those set forth on Schedule 2.1(a)(ii) attached hereto; and

(iii) all Know-How not specifically described above that is used, held for use or intended for use in, or that arose out of, or is otherwise related to, the MDSC Program.

As of the Effective Date, all right, title and interest to and risk of loss as to the Company Intellectual Property shall pass from the Company and its Affiliates to Novartis free and clear of all Liens.

2.2 No Assumption of Liabilities. Notwithstanding any other provision hereof, and except for Liabilities and obligations as LICENSEE under the Chicago License with respect to periods after the Effective Date (the “Assumed Liabilities”), Novartis and its Affiliates shall not assume or agree to, and shall not be obligated to pay, perform or discharge, any obligations, Liabilities, contracts, agreements or commitments of the Company or any of its Affiliates (including (i) any Liabilities, contracts, agreements or commitments relating to the MDSC Program or (ii) any Liabilities or obligations relating to the performance (or failure to perform) by the LICENSEE under the Chicago License on or prior to the Effective Date), all of which obligations, Liabilities, contracts, agreements and commitments shall remain the sole liability and responsibility of the Company and its Affiliates (the “Retained Liabilities”).

2.3 Chicago License. The Company hereby agrees to assign to Novartis (as the LICENSEE thereunder), and Novartis hereby agrees to accept and assume (as the LICENSEE thereunder), the Chicago License, on the Effective Date pursuant to the Assignment and Amendment Agreement in the form attached hereto as Exhibit F.

Article III

PAYMENTS

3.1 Up-Front Payment. Novartis shall pay to the Company $3,000,000 (THREE MILLION DOLLARS) within thirty (30) days of Novartis' receipt of an Invoice for such amount.

3.2 Additional Consideration.

(a) Milestone Payments. As additional consideration, Novartis shall, upon the achievement of the development milestones and sales milestones set forth below (each a "Milestone"), pay in accordance with subsection (b) the following cash payments (each a "Milestone Payment" and collectively, the "Milestone Payments"):

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(i) Development Milestones

Development Milestone

Milestone Payment

FPFV in the first Phase III

Clinical Study for a Product or

Method

[*]

First Regulatory Filing seeking

Regulatory Approval for a

Product or Method

[*]

First receipt of Regulatory

Approval in the United States for

a Product or Method

[*]

First receipt of EU Regulatory

Approval for a Product or

Method

[*]

(ii) Sales Milestones

Sales Milestone

Milestone Payment

First Calendar Year in which [*]

annual Net Sales exceed [*]

[*]

First Calendar Year in which [*]

annual Net Sales exceed [*]

[*]

First Calendar Year in which [*]

annual Net Sales exceed [*]

[*]

Each Milestone Payment shall be deemed earned as of the first achievement of the corresponding Milestone as reasonably determined by Novartis, and shall be notified by Novartis to the Company within thirty (30) days after achievement of the Milestone. For the avoidance of doubt: (i) each Milestone Payment shall become payable only upon the first occurrence of the Milestone; (ii) none of the Milestone Payments shall be payable more than once and (iii) no additional Milestone Payments shall be due for Milestones completed for the development and commercialization of any or all of the Products and Methods for additional indications or otherwise.

(iii) Payment of Milestone Payments. Novartis shall pay to the Company an amount equal to the Milestone Payment no later than sixty (60) days after receipt of an Invoice therefor, which Invoice shall be issued by the Company no earlier than the receipt by the Company of the notice sent by Novartis relating to the achievement of the applicable Milestone.

(b) RoyaltiesSubject to the terms and conditions of this Agreement, including but not limited to Section 3.3, as additional consideration Novartis shall pay to the Company a royalty of [*] percent ([*]%) on Net Sales of each Product and Method (on a Product-by-Product, Method-by-Method and country-by-country basis) by Novartis, its Affiliates and licensees and sublicensees.

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(ii) In the event that, with respect to Net Sales of Products and/or Methods, Novartis pays royalties to Third Parties for patent rights to make, use or sell Product(s) and/or Method(s), the royalties due and payable by Novartis to the Company hereunder shall be reduced by [*] percent ([*]%) of the amounts paid by Novartis to such Third Party for such patent rights; provided, however, that in no event shall any royalty payment due to the Company under this Agreement be reduced through this Section by more than [*] percent ([*]%).

(iii) Within sixty (60) days after each Calendar Quarter during the period of time during which a non-zero amount of royalties are payable under Section 3.2(b)(i) and following the First Commercial Sale of a Product or Method, until royalties are no longer payable under Section 3.2(b)(i), Novartis will provide or cause to be provided to the Company a Sales Report. The Company shall submit an Invoice to Novartis with respect to the royalty amount set forth on such Sales Report. Novartis shall pay such royalty amount within sixty (60) days after receipt of such Invoice.

(c) Technology Transfer Payment. As additional consideration, upon the completion of the technology transfer activities set forth in the Technology Transfer Plan in accordance with Section 6.1, Novartis shall pay to the Company the amounts set forth in Section 6.1(c).

3.3 Deductibility of Amounts Payable under the Chicago License. Notwithstanding any provision herein to the contrary: (i) Novartis may offset the amount of any Royalties (as defined in the Chicago License) paid by Novartis under the Chicago License (net of any deductions or credits as provided in the Chicago License) against the royalties otherwise payable to the Company pursuant to Section 3.2(b)(i), but solely as to that portion of the royalties attributable to the Product(s) or Method(s) at issue and in respect of the country(ies) at issue; and (ii) Novartis may offset the amount of any milestone payments paid by Novartis under Section 4.C of the Chicago License (net of any deductions or credits as provided in the Chicago License) against the Milestone Payments otherwise payable to the Company pursuant to Section 3.2(a)(i).

