

OPEXA THERAPEUTICS, INC.

FORM 8-K (Current report filing)

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Address	2635 TECHNOLOGY FOREST BLVD. THE WOODLANDS, TX 77381
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**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION**
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT

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

Date of Report (date of earliest event reported): February 4 , 2013

OPEXA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Texas
(State or other jurisdiction of
incorporation)

001-33004
(Commission File Number)

76-0333165
(IRS Employer Identification No.)

2635 Technology Forest Blvd., The Woodlands, Texas
(Address of principal executive offices)

77381
(Zip Code)

Registrant's telephone number, including area code: **(281) 272-9331**
N/A
(Former name or former address, if changed since last report)

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

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
 - ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
 - ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
 - ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))
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Item 1.01. Entry into a Material Definitive Agreement

On February 4, 2013, Opexa Therapeutics, Inc. (the “Company”) entered into an Option and License Agreement (the “Agreement”) with Ares Trading SA (“Merck”), a wholly owned subsidiary of Merck Serono S.A. Pursuant to the Agreement, Merck has an option (the “Option”) to acquire an exclusive, worldwide (excluding Japan) license of the Company’s Tcelna™ program for the treatment of multiple sclerosis (“MS”). Tcelna is currently in a Phase IIb clinical trial in patients with Secondary Progressive MS (“SPMS”). The Option may be exercised by Merck prior to or upon the Company’s completion of the Phase IIb Trial.

Under the terms of the Agreement, the Company will receive an upfront payment of \$5 million for granting the Option. If the Option is exercised, Merck would pay the Company an upfront license fee of \$25 million unless Merck is unable to advance directly into a Phase III clinical trial of Tcelna for SPMS without a further Phase II clinical trial (as determined by Merck), in which event the upfront license fee would be \$15 million. After exercising the Option, Merck would be solely responsible for funding development, regulatory and commercialization activities for Tcelna in MS, although the Company would retain an option to co-fund certain development in exchange for increased royalty rates. The Company would also retain rights to Tcelna in Japan, certain rights with respect to the manufacture of Tcelna, and rights outside of MS.

Based upon the achievement of development and commercial milestones by Merck for Tcelna in SPMS and relapsing remitting MS (“RRMS”), the Company would be eligible to receive one-time milestone payments totaling up to \$195 million.

If Tcelna receives regulatory approval and is commercialized by Merck, the Company would be eligible to receive royalties pursuant to a tiered structure at rates ranging from high single digits to mid teens of annual net sales. Any royalties would be subject to offset or reduction in various situations, including if third party rights are required or if patent protection is not available in an applicable jurisdiction. Opexa would also be responsible for royalty obligations to certain third parties, such as Baylor University from which Opexa originally licensed related technology. If Opexa exercises its option to co-fund certain of Merck’s development, the royalty rates payable by Merck would be increased.

The Agreement is attached hereto as Exhibit 10.1 to provide security holders with information regarding its terms. It is not intended to provide any other factual information about the Company. The representations, warranties and covenants contained in the Agreement were made only for purposes of such agreement and as of specific dates, were solely for the benefit of the parties to such agreement, and may be subject to limitations agreed upon by the contracting parties, including being qualified by confidential disclosures exchanged between the parties in connection with the execution of the Agreement.

The foregoing description of the transactions contemplated by the Agreement as well as the Agreement itself does not purport to be complete and is qualified in its entirety by reference to the Exhibit.

Item 7.01 Other Events.

On February 5, 2013, the Company issued a press release announcing execution of the Agreement described above in Item 1.01. A copy of the press release is attached hereto as Exhibit 99.1 and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
10.1 †	Option and License Agreement, dated February 4, 2013, by and between Ares Trading SA, a wholly owned subsidiary of Merck Serono S.A., and Opexa Therapeutics, Inc.
99.1	Press Release issued by Opexa Therapeutics, Inc. on February 5, 2013.

The information in Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, shall not be deemed “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934 or otherwise subject to the liabilities under that Section, nor be deemed to be incorporated by reference into the filings of the registrant under the Securities Act of 1933.

† Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

SIGNATURES

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

Dated: February 5, 2013

OPEXA THERAPEUTICS, INC.

By: /s/ Neil K. Warma
Neil K. Warma
President & Chief Executive Officer

EXHIBIT INDEX

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†	Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.

EXHIBIT 10.1

Option and License Agreement

Confidential Treatment Requested. Confidential portions of this document have been redacted and have been separately filed with the Commission.

OPTION AND LICENSE AGREEMENT

Dated February 4, 2013

By and Between

Opexa Therapeutics, Inc.

and

Ares Trading SA

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OPTION AND LICENSE AGREEMENT

THIS OPTION AND LICENSE AGREEMENT (the “ **Agreement** ”) is dated as of February 4, 2013 (the “ **Effective Date** ”) by and between Opexa Therapeutics, Inc., a corporation organized under the laws of **Texas** having a place of business at 2635 Technology Forest Boulevard, The Woodlands, TX 77381 (“ **Licensor** ”), and Ares Trading SA, a Swiss corporation having a place of business at Zone industrielle de l’Ourietaz, 1170 Aubonne, Switzerland, which is a solely owned subsidiary of Merck Serono S.A., which is a solely owned subsidiary of Merck KGaA (“ **Merck** ”). Licensor and Merck may be referred to herein as a “ **Party** ” or, collectively, as “ **Parties** .”

RECITALS:

WHEREAS, Licensor is a pharmaceutical company dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases;

WHEREAS , Licensor is currently in the process of conducting a Phase IIb clinical study of Product in the Field;

WHEREAS, Merck is engaged in the research, development, manufacturing and commercialization of pharmaceutical products and is interested in potentially developing, manufacturing and commercializing Product in the Field; and

WHEREAS , Merck desires to obtain an exclusive option to, and to potentially exercise such option to obtain, an exclusive license from Licensor, and Licensor wishes to grant such exclusive option to license, and upon exercise of such option to license to Merck, on an exclusive basis, the right to develop, manufacture and commercialize Product in the Field in the Territory, all on the terms and subject to the conditions set forth herein.

Now, T HEREOFRE , in consideration of the various promises and undertakings set forth herein, the Parties agree as follows:

ARTICLE 1 DEFINITIONS

Unless otherwise specifically provided herein, the following terms shall have the following meanings:

- 1.1 “ **Abili-T Trial** ” means that certain Phase IIb clinical study of Product being conducted by Licensor as of the Effective Date for treatment of SPMS that has the ClinicalTrials.gov Identifier NCT01684761.

- 1.2 “ **Adverse Event** ” means any serious untoward medical occurrence in a patient or subject who is administered Product, but only if and to the extent that such serious untoward medical occurrence is required under Laws to be reported to applicable Regulatory Authorities.
- 1.3 “ **Affiliate** ” means a Person that controls, is controlled by or is under common control with a Party, but only for so long as such control exists. For the purposes of this Section 1.3, the word “control” (including, with correlative meaning, the terms “controlled by” or “under the common control with”) means the actual power, either directly or indirectly through one or more intermediaries, to direct the management and policies of such Person or entity, whether by the ownership of more than fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
- 1.4 “ **Calendar Quarter** ” means each three (3) month period commencing January 1, April 1, July 1 or October 1 of any year; provided, however, that: (a) the first Calendar Quarter of the Term shall extend from the Effective Date to the end of the first full Calendar Quarter thereafter; and (b) the last Calendar Quarter of the Term shall end upon the expiration or termination of this Agreement.
- 1.5 “ **Calendar Year** ” means the period beginning on the 1st of January and ending on the 31st of December of the same year; provided, however, that (a) the first Calendar Year of the Term shall commence on the Effective Date and end on December 31 of the same year, and (b) the last Calendar Year of the Term shall commence on January 1 of the Calendar Year in which this Agreement terminates or expires and end on the date of termination or expiration of this Agreement.
- 1.6 “ **CDA** ” means that certain non-disclosure agreement by and between Licensor and Merck Serono S.A. dated February 15, 2011.
- 1.7 “ **cGCP** ” means the current standards, practices and procedures set forth in the International Conference on Harmonization (ICH) guidelines entitled “Guidance for Industry E6 Good Clinical Practice: Consolidated Guidance” including related requirements imposed by the FDA, and equivalent non-US regulations or standards, as applicable, as such standards, practices, procedures, requirements and regulations may be amended from time to time.
- 1.8 “ **cGLP** ” means the current good laboratory practice regulations promulgated by the FDA, published at 21 US C.F.R. § 58, and equivalent non-US regulations or standards, as applicable, as such current laboratory practices, regulations and equivalent non-US regulations or standards may be amended from time to time.
- 1.9 “ **cGMP** ” means those current practices, as amended from time to time, related to the manufacture of pharmaceutical products and any precursors thereto promulgated in guidelines and regulations of standard compilations including the GMP Rules of the World Health Organization, the US Code of Federal Regulations, the Guide to Inspection of Bulk Pharmaceutical Chemicals (established by the US Department of Health and Human Services), the Pharmaceutical Inspection Convention, and the European Community Guide to Good Manufacturing Practice in the production of pharmaceutical products.