3.4 Currency; Payment. All payments under this Agreement shall be payable in United States dollars. When conversion of payments from any foreign currency is required to be undertaken by Novartis, the United States dollar equivalent shall be calculated using Novartis' then-current standard exchange rate methodology as applied in its external reporting. All payments by Novartis to the Company shall be made by wire transfer of immediately available funds to an account designated by the Company prior to the Effective Date, or as may be designated by the Company from time to time upon written notice to Novartis.

3.5 Taxes. The Company will pay any and all taxes levied on account of any payments made to it under this Agreement. If any such taxes are required to be withheld by Novartis, Novartis will: (a) deduct such taxes from the payment made to the Company; (b) timely pay the taxes to the proper taxing authority; (c) send proof of payment to the Company; and (d) reasonably assist the Company in its efforts to obtain a credit for such tax payment. Each party agrees to reasonably assist the other party in lawfully claiming exemptions from and/or minimizing such deductions or withholdings under double taxation Laws or similar circumstances.

CONFIDENTIAL TREATMENT REQUESTED

3.6 Records and Audit Rights.

(a) Novartis shall (and shall cause any of its Affiliates, licensees or sublicensees to) keep complete, true and accurate books and records in accordance with IFRS in relation to this Agreement, including in relation to Net Sales and royalties. Novartis will keep (or cause to be kept) such books and records for at least three (3) years following the Calendar Quarter to which they pertain.

(b) The Company shall have the right for a period of [*] after receiving any Sales Report to appoint an internationally-recognized independent accounting firm (which is reasonably acceptable to Novartis) (the "Auditor") to inspect the relevant records of Novartis or its Affiliates to verify such reports, statements, records or books of accounts, as applicable. Before beginning its audit, the Auditor shall execute an undertaking acceptable to Novartis by which the Auditor shall keep confidential all information reviewed during such audit. The Auditor shall have the right to disclose to the Company its conclusions regarding any payments owed under this Agreement.

(c) Novartis and its Affiliates shall make their records available for inspection by such Auditor during regular business hours at such place or places where such records are customarily kept, upon receipt of reasonable advance notice from the Company, solely to verify the accuracy of the Sales Reports. Such inspection right shall not be exercised more frequently than once in any calendar year and not more than once with respect to records covering any specific period of time. The Company agrees to hold in strict confidence all information received and all information learned in the course of any audit or inspection, except to the extent necessary to enforce its rights under this Agreement or if disclosure is required by law, regulation or judicial order.

(d) The Company shall pay for such audits, as well as its own expenses associated with enforcing its rights with respect to any payments hereunder, except that in the event there is any upward adjustment in aggregate amounts payable for any year shown by such audit of more than [*] percent ([*]%) of the amount paid, Novartis shall pay for such audit (as well as promptly paying to the Company the amount of any such adjustment).

Article IV

Intellectual Property TRANSFER

4.1 Transfer of Company Intellectual Property. On the Effective Date, the Company shall deliver to Novartis patent assignments with respect to the Acquired Patents, in the form attached hereto as Exhibit B, and any other good and sufficient instruments of transfer, conveyance and assignment reasonably acceptable to Novartis, to effect a conveyance of the Company Intellectual Property to Novartis and to vest in Novartis good and marketable title to the Company Intellectual Property, free and clear of all Liens.

Article V

REPRESENTATIONS AND WARRANTIES

5.1 Representations and Warranties of the Company. The Company hereby makes the representations and warranties to Novartis as set forth in this Article V.

(a) Due Organization. The Company is a corporation duly organized, validly existing and, where applicable, in good standing under the Laws of the jurisdiction of its organization. The Company has all requisite corporate power and authority to own, lease and operate all of its properties and assets and to carry on its business as it is now being conducted.

(b) Authorization and Validity of Agreement. The Company has all requisite corporate power and authority to enter into this Agreement and the documents, certificates and instruments referred to herein or delivered pursuant hereto (collectively, the "Transaction Documents") and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance by the Company of this Agreement and the other Transaction Documents and the consummation by the Company of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate action and no other corporate action or proceeding on the part of the Company is or will be necessary. This Agreement and the other Transaction Documents have been duly and validly executed and delivered by the Company and, assuming the due authorization, execution and delivery hereof by Novartis, constitute legal, valid and binding obligations of the Company, enforceable against it in accordance with their terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or other Laws relating to or affecting creditors' rights generally and by general equity principles (whether considered in a proceeding in equity or at law).

(c) No Conflict. The execution and delivery by the Company of this Agreement does not, and the execution and delivery by the Company of each other Transaction Document will not, and the consummation of the transactions contemplated hereby and thereby will not, (i) conflict with or result in a default under or violation of (any such conflict, default or violation, a "Violation") any provision of the certificate of incorporation,

by-laws or similar organizational documents of the Company or any of its Affiliates, (ii) result in any Violation of any material contractual obligations (including the Chicago License) of the Company or any of its Affiliates, or (iii) result in any Violation of any applicable Laws.

(d) Consents. No material consent, approval, authorization, filing, notification or other Permit of any Governmental Authority or of, with or from any other Person, is required in connection with the execution and delivery of this Agreement or any of the other Transaction Documents by the Company or the consummation by the Company of the transactions contemplated hereby or thereby.

(e) Title; Sufficiency of the Assets.

(i) The Company has good, valid and marketable title, of record and beneficially, to all of the Company Intellectual Property and, subject to the terms of the Chicago License, rights under the Chicago License, and will transfer and deliver to Novartis legal and valid title to the Company Intellectual Property and rights under the Chicago License as contemplated by this Agreement, free and clear of all Liens. Without limiting the foregoing, all Liens on Company Intellectual Property and the Company's rights under the Chicago License pursuant to the Note Security Agreements have been fully released pursuant to that certain Second Amendment to Security Agreements effective as of July 31, 2009 between the Company and the Investors and such release is in full force and effect and enforceable against the Investors. For purposes hereof, “Note Security Agreements” means (i) that certain Security Agreement dated as of April 14, 2009 between the Company and certain investors named therein and (ii) that certain Security Agreement dated as of May 14, 2009 between the Company and certain investors named therein (such investors, collectively with the investors party to the Security Agreement dated as of April 14, 2009, the “Investors”).