- 1.10 “ **Change of Control** ” means, with respect to a Person: (a) a transaction or series of related transactions that results in the sale or other disposition of all or substantially all of such Person’s assets; or (b) a merger or consolidation in which such Person is not the surviving corporation or in which, if such Person is the surviving corporation, the shareholders of such Person immediately prior to the consummation of such merger or consolidation do not, immediately after consummation of such merger or consolidation, possess, directly or indirectly through one or more intermediaries, a majority of the voting power of all of the surviving entity’s outstanding stock and other securities and the power to elect a majority of the members of such Person’s board of directors; or (c) a transaction or series of related transactions (which may include a tender offer for such Person’s stock or the issuance, sale or exchange of stock of such Person) if the shareholders of such Person immediately prior to the initial such transaction do not, immediately after consummation of such transaction or any of such related transactions, own, directly or indirectly through one or more intermediaries, stock or other securities of the entity that possess a majority of the voting power of all of such Person’s outstanding stock and other securities and the power to elect a majority of the members of such Person’s board of directors.
- 1.11 “ **Clinical Trial** ” means a clinical trial in human subjects that has been approved by a Regulatory Authority and Institutional Review Board or Ethics Committee, and is designed to measure the safety and/or efficacy of Product. Clinical Trials shall include Phase II Trials and Phase III Trials.
- 1.12 “ **Combination Product** ” means Product that: (a) includes one or more distinct pharmaceutically active ingredients that is/are the subject of its/their own separate MAAs (in addition to the MAA associated with Product); or (b) is combined with one or more products, devices, pieces of equipment or components that are proprietary (i.e., not “off-the-shelf”) and provide more than *de minimis* value to such Combination Product.
- 1.13 “ **Commercialization** ” or “ **Commercialize** ” means any and all activities undertaken before and after Regulatory Approval of a MAA for Product and that relate to the marketing, promoting, distributing, importing or exporting for sale, offering for sale, and selling of Product, and interacting with Regulatory Authorities regarding the foregoing.
- 1.14 “ **Commercially Reasonable Efforts** ” means: (a) with respect to the efforts to be expended by a Party with respect to any objective, such reasonable, diligent, and good faith efforts as such Party would normally use to accomplish a similar objective under similar circumstances; and (b) with respect to any objective relating to Development or Commercialization of Product by a Party, the application by such Party, consistent with the exercise of its prudent scientific and business judgment, of diligent efforts and resources to fulfill the obligation in issue, consistent with the level of efforts such Party would devote to a product at a similar stage in its product life as Product and having profit potential and strategic value comparable to that of Product, taking into account, without limitation, commercial, legal and regulatory factors, target product profiles, product labeling, past performance, the regulatory environment and competitive market conditions in the therapeutic area, safety and efficacy of Product, the strength of its proprietary position and such other factors as such Party may reasonably consider, all based on conditions then prevailing. For clarity, Commercially Reasonable Efforts, (i) with respect to a given task or objective, will not mean that a Party guarantees that it will actually accomplish such task or objective or (ii) prior to receipt of Regulatory Approval, with respect to Development of Product in the Field in the Territory generally, will not mean that a Party is permitted to permanently stop all attempts to Develop Product for purposes of obtaining Regulatory Approval.

- 1.15 “ **Competing Product** ” means any ***, *** product in any dosage form, formulation, presentation or package configuration which exhibits activity *** by means of ***.
- 1.16 “ **Compulsory License** ” means a compulsory license under Licensor Technology obtained by a Third Party through the order, decree, or grant of a competent Governmental Body or court, authorizing such Third Party to develop, make, have made, use, sell, offer to sell or import a Competing Product or Product in the Field in any country in the Territory.
- 1.17 “ **Confidential Information** ” of a Party, means information relating to the business, operations or products of a Party or any of its Affiliates, including any Know-How, not known or generally available to the public, that such Party previously disclosed to the other Party under the CDA, discloses to the other Party under this Agreement, or otherwise becomes known to the other Party by virtue of this Agreement or the CDA.
- 1.18 “ **Controlled** ” means, with respect to (a) Patent Rights, (b) Know-How or (c) biological, chemical or physical material, that a Person or one of its Affiliates owns or has a license or sublicense to such Patent Rights, Know-How or material (or in the case of material, has the right to physical possession of such material) and has the ability to grant a license or sublicense to, or assign its right, title and interest in and to, such Patent Rights, Know-How or material as provided for in this Agreement, or as is otherwise applicable, without violating the terms of any agreement or other arrangement with any Third Party.
- 1.19 “ **Cover** ”, “ **Covering** ” or “ **Covered** ” means, with respect to Product, that the making, using, selling, or offering for sale of Product would, but for a license granted in this Agreement under the Licensor Patent Rights, infringe a Valid Claim of the Licensor Patent Rights in the country in which the activity occurs.
- 1.20 “ **Development** ” or “ **Develop** ” means, with respect to Product, the performance of all pre-clinical and clinical development (including toxicology, pharmacology, test method development and stability testing, process development, formulation development, quality control development, statistical analysis), Clinical Trials, and regulatory activities that are required to obtain Regulatory Approval of Product.
- 1.21 “ **EMA** ” means the European Medicines Agency or a successor agency thereto.

- 1.22 “ **European Commission** ” means the authority within the European Union that has the legal authority to grant Regulatory Approvals in the European Union based on input received from the EMA or other competent Regulatory Authorities.
- 1.23 “ **European Union** ” or “ **EU** ” means the European Union, as may be redefined from time to time.
- 1.24 “ **Executive Officers** ” means, together, a member of the senior management of the pharmaceutical division of Merck and the Chief Executive Officer of Licensor.
- 1.25 “ **Existing Third Party Agreement(s)** ” means the agreement(s) set forth on Schedule 1.25.
- 1.26 “ **FDA** ” means the United States Food and Drug Administration or a successor federal agency thereto.
- 1.27 “ **Field** ” means any prophylactic, palliative or therapeutic treatment, or diagnosis, of Multiple Sclerosis (“ **MS** ”), including Primary Progressive Multiple Sclerosis (otherwise known as PPMS), Secondary Progressive Multiple Sclerosis (“ **SPMS** ”) and Relapsing Remitting Multiple Sclerosis (“ **RRMS** ”).
- 1.28 “ **First Commercial Sale** ” means, on a country-by-country basis, the first commercial transfer or disposition for value of Product in the Field in such country to a Third Party by Merck, or any of its Affiliates or Sublicensees, in each case, after all Regulatory Approvals necessary for such sale or disposition have been obtained in such country.
- 1.29 “ **FTE** ” means a full time equivalent person year, comprising *** hours per year, of scientific or technical work spent on, or directly related to, Development Support, Regulatory Support or Manufacturing Support, as applicable.
- 1.30 “ **FTE Rate** ” means the annual rate of \$*** USD per FTE.
- 1.31 “ **Governmental Body** ” means any: (a) nation, principality, state, commonwealth, province, territory, county, municipality, district or other jurisdiction of any nature; (b) federal, state, local, municipal, foreign or other government; (c) governmental or quasi-governmental authority of any nature (including any governmental division, subdivision, department, agency, bureau, branch, office, commission, council, board, instrumentality, officer, official, representative, organization, unit, body or entity and any court or other tribunal); (d) multi-national or supranational organization or body; or (e) individual, entity or body exercising, or entitled to exercise, any executive, legislative, judicial, administrative, regulatory, police, military or taxing authority or power of any nature.
- 1.32 “ **IFRS** ” means the International Financial Reporting Standards, the set of accounting standards and interpretations and the framework in force on the Effective Date and adopted by the European Union as issued by the International Accounting Standards Board (IASB) and the International Financial Reporting Interpretations Committee (IFRIC), as such accounting standards may be amended from time to time.

- 1.33 “ **Indication** ” means a generally acknowledged disease or condition, a significant manifestation of a disease or condition, or symptoms associated with a disease or condition or a risk for a disease or condition for which a MAA may be obtained.
- 1.34 “ **IND** ” means an investigational new drug application submitted to applicable Regulatory Authorities for approval to commence Clinical Trials in a given jurisdiction.
- 1.35 “ **Know-How** ” means any: (a) scientific or technical information, results and data of any type whatsoever, in any tangible or intangible form whatsoever, that is not in the public domain or otherwise publicly known, including discoveries, inventions, trade secrets, devices, databases, practices, protocols, regulatory filings, methods, processes (including manufacturing processes, specifications and techniques), techniques, concepts, ideas, specifications, formulations, formulae, data (including pharmacological, biological, chemical, toxicological, clinical and analytical information, quality control, trial and stability data), case reports forms, medical records, data analyses, reports, studies and procedures, designs for experiments and tests and results of experimentation and testing (including results of research or development), summaries and information contained in submissions to and information from ethical committees, or Regulatory Authorities, and manufacturing process and development information, results and data, whether or not patentable, all to the extent not claimed or disclosed in a patent or patent application; and (b) compositions of matter, cells, cell lines, assays, animal models and physical, biological or chemical material, including drug substance samples, intermediates of drug substance samples, drug product samples and intermediates of drug product samples, and proprietary equipment, procedures or methodologies relating to the manufacturing of Product. The fact that an item is known to the public shall not be taken to exclude the possibility that a compilation including the item, and/or a development relating to the item, is (and remains) not known to the public. “Know-How” includes any rights, including copyright, database or design rights, protecting such Know-How. “Know-How” excludes Patent Rights.
- 1.36 “ **Knowledge** ” means, with respect to a matter that is the subject of a given representation, or warranty of Licensor, the knowledge of any officer or director of Licensor, or such other employee of Licensor who would reasonably be expected to have knowledge of the matter in question, has, or should reasonably be expected to have, after making reasonable inquiry into the relevant subject matter; provided, however, that any officer, director or employee of Licensor shall be deemed to have knowledge of a Third Party’s Patent Right only if such officer, director or employee has actual knowledge of such Third Party’s Patent Right or would be found to be on notice of such Third Party’s Patent Right as determined by reference to United States patent laws. “Knowingly” means with Knowledge.
- 1.37 “ **Law** ” or “ **Laws** ” means all applicable laws, statutes, rules, regulations, ordinances and other pronouncements having the binding effect of law of any Governmental Body.

- 1.38 “ **Licensor Bankruptcy Event** ” means: (a) voluntary or involuntary proceedings by or against Licensor are instituted in bankruptcy under any insolvency Law, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days (or sixty (60) days if during the Option Period) after the date of filing; (b) a receiver or custodian is appointed for Licensor; (c) proceedings are instituted by or against Licensor for corporate reorganization, dissolution, liquidation or winding-up of Licensor, which proceedings, if involuntary, shall not have been dismissed within ninety (90) days (or sixty (60) days if during the Option Period) after the date of filing; (d) substantially all of the assets of Licensor are seized or attached and not released within sixty (60) days thereafter; or (e) the deterioration of Licensor’s financial position during the Term such that Merck’s rights under this Agreement are reasonably likely to be adversely affected (as such deterioration is determined in Merck’s good faith discretion, following prior notice to Licensor and an opportunity of five (5) days for Licensor to provide a written objection to such determination setting forth in reasonable detail Licensor’s good faith basis for such objection).
- 1.39 “ **Licensor Know-How** ” means all Know-How that is Controlled by Licensor or, subject to Section 15.2(f), any of its Affiliates, as of the Effective Date or at any time thereafter during the Term, and that is: (a) *** for the Development, manufacture or Commercialization of Product; or (b) *** in the Development, manufacture or Commercialization of Product; or (c) for Know-How Controlled by Licensor or its Affiliates as of ***, *** for the (1) Development or manufacture of Product anywhere in the world for purposes of Commercializing Product in the Territory in the Field or (2) Commercialization of Product in the Territory; or (d) for Know-How *** Controlled by Licensor or its Affiliates after ***, *** for the (1) Development or manufacture of Product anywhere in the world for purposes of Commercializing Product in the Territory in the Field or (2) Commercialization of Product in the Territory.
- 1.40 “ **Licensor Patents** ” means all Patent Rights that are Controlled by Licensor or, subject to Section 15.2(f), any of its Affiliates, as of the Effective Date or at any time thereafter during the Term, and that are: (a) *** for the Development, manufacture or Commercialization of Product; or (b) *** in the Development, manufacture or Commercialization of Product; or (c) for Patent Rights Controlled by Licensor or its Affiliates as of ***, *** for the (1) Development or manufacture of Product anywhere in the world for purposes of Commercializing Product in the Territory in the Field or (2) Commercialization of Product in the Territory; or (d) for Patent Rights *** Controlled by Licensor or its Affiliates after ***, *** for the (1) Development or manufacture of Product anywhere in the world for purposes of Commercializing Product in the Territory in the Field or (2) Commercialization of Product in the Territory. Listed on Schedule 1.40 are all Licensor Patents existing as of the Effective Date; provided, that Licensor shall update Schedule 1.40 from time-to-time to include any new Licensor Patents.
- 1.41 “ **Licensor Technology** ” means the Licensor Patents and Licensor Know-How. For the avoidance of doubt, the Licensor Technology includes any Licensor Patents and/or Licensor Know-How Controlled by Licensor pursuant to any Existing Third Party Agreement or any Third Party License Agreement. For clarity, “Licensor Technology” includes: (a) the *** by *** are *** and *** in order to ***, which *** is *** to by ***, as of the Effective Date, as ***; and (b) any improvements to Product that Licensor may make on or following the Effective Date, including improvements to the *** by *** are ***, *** and *** or by *** are *** ***.

- 1.42 “ **Licensor Trademarks** ” means those trademarks set forth on Schedule 1.42 and any other trademarks that Licensor may have registered, or uses, in connection with (x) the Licensor Technology in the Field in the Territory, or (y) the Product in the Territory.
- 1.43 “ **MAA** ” means: (a) a Marketing Authorization Application, or a New Drug Application (NDA), submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. C.F.R. § 314.3 et seq; (b) a Biologics License Application submitted pursuant to the requirements of the FDA, as more fully defined in 21 U.S. C.F.R. § 601; and (c) any equivalent application submitted in any country in the Territory, including a European Marketing Authorization Application, together, in each case, with all additions, deletions or supplements thereto, and as any and all such requirements may be amended, or supplanted, at any time.
- 1.44 “ **Major EU Market** ” means any of Germany, the United Kingdom, France, Spain or Italy.
- 1.45 “ **Merck Competitor** ” means any company that (itself or through an Affiliate) is developing or commercializing a product in the Field .
- 1.46 “ **Net Sales** ” means the gross amounts invoiced by Merck or any of its Affiliates or Sublicensees for sales of Product to independent or unaffiliated Third Party purchasers of such Product, less the following deductions to the extent allocable thereto: (a) ***or *** or ***; (b) *** or *** or ***, ***, regardless of ***; (c) *** or ***; (d) *** in the *** for *** and any other ***relating to *** or *** of Product; (e) *** and *** and *** *** in connection with *** or *** of Product ***; (f) *** and *** or *** made to *** or ***, or any Third *** or ***; and (g) *** related to *** of Product paid to Third Parties (specifically excluding any commissions paid to sales personnel, sales representatives and sales agents who are employees or consultants of (or members of a contract sales force engaged by or on behalf of) Merck or its Affiliates or any Sublicensees). For clarity, sale of Product by Merck or any of its Affiliates or Sublicensees to another of these entities for resale by such entity to a Third Party shall not be deemed a sale for purposes of this definition of “Net Sales”.

If a Product under this Agreement is sold in the form of a Combination Product, then Net Sales for such Combination Product shall be determined on a country-by-country basis by mutual agreement of the Parties in good faith taking into account the perceived relative value contributions of Product and the other pharmaceutically active ingredient subject to its own separate MAA or proprietary (i.e. not off-the-shelf) component providing more than *de minimis* value in the Combination Product, as reflected in their respective market prices. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, designated by the International Chamber of Commerce, shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

In the event Product is “bundled” for sale together with one or more other products in a country (a “ **Product Bundle** ”), then Net Sales for such Product sold under such arrangement shall be determined on a country-by-country basis by mutual agreement of the Parties in good faith taking into account the relative value contributions of the Product and the other products in the Product Bundle, as reflected in their individual sales prices. In case of disagreement, an independent expert agreed upon by both Parties or, failing such agreement, the International Chamber of Commerce shall determine such relative value contributions and such determination shall be final and binding upon the Parties.

- 1.47 “ **Out-of-Pocket Expenses** ” means expenses actually paid by a Party or its Affiliate to any Third Party; provided, that “Out-of-Pocket Expenses” shall not include expenses paid to any consultants (or service providers of like kind), except for travel expenses associated with a consultant (or service provider of like kind).
- 1.48 “ **Patent Rights** ” means: (a) an issued or granted patent, including any extension, supplemental protection certificate, registration, confirmation, reissue, reexamination or renewal thereof; (b) a pending patent application, including any continuation, divisional, continuation-in-part, substitute or provisional application thereof; and (c) all counterparts or foreign equivalents of any of the foregoing issued by or filed in any country or other jurisdiction.
- 1.49 “ **Person** ” means any natural person, corporation, firm, business trust, joint venture, association, organization, company, partnership or other business entity, or any government or agency or political subdivision thereof.
- 1.50 “ **Phase II Trial** ” means a clinical trial of Product in human patients, the principal purposes of which are to make a preliminary determination that Product is safe for its intended use, to determine its optimal dose, and to obtain sufficient information about Product’s efficacy to permit the design of Phase III Trials, and which is consistent with 21 US CFR § 312.21(b).
- 1.51 “ **Phase III Trial** ” means a clinical trial of Product in human patients, which trial is designed to (a) establish that Product is safe and efficacious for its intended use and (b) (i) define warnings, precautions and adverse reactions that are associated with Product in the dosage range to be prescribed; (ii) be conducted as a pivotal trial for purposes of filing a MAA for Product; (iii) be either by itself or together with one or more other Clinical Trials having a comparable design and size, the final human Clinical Trial in support of Regulatory Approval of a MAA of Product; and (iv) be consistent with 21 US CFR § 312.21(c).
- 1.52 “ **Price Approvals** ” means, in those countries in the Territory where Regulatory Authorities may approve or determine pricing and/or pricing reimbursement for pharmaceutical products, such pricing and/or pricing reimbursement approval or determination.
- 1.53 “ **Product** ” means a preparation of autologous myelin-reactive T-cells manufactured using (i) Licensors Technology or (ii) a derivative of Licensors Technology). As of the Effective Date, Product is referred to by Licensors as “Tcelna”.

- 1.54 “ **Regulatory Authority** ” means: (a) in the US, the FDA; (b) in the EU, the EMA or the European Commission ; or (c) in any other jurisdiction anywhere in the world, any regulatory body with similar regulatory authority over pharmaceutical or biotechnology products.
- 1.55 “ **Regulatory Approval** ” means any and all approvals, licenses, registrations, or authorizations of the relevant Regulatory Authority, including Price Approvals, necessary for the Development, manufacture, use, storage, import, transport or Commercialization of Product in a particular country or jurisdiction. For the avoidance of doubt, Regulatory Approval to Commercialize Product shall include Price Approval.
- 1.56 “ **Representatives** ” means employees, consultants, contractors, advisors and agents of a Party.
- 1.57 “ **Royalty Term** ” means, on a country-by-country basis, the period from the First Commercial Sale of Product in such country until the later of: (a) ***; or (b) *** years after such First Commercial Sale of Product in such country.
- 1.58 “ **Sublicensee** ” means a Person other than an Affiliate of Merck to which Merck (or its Affiliate) has, pursuant to Section 4.2, granted sublicense rights under any of the license rights granted under Section 4.1; provided, that “Sublicensee” shall exclude distributors.
- 1.59 “ **Tax** ” or “ **Taxes** ” means any federal, state, local or foreign income, gross receipts, license, payroll, employment , excise, severance, stamp, occupation, premium, windfall profits, environmental, customs duties, capital stock, franchise, profits, withholding, social security, unemployment, disability, real property, personal property, sales, use, transfer, registration, value added, alternative or add-on minimum, estimated, or other tax of any kind whatsoever, including any interest, penalty, or addition thereto, whether disputed or not.
- 1.60 “ **Territory** ” means all the countries of the world except Japan.
- 1.61 “ **Third Party** ” means any Person other than Licensor, Merck or any of their respective Affiliates.
- 1.62 “ **Third Party Action** ” means any Action made by a Third Party against either Party that claims that Product, or Product’s use, Development, manufacture or sale in the Territory infringes or misappropriates such Third Party’s intellectual property rights.
- 1.63 “ **Third Party License Agreement** ” means any agreement entered into by a Party or its Affiliate with a Third Party, or any amendment or supplement thereto, in each case following the Effective Date, whereby royalties, fees or other payments are to be made by a Party or its Affiliate to such Third Party in connection with the grant of rights under intellectual property rights Controlled by such Third Party, which rights are *** to research, Develop, manufacture, have made, import, export, use or Commercialize Product in the Field in the Territory. Notwithstanding the foregoing, an agreement entered into by Merck or its Affiliate with a Third Party, or any amendment or supplement thereto, in each case following the Effective Date, whereby royalties, fees or other payments are to be made by Merck or its Affiliate to such Third Party in connection with the grant of rights under intellectual property rights Controlled by such Third Party, which rights have the *** effect of ***, will not be considered a Third Party License Agreement hereunder.