(ii) The Company Intellectual Property and the Company’s rights under the Chicago License comprise all the Intellectual Property assets owned or licensed by the Company and employed or used by the Company in connection with the MDSC Program. The Company Intellectual Property, the rights under the Chicago License and the rights of Novartis under this Agreement and the other Transaction Documents are sufficient, with respect to Intellectual Property assets, for Novartis to use or otherwise exploit the MDSC Program immediately following the Effective Date in substantially the same manner as currently conducted by the Company and its Affiliates.

(f) Legal Proceedings. Except for the ongoing prosecutions with various Governmental Authorities of patent applications included within the Company Intellectual Property or representing the subject of the rights under the Chicago License, there are no, and there have not been any, Proceedings pending or, to the knowledge of the Company, threatened in writing against, affecting or involving any of the Company Intellectual Property or the Chicago License.

(g) Compliance with Laws.

(i) The Company has made on a timely basis all required filings, applications and registrations with Governmental Authorities required in relation to the Company Intellectual Property , the rights under the Chicago License and the MDSC Program (including all authorizations required by the regulations of the FDA and all foreign equivalents thereof).

(ii) The Company is, and at all times has been, in compliance in all material respects with all Laws applicable to the ownership or use of the Company Intellectual Property, the rights under the Chicago License or the MDSC Program, and the Company has not received any written notice alleging facts which, if true, would constitute a failure to comply with this subsection (g)(ii).

(iii) The Company has filed with the FDA all material required notices, supplemental applications and annual or other reports in connection with the use of the Company Intellectual Property, the rights under the Chicago License or the MDSC Program.

(h) Brokers, Finders, etc. No agent, broker, investment banker, financial advisor or other firm or Person is or will be entitled to any broker’s or finder’s fee or any other similar commission or fee in connection with any of the transactions contemplated by this Agreement or the other Transaction Documents.

(i) Intellectual Property.

(i) Except for the ongoing prosecutions with various Governmental Authorities of patent applications included within the Company Intellectual Property or representing the subject of the rights under the Chicago License: (x) there are no Proceedings before any Governmental Authority (including the United States Patent and Trademark Office or equivalent authority anywhere in the world) related to any Company Intellectual Property or the rights under the Chicago License; and (y) no Company Intellectual Property or the rights under the Chicago License is the subject of any Proceeding, Order, agreement, or stipulation binding on the Company or any of its Affiliates restricting in any material respect the use, transfer, or licensing thereof by the Company or its Affiliates, or which could reasonably be expected to adversely affect the validity, use or enforceability of Company Intellectual Property.

(ii) With respect to each item of Company Intellectual Property, necessary registration, maintenance, annuities and renewal fees in connection with such Company Intellectual Property have been made and all necessary documents and certificates in connection with such Company Intellectual Property have been filed with the relevant patent authorities in the United States and other countries of the world for the purposes of maintaining such Company Intellectual Property.

(iii) The Company owns and has good and exclusive title to, in each case free and clear of any Liens, all Company Intellectual Property and the rights under the Chicago License.

(iv) Neither the Company nor any of its Affiliates has transferred ownership of, or granted any license with respect to any Company Intellectual Property or the rights under the Chicago License to any Third Party or any Affiliate of Company.

(v) To the knowledge of the Company: (i) no person has infringed or misappropriated or is infringing or misappropriating any Company Intellectual Property or the rights under the Chicago License; and (ii) excepting herefrom any Intellectual Property referenced in the files before the applicable Governmental Authorities for the various patent applications included within the Company Intellectual Property or representing the subject of the rights under the Chicago License or any validity, infringement or freedom-to-operate opinions provided to Novartis by the Company, neither the Company nor any of its Affiliates has infringed or misappropriated or is infringing or misappropriating, in connection with the use, exploitation or license of the Company Intellectual Property or the rights under the Chicago License for the MDSC Program, the Intellectual Property of any Person.

(vi) All employees, officers, contractors and consultants of the Company and its Affiliates have executed agreements requiring assignment to the Company or its Affiliates, as the case may be, of all inventions relating to the Company Intellectual Property, the rights under the Chicago License or the MDSC Program made during the course of and as a result of their association with it and obligating the individual to maintain as confidential the confidential information of the Company or its Affiliates, as the case may be, relating to the Company Intellectual Property, the rights under the Chicago License or the MDSC Program.

(vii) To the knowledge of the Company, and except as set forth in the files before the applicable Governmental Authorities for the various patent applications included within the Company Intellectual Property or representing the subject of the rights under the Chicago License or any validity, infringement or freedom-to-operate opinions provided to Novartis by the Company: (x) the Company Intellectual Property and the rights under the Chicago License are valid and enforceable; and (y) there are no matters which could reasonably be expected to affect the validity of the Company Intellectual Property or the rights under the Chicago License.

(viii) The Company has provided Novartis with a copy of all validity, infringement or freedom-to-operate opinions that are or were prepared by or on behalf of the Company or its Affiliates pertaining to Company Intellectual Property, the rights under the Chicago License or the MDSC Program.

(j) Chicago License. The Chicago License is valid and in full force and effect. The Company has complied in all material respects with its obligations required to be complied with by it to date under the Chicago License and it is not (with or without the lapse of time or the giving of notice, or both) in breach or default in any respect thereunder and, to the Company's knowledge, no other party to the Chicago License is (with or without the lapse of time or the giving of notice, or both) in breach or default in any respect thereunder. Following the Effective Date, Novartis will be permitted to exercise all rights of the LICENSEE under the Chicago License. The Company has delivered to Novartis a complete and correct copy of the Chicago License, together with all modifications and amendments thereto, which is attached as Exhibit A.