- 1.64 “ **United States** ” or “ **US** ” means the United States of America, its territories and possessions.
- 1.65 “ **USD** ” or “ **\$** ” means the lawful currency of the United States.
- 1.66 “ **Valid Claim** ” means a claim of any issued Patent Right which has not expired, lapsed or been revoked, abandoned or held unenforceable or invalid by a final decision of a court or governmental or supra-governmental agency of competent jurisdiction, unappealable or unappealed within the time allowed for appeal, and which has not been disclaimed, denied or admitted to be invalid or unenforceable through reissue, reexamination or disclaimer or otherwise .
- 1.67 **Other Terms** . The definition of each of the following terms is set forth in the section of the Agreement indicated below:

Defined Term	Section
“ Abili-T Trial Report ”	2.3
“ Action ”	9.5(b)
“ Agreement ”	Preamble
“ Alliance Manager ”	3.5
“ Basic Transfer Activities ”	7.3
“ Budget ”	5.3(a)
“ Certain Commercial License ”	8.7(d)
“ CM&C Know-How ”	7.3
“ Co-Funding Commitment ”	5.3(b)
“ Co-Funding Option ”	5.3(a)
“ Co-Funding Option Period ”	5.3(a)
“ Common Interest Agreement ”	9.5(a)(i)
“ Controlling Party ”	9.6(c)
“ Development Support ”	5.2
“ Effective Date ”	Preamble
“ Final Update ”	2.1
“ Initial Update ”	2.1
“ Intent to Exercise Notice ”	2.1
“ Joint Inventions ”	9.3
“ Joint Patents ”	9.4(c)
“ Joint Steering Committee ” and “ JSC ”	3.1
“ JSC Discussion Disputes ”	3.4
“ Licensor ”	Preamble
“ Licensor Indemnities ”	12.1
“ *** ”	8.7(c)

“ Manufacturing Support ”	7.3
“ Manufacturing Technology Transfer ”	7.3
“ Manufacturing Technology Transfer Plan ”	7.3
“ Merck ”	Preamble
“ Merck Indemnities ”	12.2
“ Merck Patent ”	9.4(f)
“ MS ”	1.27
“ Non-Escalable Dispute ”	14.1
“ Option ”	2.1
“ Option Exercise Date ”	2.1
“ Option Fee ”	8.2
“ Option Period ”	2.1
“ Party ” and “ Parties ”	Preamble
“ Product Bundle ”	1.46
“ Regulatory Support ”	6.3
“ Right of First Refusal ”	13.5(c)
“ Right of First Refusal Notice Period ”	13.5(c)(ii)
“ RRMS ”	1.27
“ Sole Inventions ”	9.3
“ SPMS ”	1.27
“ Supplemental Data ”	2.3
“ Supplemental Data Update ”	2.1
“ Supply Agreement ”	7.1
“ Term ”	13.1

ARTICLE 2 OPTION AND ABILI-T TRIAL

- 2.1 **Option** . Licensor hereby grants to Merck an exclusive option (the “ **Option** ”) to obtain the licenses set forth in Section 4.1. Merck may indicate its intent to exercise the Option, at any time beginning on the Effective Date and ending at 11:59 PM ET on the date that is *** days after the date of the receipt by Merck of (i) the Abili-T Trial Report and, if applicable, the Supplemental Data and (ii) an update to Schedule 11.2 reflecting changes to such schedule arising between the Effective Date and the date of submission of such updated Schedule 11.2 (“ **Initial Update** ”), and, if applicable, the Supplemental Data Update (such *** day period, the “ **Option Period** ”), by providing written notice to Licensor (the “ **Intent to Exercise Notice** ”). The Initial Update shall be provided by Licensor contemporaneously with the Abili-T Trial Report. In the event that Merck requests Supplemental Data in accordance with Section 2.3, Licensor shall, contemporaneously with providing the Supplemental Data, provide to Merck a further updated Schedule 11.2 reflecting changes to such schedule arising between the date of submission of the Initial Update and the date of submission of such further updated Schedule 11.2 (“ **Supplemental Data Update** ”). Upon Licensor’s receipt of the Intent to Exercise Notice, Licensor shall provide to Merck a further updated Schedule 11.2 reflecting changes to such schedule arising between the later of the date of submission of the Initial Update, or, if applicable, the date of submission of the Supplemental Data Update, and the date of submission of such further updated Schedule 11.2 (the “ **Final Update** ”). Merck shall have *** days from the date of its receipt of the Final Update to reject in writing the Intent to Exercise Option Notice. In the event that Merck does not reject the Intent to Exercise Notice within *** days from the date of its receipt of the Final Update, then the eleventh business day from the date of its receipt of the Final Update shall be deemed the “ **Option Exercise Date** ”. If Merck (a) does not submit the Intent to Exercise Notice prior to the end of the Option Period, or (b) rejects the Intent to Exercise Notice within *** days from the date of its receipt of the Final Update, then the Option will expire, the Option Exercise Date will not have occurred and Merck will have no remaining rights with respect to Licensor Technology or the Product. Notwithstanding the foregoing, the Initial Update, the Supplemental Data Update and the Final Update shall not be deemed to cure any breach of any given representation or warranty as may exist as of the Effective Date.

- 2.2 **Continued Performance of Abili-T Trial** . Licensors are responsible at their own cost, either by themselves or via subcontractors, for executing the Abili-T Trial. Licensors are responsible at their own cost for all supply of material for the Abili-T Trial. Licensors will use Commercially Reasonable Efforts to complete the Abili-T Trial in accordance with the timeline and budget attached hereto as Schedule 2.2, and will use sound and ethical business and scientific practices, in compliance in all material respects with all Laws (including, to the extent applicable, cGCP, cGLP, and cGMP,) in conducting the Abili-T Trial. Licensors shall update Merck with summary reports of the progress of the Abili-T Trial, from time to time upon Merck's request; provided, that Merck shall have no financial or other obligations with respect to the performance of the Abili-T Trial. Licensors shall keep and maintain separate and complete books and records of account relating to the Abili-T Trial.
- 2.3 **Abili-T Trial-related Reporting** . Within *** days of Licensors' completion of the Abili-T Trial, Licensors shall deliver to Merck a detailed and complete written description and analysis of the results of the Abili-T Trial (the "**Abili-T Trial Report**"). Within *** days of Merck's receipt of the Abili-T Trial Report, Merck may request additional data and information as is reasonably available to Licensors relating to the Abili-T Trial ("**Supplemental Data**"). If Merck requests any Supplemental Data, then Licensors shall deliver to Merck such Supplemental Data within *** days of Merck's request.

ARTICLE 3 GOVERNANCE

- 3.1 **Joint Steering Committee** . The Parties agree to establish, promptly after the Effective Date, a joint committee ("**Joint Steering Committee**" or "**JSC**") for: (a) prior to the Option Exercise Date, the purpose of sharing information with no decision-making authority; and (b) from and after the Option Exercise Date, the overall oversight of the Parties' activities with respect to the Development and Manufacture of Product in the Field with decision-making authority with respect thereto and, subject to ARTICLE 14, to resolve disputes between the Parties.

- 3.2 **Joint Steering Committee Membership** . Licensors and Merck shall each designate three (3) Representatives to serve on the Joint Steering Committee by written notices to the other Party, which Representatives shall represent development, regulatory and manufacturing functions from each Party. Either Party may designate substitutes for its Representatives if one (1) or more of such Party's designated Representatives are unable to be present at a meeting. From time to time, each Party may replace its Representatives by written notice to the other Party specifying the prior Representative(s) and their replacement(s). Prior to the Option Exercise Date, Licensors shall designate one (1) of its Representatives as the chairperson of the JSC and, after the Option Exercise Date, Merck shall designate one (1) of its Representatives as the chairperson of the JSC. The chairperson shall be responsible for (a) calling meetings, (b) preparing and issuing minutes of each such meeting within thirty (30) days thereafter and (c) preparing and circulating an agenda for the upcoming meeting, but shall have no special authority over the other members of the Joint Steering Committee, and shall have no additional voting rights or powers beyond those held by the other JSC members.
- 3.3 **Joint Steering Committee Meetings** . The Joint Steering Committee shall hold at least one (1) meeting per year, at such times as it elects to do so, until Merck's receipt of the first Regulatory Approval of the Product at which time the Joint Steering Committee shall disband. Meetings of the Joint Steering Committee shall be effective only if at least one (1) Representative of each Party is present or participating. The Joint Steering Committee may meet either: (a) in person at either Party's facilities or at such locations as the Parties may otherwise agree; or (b) by audio or video teleconference. Each Party may invite non-members to participate in the discussions and meetings of the Joint Steering Committee; provided, that such participants shall have no voting rights or powers and shall be subject to the confidentiality provisions set forth in ARTICLE 10. Additional meetings of the Joint Steering Committee may also be held with the consent of each Party, or as required under this Agreement, and neither Party shall unreasonably withhold or delay its consent to hold such an additional meeting. Each Party shall be responsible for all of its own expenses incurred in connection with participating in the Joint Steering Committee.
- 3.4 **Joint Steering Committee Decisions** . Actions to be taken by the Joint Steering Committee shall be taken only following a unanimous vote, with each Party having one (1) vote. If, following the Option Exercise Date, the Joint Steering Committee fails to reach unanimous agreement on a matter before it for decision for a period in excess of fifteen (15) days, then Merck shall have decision-making authority regarding such matter; provided, that (i) such decisions must conform to the requirements of this Agreement and shall not impose additional obligations or expense on Licensors, and (ii) Merck shall not have decision-making authority with respect to a dispute regarding (1) the initial Manufacturing Technology Transfer Plan to be agreed by the Parties in accordance with Section 7.3(a), (2) the interpretation of this Agreement, (3) whether a breach of this Agreement has occurred, or (4) any amendment to this Agreement, any agreements contemplated hereunder or the Parties' rights or obligations hereunder or under any such contemplated agreement (collectively, (1) through (4), inclusive, "**JSC Discussion Disputes**"). JSC Discussion Disputes shall be subject to resolution in accordance with Section 14.2.

- 3.5 **Alliance Managers** . Promptly following the Effective Date, each Party shall designate an individual to serve as the main point of contact for such Party to exchange information, facilitate communication and coordination of the Parties' activities under this Agreement relating to Product, and provide day-to-day support to the JSC (each, an "**Alliance Manager** "). Each Alliance Manager shall be experienced in project management, shall have appropriate experience in the pharmaceutical industry, and may serve as a representative of its respective Party on the JSC. The Alliance Managers may attend all meetings between the Parties, including committee meetings, and shall also work together to facilitate the resolution of any potential disputes between the Parties. Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party.

ARTICLE 4

L LICENSES AND OTHER RIGHTS

- 4.1 **Grant of License to Merck** . Subject to the terms and conditions of this Agreement, upon the Option Exercise Date, Licensor hereby grants to Merck and its Affiliates an exclusive (even as to Licensor), royalty-bearing right and license (with the right to sublicense, subject to the provisions of Section 4.2) under the Licensor Technology to (a) research, have researched, Develop, have Developed, manufacture, have manufactured, use and have used Product anywhere in the world in the Field for purposes of Commercializing Product in the Territory in the Field and (b) Commercialize or have Commercialized Product in the Territory in the Field. In addition, subject to the terms and conditions of this Agreement, upon the Option Exercise Date, Licensor hereby grants to Merck and its Affiliates an exclusive (even as to Licensor), right and license (with the right to sublicense, subject to the provisions of Section 4.2) to use and reproduce the Licensor Trademarks in connection with the exercise of their other rights under this Section 4.1. Merck *** and *** that it ***.
- 4.2 **Grant of Sublicense by Merck** . Merck shall have the right, in its sole discretion, to grant sublicenses, in whole or in part, under the licenses granted in Section 4.1. Any sublicense granted or entered into by Merck as contemplated by this Section 4.2 (x) shall not relieve Merck from any of its obligations under this Agreement and (y) shall impose upon the sublicensee's exercise of such license rights obligations of confidentiality and non-use substantially similar to those contained in ARTICLE 10.
- 4.3 **Exclusivity** .
- (a) **Competing Products** . Licensor and, subject to the final sentence of Section 15.2(f), its Affiliates shall not, during the Term, develop, have developed, manufacture, have manufactured, use, sell, have sold, offer for sale, import or export a Competing Product in the Field in the Territory nor enter into any relationship with any Third Party with respect thereto. Such restriction shall remain in effect in the event of a Change of Control of Licensor and shall apply to the successor or assignee of Licensor. In the event that Licensor enters into such activities, it shall be deemed to be in material breach of this Agreement and Merck shall have the right to terminate this Agreement in accordance with 13.3(a); provided that such remedy shall not be exhaustive with respect to breach by Licensor of this Section 4.3.

(b) **Protection of the Field** . Licensor covenants and agrees that neither it nor its Affiliates (nor any permitted Third Party under Section 4.4(c)) shall, either directly or indirectly, market, distribute or sell any Competing Product that uses, or is manufactured using, or is derived from, Licensor Technology for Indications in the Field in the Territory. As to Indications in the Field in the Territory, Licensor shall: (i) not engage in any advertising activities relating to any Competing Product for Indications in the Field in the Territory; and (ii) not solicit orders from any prospective purchaser of Competing Product (or Product) for Indications in the Field in the Territory. If Licensor receives any order from a prospective purchaser of a Competing Product for Indications in the Field in the Territory, Licensor shall immediately refer such order to Merck and not accept such order or deliver (or cause to be delivered) any such Competing Product under such order. If Licensor has a reasonable basis to conclude that its customer, sublicensee or distributor is engaged in the sale or distribution of any Competing Product in the Field in the Territory that uses, or is manufactured using, or is derived from, Licensor Technology, then Licensor shall take all reasonable steps (including cessation of sales to such customer) necessary to limit such sale or distribution in the Field in the Territory. Without limitation of the foregoing, Licensor further covenants and agrees that neither it nor its Affiliates (nor any permitted Third Party under Section 4.4(c)) shall, either directly or indirectly, market, distribute or sell any Competing Product that uses, or is manufactured using, Licensor Technology for use outside of the Field in the Territory (to the extent permitted under this Agreement) in a formulation or product presentation that is susceptible for use in the Field. Furthermore, Licensor covenants and agrees that neither it nor its Affiliates (nor any permitted Third Party under Section 4.4(c)) shall, either directly or indirectly, develop, market, distribute or sell Product (1) in the Field in the Territory (except by Merck under this Agreement) or (2) outside the Field in the Territory in a formulation or other manner that is susceptible to use in the Field.

4.4 **Japan Development and Right of First Negotiation** .

(a) **Development of Product in Japan** . If Licensor or its Affiliate, or, subject to the remainder of this Section 4.4, its licensee or assignee pursues the Development or Commercialization of Product in Japan or any country removed from the Territory pursuant to Section 13.2, then the Parties shall share data and information regarding Development, Commercialization and reporting of Adverse Events with respect to Product as may be necessary for or otherwise required by applicable Governmental Bodies with respect to securing or maintaining Regulatory Approval for Product in Japan (and other countries outside the Territory) or the Territory as applicable. For clarity, in the event that Japan is added to the Territory hereunder in accordance with the remainder of this Section 4.4, then this Section 4.4(a) shall be of no further force or effect.

(b) **Japan-Related Notice** . If Licensor intends to grant, or is considering granting, to any Third Party the right to Develop or Commercialize Product in the Field in Japan, then Merck shall have the right of first negotiation with respect to such rights, which shall obligate Licensor to negotiate exclusively with Merck for inclusion of Japan in the Territory for the time periods and subject to the terms of this Section 4.4. Licensor shall notify Merck in writing in the event Licensor intends to grant, or is considering granting, to any Third Party the right to Develop or Commercialize Product in the Field in Japan and Merck shall notify Licensor in writing within *** days after receipt of such notice from Licensor whether Merck desires to exercise its right of first negotiation set forth in this Section 4.4(a).

(c) **Right of First Negotiation** . If Merck exercises such right of first negotiation, then (i) Licensor shall promptly provide Merck with an appropriately detailed data/diligence package of information then available to Licensor in order to enable Merck to assess the opportunity, and (ii) the Parties shall negotiate in good faith the terms of an appropriate amendment to this Agreement to include Japan in the Territory. If Licensor and Merck are unable to enter into an appropriate amendment with respect to such transaction within *** days after Licensor receives notice of Merck's election (or such longer period as may be mutually agreed upon by the Parties), despite each Party's reasonable efforts to do so, then Licensor shall be permitted to grant such Development or Commercialization rights in the Field in Japan to a Third Party within *** following the termination of negotiations with Merck; provided, that Licensor may only grant such rights to a Third Party on material terms in the aggregate more favorable to Licensor than the last set of terms offered by Merck (it being understood that the evaluation and comparison of such terms shall take into account the relative capabilities of Merck and such Third Party to effectively Develop or Commercialize Product in the Field in Japan). In the event that Licensor does not enter into a definitive agreement with a Third Party for the right to Develop or Commercialize Product in the Field in Japan within such *** period, then Licensor shall be subject to the terms of this Section 4.4 in the event that it subsequently proposes to grant to any Third Party the right to Develop or Commercialize the Product in the Field in Japan.