(k) Solvency. The Company is not now insolvent and will not be rendered insolvent by consummating the transactions contemplated by this Agreement and the other Transaction Documents. As used in this section, "insolvent" means that the sum of the debts and other probable Liabilities of the Company exceeds the present fair saleable value of the Company's assets. Immediately after giving effect to the transactions contemplated by this Agreement and the Transaction Documents: (i) the Company will be able to pay its Liabilities as they become due in the usual course of its business; (ii) the Company will not have unreasonably small capital with which to conduct its present or proposed business; (iii) the Company will have assets (calculated at fair market value) that exceed its Liabilities; and (iv) taking into account all pending and threatened litigation, final judgments against the Company in actions for money damages are not reasonably anticipated to be rendered at a time when, or in amounts such that, the Company will be unable to satisfy any such judgments promptly in accordance with their terms (taking into account the maximum probable amount of such judgments in any such actions and the earliest reasonable time at which such judgments might be rendered) as well as all other obligations of the Company. The cash available to the Company, after taking into account all other anticipated uses of the cash, will be sufficient to pay all such debts and judgments promptly in accordance with their terms.

(l) Regulatory Status. The Company has not received any written notice that any filing with any Governmental Authority in relation to the Company Intellectual Property is not currently in good standing. The Company has filed with the FDA all required notices, supplemental applications and annual or other reports, relating to the Company Intellectual Property. The Company has delivered to Novartis copies of all

material (i) reports of inspection observations, (ii) establishment inspection reports, and (iii) warning letters, as well as any other material documents received by the Company from the FDA or any other Governmental Authority relating to the Company Intellectual Property or MDSC Program that assert ongoing material lack of compliance with any Laws (including regulations promulgated by the FDA and any other Governmental Authority) by the Company.

5.2 Representations and Warranties of Novartis. Novartis hereby makes the representations and warranties to Company as set forth in this Article V.

(a) Due Organization. Novartis is a corporation duly incorporated or otherwise organized, validly existing and in good standing under the Laws of its jurisdiction of incorporation or organization.

(b) Authorization and Validity of Agreement. Novartis has all requisite corporate power and authority to enter into this Agreement and the other Transaction Documents and to consummate the transactions contemplated hereby and thereby. The execution, delivery and performance by Novartis of this Agreement and the other Transaction Documents and the consummation by Novartis of the transactions contemplated hereby and thereby have been duly and validly authorized by all necessary corporate action of Novartis and no other corporate action or proceeding on the part of Novartis is or will be necessary for the execution, delivery and performance by Novartis of this Agreement or the other Transaction Documents and the consummation by Novartis of the transactions contemplated hereby or thereby. This Agreement and the other Transaction Documents have been duly and validly executed and delivered by Novartis and, assuming the due authorization, execution and delivery hereof by the Company, constitute legal, valid and binding obligations of Novartis, enforceable against Novartis in accordance with its terms, except as may be limited by bankruptcy, insolvency, reorganization, moratorium or other Laws relating to or affecting creditors' rights generally and by general equity principles (whether considered in a proceeding in equity or at law).

(c) No Conflict. The execution and delivery by Novartis of this Agreement or any of the other Transaction Documents does not, and the consummation of the transactions contemplated hereby and thereby will not, (i) result in any Violation of any provision of the articles or certificate of incorporation, by-laws or similar organizational documents of Novartis or any of its Affiliates, (ii) result in any Violation of any material contractual obligations of Novartis or any of its Affiliates or (iii) result in any Violation of any applicable Laws.

(d) Consents. No material consent, approval, authorization, filing, notification or other Permit of any Governmental Authority or of, with or from any other Person, is required in connection with the execution and delivery of this Agreement or any of the other Transaction Documents by Novartis or the consummation by Novartis of the transactions contemplated hereby or thereby.

(e) Brokers, Finders, etc. None of Novartis nor any of its Affiliates has employed any agent, broker, investment banker, financial advisor or other firm or Person in connection with the transactions contemplated by this Agreement, who is entitled to a fee or commission in connection with such transactions.

Article VI

COVENANTS

6.1 Technology Transfer.

(a) The Company shall perform the activities set forth in the technology transfer plan attached hereto as Exhibit C (the "Technology Transfer Plan") in a diligent, efficient and timely manner. The Company shall, for the relevant periods contemplated by the Technology Transfer Plan (but not extending beyond the first (1st) anniversary of the Effective Date), appoint two (2) FTEs who have sufficient expertise and knowledge with the Company Intellectual Property, the rights under the Chicago License and the MDSC Program to perform the activities required of the Company as set forth in the Technology Transfer Plan. In addition, all Intellectual Property generated by said FTEs with respect to and while carrying out the Technology Transfer Plan shall be the sole property of Novartis.

(b) The Company shall at all times bear all of the costs of its FTEs involved in the technology transfer activities contemplated in the Technology Transfer Plan.

(c) The parties anticipate that all of the technology transfer activities set forth in the Technology Transfer Plan, including both the activities relating to the transfer of Know-How and other information to Novartis or its designated Affiliate and the training activities, shall be completed within one (1) year after the Effective Date. Upon successful transfer to Novartis of all of the materials set forth on Schedule 2.1(a)(ii) (the "Transfer Date"), Novartis shall pay to the Company Five Hundred Thousand Dollars ($500,000). Provided that the criteria for the preceding payment have been met, Novartis shall pay to the Company another Five Hundred Thousand Dollars ($500,000) upon the earlier of the following: (i) such time as the training and qualification experiment milestones set forth in Stage 1, Phase 2 of the Technology Transfer Plan have been met; or (ii) six (6) months after the Transfer Date so long as the accomplishment of the training and qualification experiment milestones referenced above have not been materially impeded by the Company during such six (6) month period. Novartis shall pay each such amount no later than thirty (30) days after receipt of an Invoice for such amount which shall be issued by the Company no earlier than the completion of the event or time frame set forth above.

CONFIDENTIAL TREATMENT REQUESTED

6.2 [*]

6.3 Public Announcements. No party to this Agreement shall originate any publicity, news release or other public announcement, written or oral, whether relating to this Agreement, the terms of this Agreement or the existence of any arrangement between the parties, without the prior written consent of the Company (in the case of origination by Novartis) or Novartis (in the case of origination by the Company), whether named in such publicity, news release or other public announcement or not, except where such publicity, news release or other public announcement is required by Law; provided, however, in such event, the party issuing such publicity, news release or other public announcement shall still be required to consult with the Company or Novartis, as applicable, whether named in such publicity, news release or public announcement or not, a reasonable time but no less than 72 hours prior to its release to allow the Company or Novartis, as applicable, to comment thereon and, after its release, shall provide the other party with a copy thereof. If any party, based on the advice of its counsel, determines that this Agreement, or any of the other documents executed in connection herewith, must be filed with the SEC, then such party, prior to making any such filing, shall provide the Company or Novartis, as applicable, and its counsel with a redacted version of this Agreement (or any Transaction Documents or other related documents) which it intends to file and will give due consideration to any comments provided by the Company or Novartis, as applicable, or its counsel and use reasonable efforts to ensure the confidential treatment by the SEC of those sections specified by the Company or Novartis, as applicable, or its counsel.

6.4 Confidentiality. The Company shall, and shall cause its Affiliates to, hold in confidence all proprietary, secret or confidential information of Novartis and its Affiliates disclosed to the Company and its Affiliates in the course of this Agreement, and, following the Effective Date, all information relating to the Company Intellectual Property, the rights under the Chicago License and the MDSC Program (collectively, “Confidential Information”). The Company shall not disclose or use such Confidential Information, except to the extent such Confidential Information (a) is (at the time of disclosure) or becomes (after the time of disclosure) known to the public or part of the public domain through no breach of this Agreement by the Company or its Affiliates; (b) was known to, or was otherwise in the possession of, the Company or its Affiliates prior to the time of disclosure by Novartis or any of its Affiliates; (c) is disclosed to the Company or an Affiliate on a non-confidential basis by a Third Party who is entitled to disclose it without breaching any confidentiality obligation to Novartis or any of its Affiliates; or (d) is independently developed by or on behalf of the Company or its Affiliates, as evidenced by its written records, without reference to the Confidential Information disclosed by Novartis or its Affiliates under this Agreement. In the event the Company or its Affiliates is required to disclose Confidential Information of Novartis and/or its Affiliates by Law or in connection with bona fide legal process, such disclosure shall not be a breach of this Agreement; provided, that the Company (i) informs Novartis as soon as reasonably practicable of the required disclosure; (ii) limits the disclosure to the required purpose; and (iii) at Novartis’ request and expense, assists in good faith in an attempt to object to or limit the required disclosure.

CONFIDENTIAL TREATMENT REQUESTED

6.5 Non-Competition.

(a) For a period of [*] after the Effective Date, neither the Company nor any of its Affiliates shall, anywhere in the world, directly or indirectly, research, develop, manufacture or commercialize any product using or derived from MDSCs (or license or collaborate with a Third Party or an Affiliate of the Company to do any of the foregoing), provided that (i) if the Company is acquired by or merges with a Third Party, and such Third Party (or its affiliates prior to such acquisition or merger) has a bona-fide MDSC program prior to the date of execution of the definitive agreement for such acquisition or merger, such Third Party (and its affiliates other than the Company and any of its Affiliates existing prior to such acquisition or merger) shall not be bound by this Section 6.5(a), and (ii) if the Company is acquired by or merges with a Third Party more than [*] after the Effective Date, such Third Party (and its affiliates other than the Company and any of its Affiliates existing prior to such acquisition or merger) shall not be bound by this Section 6.5(a). Notwithstanding the foregoing, the Company and its Affiliates (existing prior to such acquisition or merger) shall not disclose any of their Know-How related to the MDSC Program which is not otherwise excepted from Section 6.4 pursuant to Section 6.4(a), (c) or (d) to such Third Party or its affiliates and such Third Party and its affiliates shall be barred from using such Know-How which is not otherwise excepted from Section 6.4 pursuant to Section 6.4(a), (c) or (d) (including such clauses as applied to such Third Party and its affiliates as though they were, for purposes of such clauses, the Company and its Affiliates) in their MDSC program.

(b) If any court or other Governmental Authority determines that the scope or terms of Section 6.5(a), or any part thereof, is unenforceable because of the duration of such provision or the area covered thereby, such court or other Governmental Authority shall have the power to reduce the duration or area of such provision and, in its reduced form, such provision shall then be enforceable and binding on the Company.

6.6 Availability of Records. Subject to Section 6.4, after the Effective Date, the Company, on the one hand, and Novartis, on the other hand, shall make available to each other party and its Affiliates and Representatives during normal business hours when reasonably requested, all information, records and documents related to the Company Intellectual Property, rights under the Chicago License or MDSC Program in its possession and shall (to the extent not transferred to the other party) preserve all such information, records and documents until the later of: (i)

six (6) years after the Effective Date; or (ii) the required retention period under any applicable Laws for all such information, records or documents. Novartis and the Company shall also make available to each other during normal business hours, when reasonably requested, personnel responsible for preparing or maintaining information, records and documents, in connection with Regulatory Filings, litigation or potential litigation, each as it relates to the Company Intellectual Property, rights under the Chicago License or MDSC Program prior to the Effective Date (with respect to the Company) or from and after the Effective Date (with respect to Novartis).