ARTICLE 5 DEVELOPMENT AND COMMERCIALIZATION OF PRODUCT POST OPTION EXERCISE DATE

- 5.1 **Development of Product by Merck** . From and after the Option Exercise Date, Merck shall have the exclusive right, and sole responsibility and decision-making authority, to research and Develop Product in the Field for the Territory and to conduct (either itself or through its Affiliates, agents, subcontractors and/or Sublicensees) all Clinical Trials and non-clinical studies Merck believes appropriate to obtain Regulatory Approval for Product in the Field in the Territory. For clarity, Licensor shall remain responsible for Developing the Product in the Field for Regulatory Approval outside of the Territory. Licensor acknowledges and agrees that Merck may conduct Clinical Trials (or other Development activities) outside of the Territory but solely for the purpose of Developing Product for Commercialization in the Territory.
- 5.2 **Licensor Support in Development** . As soon as reasonably practicable after the Option Exercise Date, but in no event later than *** days following the Option Exercise Date, Licensor will transfer to Merck, at Licensor's cost and expense, all Licensor Know-How (except for Licensor Know-How relating to the manufacture of Product, which is the subject of Section 7.3). Without limitation of the foregoing, from and after the Option Exercise Date, Licensor shall make its Representatives that are knowledgeable regarding the Licensor Technology or Product (including the properties and functions thereof) available to Merck for scientific and technical explanations, advice and on-site support that may reasonably be required by Merck relating to the Development of Product (the "**Development Support**"). The Development Support shall be provided by Licensor free-of-charge; provided, that, (i) Merck shall reimburse Licensor for the travel expenses reasonably incurred (in accordance with Merck's travel policies, which will be provided to Licensor upon request) by all employees and consultants of Licensor in the performance of Development Support on-site at facilities of Merck, its Affiliates or Third Parties specified by Merck or its Affiliates; and (ii) from and after the date that is *** after the date that Merck has received all Licensor Know-How (except for Licensor Know-How relating to the manufacture of Product, which is the subject of Section 7.3), Merck shall pay Licensor the FTE Rate for each FTE providing Development Support to Merck.

5.3 Development Funding Option .

(a) **Co-Funding Option** . Merck hereby grants Licensor an option (the “ **Co-Funding Option** ”) to increase the royalty rates payable under Section 8.5(a) in consideration for Licensor co-funding, with Merck, the Development of Product for the first Indication in the Field that Merck chooses to pursue. Prior to Merck’s start of the first Phase III Trial for Product, Merck shall deliver to Licensor a reasonably detailed budget for all of the activities then estimated in good faith by Merck to be (or have been) conducted for the Development of Product for the first Indication (the “ **Budget** ”); provided, that (i) Licensor shall make appropriate representatives available to discuss with Merck any concerns Merck may have regarding Licensor’s ability to cover the Co-Funding Commitment for the following *** period, including concerns arising from Merck’s review of publicly available financial information (and, in the case such concerns exist, Licensor shall provide reasonable evidence that Licensor has immediate access to committed funds (e.g. cash on hand, loans, etc.) as required to cover the Co-Funding Commitment for the following *** period) and (ii) in addition, in the event that Licensor is no longer a publicly traded company, such written notice shall contain reasonable evidence that Licensor has immediate access to committed funds (e.g. cash on hand, loans, etc.) as required to cover the Co-Funding Commitment for the following *** period. Licensor may exercise the Co-Funding Option by providing written notice to Merck of such exercise at any time prior to *** days following Merck’s delivery to Licensor of the Budget and satisfaction of the procedures contemplated by the foregoing proviso (the “ **Co-Funding Option Period** ”). In the event Licensor exercises the Co-Funding Option, Licensor shall continue to comply with the foregoing proviso upon Merck’s request from time-to-time. If Licensor does not provide the aforementioned evidence within *** days of Merck’s request, when applicable, or fails to make appropriate representatives available and/or is unable to reasonably address Merck’s concerns, then Section 8.5(c) shall have no further force or effect.

(b) **Co-Funding Commitment** . Upon exercise of the Co-Funding Option, Licensor shall become responsible for *** percent (***) of the costs incurred by Merck and associated with the Development of Product for the first Indication in the Field that Merck chooses to pursue, including costs incurred by Merck on or prior to the date of Licensor's exercise of its Co-Funding Commitment (the "**Co-Funding Commitment**"). Merck shall invoice Licensor on a Calendar Quarter basis for Licensor's Co-Funding Commitment, which invoices shall identify the amounts invoiced with reference to the amounts set forth in the Budget. Licensor shall pay such invoices within *** days of receipt; provided, that, in the event that Licensor does not pay a given invoice by its due date, Merck shall have the right to offset the amount of such invoice against amounts due from Merck to Licensor. In the event that Licensor exercises the Co-Funding Option, Licensor shall have audit rights as set forth in Section 8.13 *mutatis mutandis* with respect to any invoices submitted to Licensor for payment.

(c) **Licensor Development Activities** . Unless otherwise agreed by the Parties in a separate written agreement (including a properly executed amendment to this Agreement), from and after the Option Exercise Date, the exercise by Licensor of the Co-Funding Option shall not entitle Licensor to be involved in the Development of Product in the Field for the Territory on an operational basis.

5.4 **Commercialization** . From and after the Option Exercise Date, Merck shall have the exclusive right, and sole responsibility and decision-making authority, to Commercialize Product in the Field in the Territory itself or through one or more Affiliates or Sublicensees or other Third Parties selected by Merck and shall have the sole decision-making authority and responsibility in all matters relating to the Commercialization of Product in the Field in the Territory.

5.5 **Diligence by Merck** . Subject to Licensor's fulfillment of its obligations under this Agreement, Merck shall, from and after the Option Exercise Date, use Commercially Reasonable Efforts to Develop and Commercialize Product in the Field in ***; provided, that such Development and Commercialization obligations shall be expressly conditioned on the continuing absence of any material adverse condition or event relating to the safety or efficacy of the Product, legal impediments, or Third Party intellectual property rights, and Merck's obligation to Develop and Commercialize Product in Field in the Territory shall be delayed or suspended so long as, in Merck's reasonable opinion, any such material condition or event exists. Merck shall have the exclusive right to determine, in its sole discretion, the launch strategy for Product in the Field in the Territory, subject to its exercise of Commercially Reasonable Efforts and the availability of any necessary Third Party licenses or other rights. Activities by Merck's Affiliates and Sublicensees will be considered as Merck's activities under this Agreement for purposes of determining whether Merck has complied with its obligation to use Commercially Reasonable Efforts. For clarity, Merck shall have no obligation to Develop or Commercialize Product in any particular country or countries, except as expressly provided in this Section 5.5. Merck shall be relieved of its diligence obligations under this Section 5.5 starting from the date on which Merck provides Licensor with a termination notice pursuant to Section 13.2 or 13.3.

- 5.6 **Right to Subcontract of Merck** . Merck may exercise any of its rights, or perform any of its obligations, under this Agreement (including any of the rights licensed in Section 4.1) by subcontracting the exercise or performance of all or any portion of such rights and obligations on Merck's behalf. Any subcontract granted or entered into by Merck as contemplated by this Section 5.6 of the exercise or performance of all or any portion of the rights or obligations that Merck may have under this Agreement shall not relieve Merck from any of its obligations under this Agreement.
- 5.7 **Trade Marks** . As between Licensor and Merck, from and after the Option Exercise Date, Merck shall have the sole authority to select trademarks for Product in the Field in the Territory and shall own all such trademarks; provided, that Licensor shall retain ownership of all Licensor Trademarks. Licensor shall maintain the Licensor Trademarks for the duration of the Term at its sole cost and expense. Notwithstanding the foregoing, from and after the Option Exercise Date, upon Merck's request, Licensor shall assign to Merck ownership in the Territory of any given Licensor Trademarks and following such assignment such Licensor Trademark(s) shall be owned in the Territory by Merck and Merck shall be responsible for the cost and expense of maintaining such assigned Licensor Trademark(s) in the Territory.
- 5.8 **Reporting** . From and after the Option Exercise Date, every six (6) months each Party will provide the other Party with a written report summarizing in reasonable detail its major Development activities conducted, including material data and other information obtained in connection therewith, during the preceding six (6) month period. All such reports provided to such other Party pursuant to this Section 5.8 shall be for informational purposes only and shall not be interpreted to increase or expand a Party's obligations under this Agreement and shall be treated as Confidential Information of the providing Party hereunder. Notwithstanding the foregoing, upon Merck's receipt of Regulatory Approval for Product, Merck's obligation to provide reports under this Section 5.8 shall become limited to its Development activities pertaining to the U.S. and the Major EU Markets and shall only be required when Merck has actually conducted Development activities pertaining to the U.S. or the Major EU Markets during any such six (6) month period.
- 5.9 **Procedures for Technology Transfer** . The technology transfers set forth in Section 5.2, Section 6.3 and Section 7.3 shall occur in an orderly fashion and in a manner such that the value, usefulness and confidentiality of the transferred Licensor Know-How and regulatory documentation are preserved in all material respects. Promptly following the Option Exercise Date, and thereafter during the Term, Licensor shall provide to Merck full and prompt disclosure, but in no event less frequently than ***, of any Licensor Technology (including CM&C Know-How) that becomes Controlled by Licensor or any of its Affiliates after the Effective Date and that is necessary to Merck to conduct its activities or exercise its rights as contemplated hereunder and shall, in the case of any such Licensor Know-How (including CM&C Know-How), promptly following such disclosure, transfer to Merck such Licensor Know-How (including CM&C Know-How).