6.7 Prosecution of Patent Applications. Novartis shall exercise commercially reasonable efforts (i) to obtain (or to cause to be obtained) the broadest patent protection reasonably available from each patent application within the Acquired Patents on or before the date that is [*] following the respective filing date for such application; and (ii) maintain in force the patents and patent applications of the Acquired Patents. For purposes of this Section 6.7, any assessment of whether or not pursuit and maintenance of patent protection is commercially reasonable shall exclude any consideration of whether any other Intellectual Property is available to Novartis.

CONFIDENTIAL TREATMENT REQUESTED

6.8 Transferees. Without limiting the provisions of Section 8.7, Novartis shall not transfer any Company Intellectual Property or any rights under the Chicago License without causing any transferee to assume (and any successor to any Company Intellectual Property or any rights under the Chicago License shall take subject to) the obligations of Novartis under this Agreement (as though any such party were Novartis), including without limitation the obligation to cause any successive transferee(s) (or successor(s)) to be subject to this Section 6.8.

Article VII

INDEMNIFICATION

7.1 Indemnification by the Company. (a) From and after the Effective Date, the Company shall indemnify Novartis and its Affiliates and each of their respective officers, directors, employees, stockholders, agents and representatives against, and hold them harmless from and against, any and all Losses, as incurred (payable promptly upon written request), arising from, in connection with or otherwise with respect to:

(i) any breach of any representation or warranty of the Company contained in this Agreement or in any document delivered in connection herewith;

(ii) the failure by the Company to perform any covenant, agreement, obligation or undertaking contained in this Agreement or in any document delivered in connection herewith;

(iii) all Retained Liabilities; and

(iv) the failure to comply with statutory provisions relating to bulk sales and transfers, if applicable, with respect to the transactions contemplated by this Agreement.

(b) Indemnification by Novartis. From and after the Effective Date, Novartis shall indemnify the Company and its Affiliates and each of their respective officers, directors, employees, stockholders, agents and representatives against, and hold them harmless from and against, any and all Losses, as incurred (payable promptly upon written request), arising from, in connection with or otherwise with respect to: any breach of any representation or warranty of Novartis contained in this Agreement or in any document delivered in connection herewith;

(ii) the failure by Novartis to perform any covenant, agreement, obligation or undertaking contained in this Agreement or in any document delivered in connection herewith;

(iii) the Assumed Liabilities; and

(iv) any claim or other Liability relating to, or any adverse event arising in connection with, the development, manufacture, use, sale, licensing or other disposition of any Product or Method (whether such claim is based on contract, tort, negligence, strict liability or any other theory of liability), by Novartis, an Affiliate of Novartis, or their licensees or sublicensees.

7.2 Indemnification Procedure.

(a) A party seeking indemnification hereunder (the “Indemnified Party”) shall notify the other party (the “Indemnifying Party”) in writing (each, an “Indemnification Claim Notice”) reasonably promptly after the assertion against the Indemnified Party of any claim or fact in respect of which the Indemnified Party intends to base a claim for indemnification hereunder (“Claim”), but the failure or delay to so notify the Indemnifying Party shall not relieve the Indemnifying Party of any obligation or liability that it may have to the Indemnified Party, except to the extent that the Indemnifying

Party demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. The Indemnification Claim Notice shall contain a description of the Claim and the nature and amount of the Claim (to the extent that the nature and amount of such Claim is known at such time). Upon the request of the Indemnifying Party, the Indemnified Party shall furnish promptly to the Indemnifying Party copies of all correspondence, communications and official documents (including court documents) received or sent in respect of such Claim.

(b) Subject to the provisions of subsections (c) and (d) below, the Indemnifying Party shall have the right, upon written notice given to the Indemnified Party within thirty (30) days after receipt of the Indemnification Claim Notice to assume the defense and handling of such Claim, at the Indemnifying Party's sole expense, in which case the provisions of subsection (c) below shall govern. The assumption of the defense of a Claim by the Indemnifying Party shall not be construed as acknowledgement that the Indemnifying Party is liable to indemnify any indemnitee in respect of the Claim, nor shall it constitute a waiver by the Indemnifying Party of any defenses it may assert against any Indemnified Party's claim for indemnification. In the event that it is ultimately decided that the Indemnifying Party is not obligated to indemnify or hold an indemnitee harmless from and against the Claim, the Indemnified Party shall reimburse the Indemnifying Party for any and all reasonable costs and expenses (including reasonable attorneys' fees and costs of suit) and any losses reasonably incurred by the Indemnifying Party in its defense of the Claim. If the Indemnifying Party does not give written notice to the Indemnified Party, within thirty (30) days after receipt of the Indemnification Claim Notice, of the Indemnifying Party's election to assume the defense and handling of such Claim, the provisions of subsection (d) below shall govern.

(c) Upon assumption of the defense of a Claim by the Indemnifying Party: (i) the Indemnifying Party shall have the right to and shall assume sole control and responsibility for dealing with the Claim; (ii) the Indemnifying Party may, at its own cost, appoint as counsel in connection with conducting the defense and handling of such Claim any law firm or counsel reasonably selected by the Indemnifying Party; (iii) the Indemnifying Party shall keep the Indemnified Party informed of the status of such Claim; and (iv) the Indemnifying Party shall have the right to settle the Claim on any terms the Indemnifying Party chooses; provided, however, that it shall not, without the prior written consent of the Indemnified Party (which shall not be unreasonably withheld, delayed or conditioned), agree to a settlement of any Claim which could lead to liability or create any financial or other obligation on the part of the Indemnified Party for which the Indemnified Party will not be indemnified hereunder or which admits any wrongdoing or responsibility for the Claim on behalf of the Indemnified Party. The Indemnified Party shall cooperate with the Indemnifying Party and shall be entitled to participate in, but not control, the defense of such Claim with its own counsel and at its own expense. In particular, the Indemnified Party shall furnish such records, information and testimony, provide witnesses and attend such conferences, discovery proceedings, hearings, trials and appeals as may be reasonably requested in connection therewith. Such cooperation shall include access during normal business hours by the Indemnifying Party to, and reasonable retention by the Indemnified Party of, records and information that are reasonably relevant to such Claim, and making the Indemnified Party, its indemnitees and its and their employees and agents available on a mutually convenient basis to provide additional information and explanation of any records or information provided.

(d) If the Indemnifying Party does not give written notice to the Indemnified Party as set forth in subsection (b) or fails to conduct the defense and handling of any Claim in good faith after having assumed such, the Indemnified Party may, at the Indemnifying Party's expense, select counsel reasonably acceptable to the Indemnifying Party in connection with conducting the defense and handling of such Claim and defend or handle such Claim in such manner as it may deem appropriate. In such event, the Indemnified Party shall keep the Indemnifying Party timely apprised of the status of such Claim and shall not settle such Claim without the prior written consent of the Indemnifying Party, which consent shall not be unreasonably withheld, delayed or conditioned. If the Indemnified Party defends or handles such Claim, the Indemnifying Party shall cooperate with the Indemnified Party, at the Indemnified Party's request but at no expense to the Indemnified Party, and shall be entitled to participate in the defense and handling of such Claim with its own counsel and at its own expense.

7.3 Special, Indirect and Other Losses. NEITHER PARTY NOR ANY OF ITS AFFILIATES SHALL BE LIABLE IN CONTRACT, TORT, NEGLIGENCE, BREACH OF STATUTORY DUTY OR OTHERWISE FOR ANY SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES OR FOR ANY ECONOMIC LOSS OR LOSS OF PROFITS SUFFERED BY THE OTHER PARTY, EXCEPT TO THE EXTENT ANY SUCH DAMAGES ARE REQUIRED TO BE PAID TO A THIRD PARTY AS PART OF A CLAIM FOR WHICH A PARTY PROVIDES INDEMNIFICATION UNDER THIS ARTICLE VII.

Article VIII

MISCELLANEOUS

8.1 Notices. All notices and other communications hereunder shall be in writing and shall be deemed duly given (a) on the date of delivery if delivered personally, or by telecopy or facsimile, upon confirmation of receipt, (b) on the date of confirmed receipt if delivered by a recognized next-day courier service or (c) on the date of confirmed receipt if delivered by registered or certified mail return receipt requested, postage prepaid. All notices hereunder shall be delivered as set forth below, or pursuant to such other instructions as may be designated in writing by the party to receive such notice:

(i) if to the Company:

Opexa Therapeutics, Inc.

2635 N. Crescent Ridge Drive

The Woodlands, TX 77381

Attention: Chief Financial Officer

Facsimile: (281) 872-8585

(ii) if to Novartis:

Novartis Institutes for BioMedical Research, Inc.

250 Massachusetts Avenue

Cambridge, MA 02139

Attention: General Counsel

Facsimile: (617) 871-3349

8.2 Counterparts; Facsimile Signature. This Agreement may be executed in any number of counterparts, each of which shall be considered one and the same agreement and shall become effective when all counterparts have been signed by each of the parties and delivered to the other party, it being understood that the parties need not sign the same counterpart. Any party may execute this Agreement by facsimile or scanned signature, and the other parties will be entitled to rely on such facsimile or scanned signature as conclusive evidence that this Agreement has been duly executed by such party.

8.3 Bulk Sales. The parties hereto agree to waive compliance with the provisions of the Laws of any jurisdiction relating to a bulk sale or transfer of assets that may be applicable to the transactions contemplated by this Agreement; provided, however, that to the extent Novartis is required to make any payments with respect to any provisions of the Laws of any jurisdiction relating to a bulk sale or transfer of assets that may be applicable to the transactions contemplated by this Agreement, the Company shall fully indemnify Novartis for such payments pursuant to Section 7.1(a)(iv).

8.4 Further Assurances. From time to time after the Effective Date and without further consideration, the parties hereto shall, and shall cause their respective Affiliates to, execute, acknowledge and deliver such documents and instruments of conveyance, assignment, assumption, transfer and delivery and take or cause to be taken such other actions as Novartis or the Company, as applicable, may reasonably request in order to carry out the purpose and intention of this Agreement, including, without limitation, to consummate more effectively the purchase, sale, conveyance, assignment, assumption, transfer and delivery of the Company Intellectual Property as contemplated by this Agreement, to vest in Novartis title to the Company Intellectual Property, to assign the Chicago License to Novartis or as otherwise appropriate to consummate the transactions contemplated by this Agreement.

8.5 Entire Agreement. This Agreement and the other Transaction Documents constitute the entire agreement among the parties hereto with respect to the subject matter hereof and terminate and supersede all prior agreements and understandings, including the Confidentiality Agreement, oral and written, among the parties hereto with respect to the subject matter hereof and thereof.

8.6 No Third-Party Beneficiaries. This Agreement shall inure to the benefit of and be binding upon the parties hereto and their respective successors and assigns. Except as provided in Article 7 with respect to the indemnification of various non-parties, nothing in this Agreement, expressed or implied, is intended to or shall confer on any Person other than the parties hereto or their respective successors and assigns, any rights, remedies or Liabilities under or by reason of this Agreement.

8.7 Assignment. Neither this Agreement nor any of the rights, interests or obligations hereunder shall be assigned by any of the parties hereto, in whole or in part (whether by operation of law or otherwise), without the prior written consent of the other party (which consent shall not be unreasonably withheld, delayed or conditioned), and any attempt to make any such assignment without such consent shall be null and void; provided, however, that (i) Novartis may assign in writing its rights and obligations, in whole or in part, to one or more of its Affiliates, and (ii) Novartis may assign in writing all of its rights and obligations to a Third Party in connection with a sale or assignment of all or substantially all of the assets to which this Agreement relates.