ARTICLE 6 REGULATORY MATTERS

- 6.1 **Regulatory Filings** . From and after the Option Exercise Date and during the Term (and thereafter if the Term ends pursuant to the expiration of the last to expire of the Royalty Terms), Merck (or one of its Affiliates, Sublicensees or designees) shall own and maintain all regulatory filings and Regulatory Approvals for Product, including all INDs and MAAs, in the Field in the Territory. For clarity, prior to the Option Exercise Date, Licensor will own, hold and maintain all Regulatory Approvals for Product.
- 6.2 **Communications with Authorities** . From and after the Option Exercise Date and during the Term (and thereafter if the Term ends pursuant to the expiration of the last to expire of the Royalty Terms), Merck (or one of its Affiliates, Sublicensees or designees) shall be responsible, and act as the sole point of contact, for communications with Regulatory Authorities in connection with the Development, Commercialization and manufacturing of Product in the Field for the Territory. Following the Option Exercise Date, Licensor shall not initiate, with respect to Product in the Field for the Territory, any meetings or contact with Regulatory Authorities without Merck's prior written consent. To the extent Licensor receives any written or oral communication from any Regulatory Authority relating to Product in the Field in the Territory, Licensor shall: (a) refer such Regulatory Authority to Merck; and (b) as soon as reasonably practicable (but in any event within twenty-four (24) hours), notify Merck and provide Merck with a copy of any written communication received by Licensor or, if applicable, complete and accurate minutes of such oral communication. At the request of Merck, Licensor shall make available to Merck a qualified Representative who shall, together with the Representatives of Merck, participate in and contribute to meetings with the Regulatory Authorities with respect to regulatory matters relating to the Licensor Technology or Product; provided, that (i) Merck shall reimburse Licensor for the travel expenses reasonably incurred (in accordance with Merck's travel policies, which will be provided to Licensor upon its request) by such Representative; and (ii) from and after the date that is three (3) months after the date that Merck has received all applications and filings made by or on behalf of Licensor with any Regulatory Authority with respect to Product in the Field in the Territory, including any IND, MAA or orphan drug designations or any other application for regulatory consultations or consideration, including sponsorship thereof, Merck shall pay Licensor the FTE Rate for each such Representative FTE providing support (for clarity, prior to such date, the support described in this Section 6.2 shall be provided by Licensor free of charge, except for travel expenses as detailed above).
- 6.3 **Licensor Support in Regulatory Matters** . As soon as reasonably practicable after the Option Exercise Date, but in no event later than *** days following the Option Exercise Date, Licensor will (to the extent allowed or consented to by Law), at Licensor's cost and expense, assign to Merck all applications and filings made by or on behalf of Licensor with any Regulatory Authority with respect to Product in the Field in the Territory, including any IND, MAA or orphan drug designations or any other application for regulatory consultations or consideration, including sponsorship thereof. Without limitation of the foregoing, from and after the Option Exercise Date, Licensor shall make its Representatives that are knowledgeable regarding the Licensor Technology or Product available to Merck for regulatory explanations, advice and on-site support that may reasonably be required by Merck relating to regulatory matters (including preparation and filing for any INDs and MAAs and obtaining and maintaining Marketing Authorizations) (the "**Regulatory Support**"); provided, that, except for so long as ***, Licensor shall have no obligation to dedicate more than *** FTEs to provide Regulatory Support more than *** following the date that Merck has received all applications and filings made by or on behalf of Licensor with any Regulatory Authority with respect to Product in the Field in the Territory, including any IND, MAA or orphan drug designations or any other application for regulatory consultations or consideration, including sponsorship thereof. Merck shall reimburse Licensor for the travel expenses reasonably incurred (in accordance with Merck's travel policies, which will be provided to Licensor upon its request). From and after the date that is *** after the date that Merck has received all applications and filings made by or on behalf of Licensor with any Regulatory Authority with respect to Product in the Field in the Territory, including any IND, MAA or orphan drug designations or any other application for regulatory consultations or consideration, including sponsorship thereof, Merck shall pay Licensor the FTE Rate for each FTE providing Regulatory Support to Merck (for clarity, prior to such date, Regulatory Support shall be provided by Licensor free of charge, except for travel expenses as detailed above).

- 6.4 **Recalls** . From and after the Option Exercise Date, Merck shall have the sole right to determine whether and how to implement a recall or other market withdrawal of Product from the Field in the Territory.
- 6.5 **Pharmacovigilance Agreement** . The Parties shall, as soon as practical following the Option Exercise Date, negotiate in good faith and enter into a safety data exchange agreement relating to Product, which shall set forth standard operating procedures governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions/adverse events sufficient to permit each Party to comply with its regulatory and other legal obligations within applicable timeframes.

ARTICLE 7 MANUFACTURING

- 7.1 **Supply Agreement** . From and after the Option Exercise Date, in the event that Licensor can demonstrate, to Merck's reasonable satisfaction, the requisite quality, capacity and ability to scale up to fully meet Merck's supply requirements, the Parties will enter into a supply agreement covering Licensor's supply of *** Product required by Merck for Development (including clinical) and Commercialization purposes in the Field for the US (the "**Supply Agreement**"). The Supply Agreement will include customary terms and conditions for a supply agreement, including provisions with respect to pricing, forecasting requirements, warranties, indemnities, recalls, shelf life, safety stock maintenance, supply disruption trigger events and contingency measures, termination and force majeure, as well as provisions covering audits, validation, quality control and complaints.

7.2 **Merck Manufacturing** . From and after the Option Exercise Date, and subject to any supply of Product by Licensor to Merck under the Supply Agreement as provided in Section 7.1, Merck shall have the right to manufacture Product (i) for the Field for the Territory outside the United States, and (ii) as a *** source for clinical and commercial supply for the Field in the US, in each case, itself or through one or more Affiliates or Sublicensees or other Third Parties selected by Merck.

7.3 **Manufacturing Technology Transfer** .

(a) **Manufacturing Technology Transfer Generally** . In furtherance of Section 7.2, the Parties shall undertake the technology transfer described in this Section 7.3 (“**Manufacturing Technology Transfer**”) in accordance with a manufacturing technology transfer plan (the “**Manufacturing Technology Transfer Plan**”) to be agreed upon by the Parties on or prior to the *** month anniversary of the Option Exercise Date; provided, that, in the event that the Parties are unable to finalize the Manufacturing Technology Transfer Plan on or prior to such date, any items or matters remaining in dispute shall be referred to the JSC for discussion and potential resolution. The Parties will commence the Manufacturing Technology Transfer promptly upon finalization of the Manufacturing Technology Transfer Plan. The costs and expenses associated with Licensor’s performance of the Basic Transfer Activities and the Manufacturing Support shall be as set forth in Section 7.3(b) unless the Parties otherwise mutually agree in the Manufacturing Technology Transfer Plan.

(b) **Manufacturing Technology Transfer Plan Contents** . The Manufacturing Technology Transfer Plan will: (a) specify goals and estimated time lines for the achievement of the Manufacturing Technology Transfer; (b) identify all Licensor Know-How that relates to the manufacture of Product and all such information as is reasonably anticipated to become a part of the Chemistry, Manufacturing and Controls section of a regulatory submission document included in an MAA, as set forth in 21 C.F.R. § 314.50 (collectively, “**CM&C Know-How**”) (including all information necessary for successful operation of the transferred process and all biochemical and biophysical analytical assays, in vitro assays and in vivo assays); (c) specify the activities related to implementation of such technology in Merck’s or its designee’s facilities; (d) set forth those obligations assigned to each Party with respect to such technology transfer (such obligations assigned to Licensor being referred to herein as the “**Basic Transfer Activities**”); and (e) set forth the terms and conditions under which additional Licensor shall make Representatives that are knowledgeable regarding the manufacture of the Product (including Licensor Technology applying thereto) available to Merck for scientific and technical explanations, advice and support beyond the Basic Transfer Activities (the “**Manufacturing Support**”) provided, that, (i) Merck shall reimburse Licensor for the travel expenses reasonably incurred (in accordance with Merck’s travel policies, which will be provided to Licensor upon its request) by all employees and consultants of Licensor in the performance Manufacturing Support (as opposed to Basic Transfer Activities) on-site at facilities of Merck, its Affiliates or Third Parties specified by Merck or its Affiliates; and (ii) Merck shall pay Licensor the FTE Rate for each FTE providing Manufacturing Support (as opposed to Basic Transfer Activities) to Merck.

ARTICLE 8 FINANCIAL PROVISIONS

- 8.1 **Initial Fee** . In consideration of Licensor's grant of the Option to Merck hereunder, Merck shall pay, or cause to be paid, to Licensor a fee of five million USD (\$5,000,000), within *** days following the Effective Date. Payment of the initial fee shall be subject to any withholding tax obligations set forth in Section 8.14.
- 8.2 **Option Exercise Fee** . In partial consideration of Licensor's grant of the rights and licenses to Merck hereunder and Licensor's performance of its obligations hereunder, Merck shall pay, or cause to be paid, to Licensor a one (1)-time, non-refundable fee (" **Option Fee** ") of twenty five million USD (\$25,000,000), within *** days following the Option Exercise Date; provided, that if Merck is unable to advance directly into performing a Phase III Trial for Product for SPMS without a further Phase II Trial (as determined by Merck in its sole discretion), then the Option Fee shall be fifteen million USD (\$15,000,000); provided, further, that if, subsequent to Merck's initial determination that it is unable to advance directly into performing a Phase III Trial without a further Phase II Trial and payment of the lower Option Fee, Merck does advance directly into performing a Phase III Trial for Product for SPMS without conducting such a further Phase II Trial, then Merck shall pay to Opexa an additional ten million USD (\$10,000,000) within *** days following commencement of such Phase III Trial. Payment of the Option Fee shall be subject to any withholding tax obligations set forth in Section 8.14.
- 8.3 **Milestone Payments** .
- (a) **Development, Regulatory and First Commercial Sale Milestones** . As further partial consideration for Licensor's grant of the rights and licenses to Merck hereunder and Licensor's performance of its obligations hereunder, following the Option Exercise Date, Merck shall pay, or cause to be paid, to Licensor the following milestone payments upon the achievement of the milestone events described below. Merck shall promptly (but in any event within *** days) notify Licensor in writing of the achievement of any such milestone event and Licensor shall issue Merck an invoice for the amount of the corresponding milestone payment, which invoice Merck shall pay within *** days following receipt of such invoice.

Milestone event	Milestone payment
***	*
***	*
***	*
***	*
***	*
***	*
Total regulatory and first commercial sale milestones (US) (Exclusive of RRMS)	\$35,000,0
Total regulatory (EU) and first commercial sale (up to three major EU countries) milestones (Exclusive of RRMS)	\$30,000,0
Total first commercial sale milestone ex-US and EU (Exclusive of RRMS)	\$5,000,0
Total regulatory and first commercial sale milestones in SPMS (Exclusive of RRMS)	\$70,000,0
Total development, regulatory and first commercial sale milestones (Solely for RRMS)	\$40,000,0
Total milestones	\$110,000,0

(b) **Frequency of Milestone Payments** . With respect to each milestone, the milestone payments to be made under this Agreement shall be due and payable, subject to Section 8.3(c), no more than twice, regardless of the number of Products Developed or Commercialized, or the number of Indications pursued or approved or whether a Product is discontinued after a milestone payment has been made; provided, that the milestone payments may be made *** only in the event that Merck pursues *** and another Indication in the Field.