8.8 Amendment and Modification; Waiver. This Agreement may not be amended, modified or supplemented, except by an instrument in writing signed on behalf of each of the parties hereto. The failure of any party to assert a right hereunder or to insist upon compliance with any term or

condition of this Agreement shall not constitute a waiver of that right or excuse a similar subsequent failure to perform any such term or condition by the other party. No waiver shall be effective unless it has been given in writing and signed by the party giving such waiver.

8.9 Enforcement; Jurisdiction. The parties agree that irreparable damage would occur in the event that any of the provisions of this Agreement were not performed in accordance with their specific terms or were otherwise breached. It is accordingly agreed that the parties shall be entitled to an injunction or injunctions to prevent breaches of this Agreement and to enforce specifically the terms and provisions of this Agreement in any federal court or state court sitting in the State of New York, this being in addition to any other remedy to which they are entitled at law or in equity subject to the terms hereof. In addition, each of the parties hereto (a) hereby irrevocably agrees that any legal action or proceeding with respect to this Agreement or for recognition and enforcement of any judgment in respect hereof brought by another party hereto or its successors or assigns may be brought and determined in the federal courts located in the State of New York, and each party hereto hereby irrevocably submits with regard to any such action or proceeding for itself and in respect of its property, generally and unconditionally, to the exclusive jurisdiction of the aforesaid courts, and (b) irrevocably waives, and agrees not to assert, by way of motion, as a defense, counterclaim or otherwise, in any action or proceeding with respect to this Agreement, (i) any claim that it is not personally subject to the jurisdiction of the above-named courts for any reason other than the failure to lawfully serve process, (ii) that it or its property is exempt or immune from jurisdiction of any such court or from any legal process commenced in such courts (whether through service of notice, attachment prior to judgment, attachment in aid of execution of judgment, execution of judgment or otherwise), and (iii) to the fullest extent permitted by applicable Law, that (A) the suit, action or proceeding in any such court is brought in an inconvenient forum, (B) the venue of such suit, action or proceeding is improper and (C) this Agreement, or the subject matter hereof, may not be enforced in or by such courts.

8.10 Waiver of Jury Trial. EACH OF THE PARTIES TO THIS AGREEMENT HEREBY IRREVOCABLY WAIVES, TO THE FULLEST EXTENT PERMITTED BY LAW, ALL RIGHTS TO A TRIAL BY JURY IN ANY ACTION, PROCEEDING OR COUNTERCLAIM (WHETHER BASED ON CONTRACT, TORT OR OTHERWISE) ARISING OUT OF OR RELATING TO THIS AGREEMENT OR ANY OF THE TRANSACTIONS CONTEMPLATED HEREBY.

8.11 Costs and Expenses. Regardless of whether the transactions contemplated by this Agreement are consummated and except as otherwise expressly provided in this Agreement, the Company, on the one hand, and Novartis, on the other hand, shall each bear their own costs and expenses (including, without limitation, attorneys' fees and costs) incurred in connection with this Agreement and the transactions contemplated by this Agreement.

8.12 Mutual Drafting. The parties hereto have been represented by counsel who have carefully negotiated the provisions hereof. As a consequence, the parties do not intend that the presumptions of any Laws or rules relating to the interpretation of contracts against the drafter of any particular clause should be applied to this Agreement and therefore waive their effects. The provisions of this Agreement shall be interpreted in a reasonable manner to effect the intent of the parties.

8.13 Governing Law. This Agreement shall be governed by, and construed and interpreted in accordance with, the laws of the State of New York, without giving effect to the principles of conflict of laws thereof.

8.14 Severability. Any term or provision of this Agreement which is invalid or unenforceable in any jurisdiction shall, as to that jurisdiction, be ineffective to the extent of such invalidity or unenforceability and shall not render invalid or unenforceable the remaining terms and provisions of this Agreement or affect the validity or enforceability of any of the terms or provisions of this Agreement in any other jurisdiction. If any provision of this Agreement is so broad as to be unenforceable, the provision shall be interpreted to be only so broad as is enforceable.

8.15 Corporate Citizenship. Novartis gives preference to Third Parties who share Novartis' societal and environmental values, as set forth in the Novartis Policy on Corporate Citizenship and Novartis Corporate Citizenship Guideline #5, both of which are attached as Exhibit E and incorporated herein by reference. Accordingly, Company represents and warrants that this Agreement will be performed in material compliance with all applicable Laws and regulations, including, without limitation, Laws and regulations relating to health, safety and the environment, fair labor practices and unlawful discrimination.

8.17 Privacy Notice. This Agreement contains information such as name, signature and contact information (the "Personal Information") that identifies or describes one or more individuals. This Agreement, and the Personal Information contained herein, from time to time may be transferred to, stored or otherwise processed in the United States or other countries that have privacy and data protection Laws that differ from, or are not as stringent as, those where the Agreement was executed or where the individual(s) resides. The Personal Information disclosed in this Agreement will be used for the purposes of administration and enforcement of this Agreement and/or other actual or potential legal and business transactions involving the parties. Storage or processing of Personal Information disclosed in this Agreement may be electronic and/or off line. Execution and delivery of this Agreement constitutes the representation by each party that if required by the privacy Laws applicable to such individuals, the individuals identified herein by such party have been notified of and have consented to, the transfer, storage, and processing of such Personal Information, as described in this Section.

[Remainder of page intentionally left blank.]

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IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed and delivered as of the date first above written.

OPEXA THERAPEUTICS, INC.

By:

/s/ Neil K. Warma

Name:

Neil K. Warma

Title:

President and CEO

NOVARTIS INSTITUTES FOR BIOMEDICAL RESEARCH, INC.

By:

/s/ Mark C. Fishman, M.D.

Name:

Mark C. Fishman, M.D.

Title:

President and CEO

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