(c) ***

8.4 **Commercial Event Payments** . Following the Option Exercise Date, as further partial consideration for Licensor's grant of rights and licenses to Merck hereunder and Licensor's performance of its obligations hereunder, Merck shall pay Licensor the following non-refundable amounts for the first achievement of the following commercial event milestones calculated on the basis of total Net Sales in the Field in the Territory:

(i) \$*** for the first Calendar Year in which the aggregate annual Net Sales of Product in the Field in the Territory, determined in accordance with Section 8.5(b), exceed \$***;

(ii) \$*** for the first Calendar Year in which the aggregate annual Net Sales of Product in the Field in the Territory, determined in accordance with Section 8.5(b), exceed \$***;

(iii) \$*** for the first Calendar Year in which the aggregate annual Net Sales of Product in the Field in the Territory, determined in accordance with Section 8.5(b), exceed \$***;

(iv) \$*** for the first Calendar Year in which the aggregate annual Net Sales of Product in the Field in the Territory, determined in accordance with Section 8.5(b), exceed \$***;

Merck shall deliver written notice to Licensor within *** days of the end of the Calendar Year in which a commercial event milestone occurs and Licensor shall issue Merck an invoice for the amount of the corresponding commercial event milestone payment, which invoice Merck shall pay within *** days following receipt of such invoice.

For the avoidance of doubt, each aforementioned commercial event milestone payment shall be made only once, regardless of the number of Products achieving the commercial event milestones, or the number of Calendar Years in which a Product achieves such commercial event milestone. For example, if for a Calendar Year, aggregate annual worldwide Net Sales in all Indications for a particular Product are \$600,000,000, then the total commercial event milestone payments earned shall be \$***, and the commercial event milestone payments set forth in *** above shall no longer be triggered by any Product in any Calendar Year.

For the avoidance of doubt, the total maximum milestones payable under this Section 8.4 shall not exceed \$85,000,000, of which milestone payments of \$55,000,000 are achievable at annual Net Sales targets in excess of \$1,000,000,000.

8.5 **Royalty Payments for Product .**

(a) **Royalty Rate .** As further consideration for Licensor's grant of the rights and licenses to Merck hereunder and Licensor's performance of its obligations hereunder, Merck shall, during the Royalty Term, pay to Licensor a royalty on aggregate annual Net Sales of Product in the Field in the Territory for each Calendar Year at the percentage rates set forth below (subject to Sections 8.5(c), 8.6 and 8.7):

Annual Net Sales of Product in the Field in the Territory per Calendar Year USD	Incremental Royalty Rate
For Net Sales of Product from \$0 up to and including \$500,000,000	8%
For that portion of Net Sales of Product that are greater than \$500,000,000 and less than or equal to \$1,000,000,000	***%
For that portion of Net Sales of Product that are greater than \$1,000,000,000 and less than or equal to \$2,000,000,000	***%
For that portion of Net Sales of Product that are greater than \$2,000,000,000	15%

By way of illustration, assume in a Calendar Year, during the Royalty Term, that (i) aggregate annual Net Sales of a Product total \$2,100,000,000 and (ii) no adjustments or deductions to payments under this ARTICLE 8 apply. The total royalties due and payable by Merck to Licensor for such Net Sales would be \$***, calculated as follows:

$\$500,000,000 \times ***\% = \$***$

$\$500,000,000 \times ***\% = \$***$

$\$1,000,000,000 \times ***\% = \$***$

$\$100,000,000 \times ***\% = \$***$

Total Royalty = \$***

(b) **Net Sales Subject to Royalty Payments** . For purposes of determining whether a royalty threshold or a commercial event milestone described in Section 8.4 has been attained, only Net Sales that are subject to a royalty payment shall be included in the total amount of Net Sales and any Net Sales that are not subject to a royalty payment shall be excluded. In addition, in no event shall the manufacture of Product give rise to a royalty obligation. For clarity, Merck's obligation to pay royalties to Licensor under this ARTICLE 8 is imposed only once with respect to the same unit of Product regardless of the number of Licensor Patents pertaining thereto.

(c) **Increased Royalty Rates Tied to Co-Funding Commitment** . Following exercise by Licensor of the Co-Funding Option and subject to Section 5.3(a) and Licensor's continuing satisfaction of its Co-Funding Commitment, the tiered royalty percentages set forth in Section 8.5(a) shall be replaced with 10%, ***, ***% and 18%.

8.6 **Compulsory License** . In the event that Licensor or Merck receives a request for a Compulsory License anywhere in the world, it shall promptly notify the other Party and Merck shall use Commercially Reasonable Efforts to oppose the imposition of such a Compulsory License. If any Third Party obtains a Compulsory License in any country in the Territory, then Licensor or Merck (whoever has first notice) shall promptly notify the other Party. Thereafter, as of the date the Third Party obtained such Compulsory License in such country, the royalty rate payable under Section 8.5 to Licensor for Net Sales in such country will be adjusted to equal any lower royalty rate granted to such Third Party for such country with respect to the sales of Product therein. In addition, should Merck grant a Sublicense to a Third Party in any country of the Territory in a good faith effort to avoid the imposition of such a Compulsory License, the royalty rate payable under Section 8.5 to Licensor for Net Sales in such country shall also be adjusted to match any lower royalty rate payable by such Sublicensee for such country under such Sublicense.

8.7 **Reductions, Deductions and Reimbursements** .

(a) **Know-How Royalty** . The royalty rates set forth in Section 8.5(a) applicable to the Net Sales of a Product in a country will be reduced by *** percent (***) during any period there exists no Valid Claim of a Licensor Patent in such country that Covers such Product in such country.

(b) **Third Party License Agreements** . Subject to the terms and conditions of this Agreement, if Merck or any of its Affiliates or Sublicensees enter into a Third Party License Agreement(s) (other than a Third Party License Agreement(s) referred to in Section 8.7(d)), Merck will be entitled to deduct from any amount payable to Licensor under Section 8.5 (from the amount calculated by consideration of the then applicable royalty rate), an amount equal to *** percent (***) of any amounts paid by Merck, its Affiliates or Sublicensees pursuant to such Third Party License Agreement(s)***; provided, that such deductions may not reduce the amount of royalties payable by Merck to Licensor for any *** by more than *** percent (***) of the amount that would otherwise be due. Excess amounts that Merck is not allowed to deduct pursuant to the foregoing proviso will be carried forward into future ***.

(c) **Existing Third Party Agreements** . Licensor shall be responsible for the timely payment of any amounts due under any Existing Third Party Agreement, and in the event that Licensor shall fail to make on a timely basis any payment when due under such Existing Third Party Agreement, Merck shall have the right to make such payment on behalf of Licensor. In such event, Licensor shall promptly reimburse Merck any such amounts paid by Merck or, at Merck's election, Merck may offset such amounts paid by Merck against any amounts payable to Licensor hereunder. In the event that Licensor enters into an agreement with *** (or one of its Affiliates) (" *** ") in respect of the use of *** in *** of Product (as contemplated in Schedule 11.2), such agreement shall be deemed an Existing Third Party Agreement.

(d) **Certain Commercial License** . Solely with respect to amounts due to *** in connection with any Third Party License Agreement(s) that Merck, its Affiliates or Sublicensees may obtain from Life in respect of the use of *** in *** of Product (as contemplated in Schedule 11.2) (" **Certain Commercial License** "), Merck may offset commercially reasonable amounts paid by Merck, its Affiliates or Sublicensees pursuant to such Certain Commercial License from any amount payable to Licensor under this ARTICLE 8 (without any limitations on such off-set right).

8.8 **Timing of Payment** . Royalties payable under Section 8.5(a) shall be payable on actual Net Sales and shall accrue at the time the invoice for the sale of Product is delivered. Royalty obligations that have accrued during a particular Calendar Quarter shall be paid, on a Calendar Quarter basis, within *** days after the end of each Calendar Quarter during which the royalty obligation accrued.

8.9 **Mode of Payment and Currency; Invoices** .

(a) **Currency** . All payments to Licensor hereunder shall be made by deposit of USD in the requisite amount to such bank account as Licensor may from time to time designate by written notice to Merck. With respect to sales not denominated in USD, Merck shall convert applicable sales in foreign currency into USD by using the then current and reasonable standard exchange rate methodology applied to its external reporting. Based on the resulting sales in USD, the then applicable royalties shall be calculated. The Parties may vary the method of payment set forth herein at any time upon mutual written agreement, and any change shall be consistent with the local Law at the place of payment or remittance.

(b) **Invoices** . Licensor shall address its invoices to:

Ares Trading SA
Zone industrielle de l'Ouriettaz
1170 Aubonne
Switzerland

With a copy to:

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany
Attn: ***, Alliance Management

- 8.10 **Royalty Reports and Records Retention** . Within *** days after the end of each Calendar Quarter during which Product has been sold, Merck shall deliver to Licensor, together with the applicable royalty payment due for such Calendar Quarter, a written report of Net Sales on a Product by Product and country by country basis subject to royalty payments for such Calendar Quarter. Such report shall be deemed "Confidential Information" of Merck subject to the obligations of ARTICLE 10 of this Agreement. For *** after each sale of Product occurs, Merck shall, and shall ensure that its Affiliates and Sublicensees, keep complete and accurate records of such sale in sufficient detail to confirm the accuracy of the royalty calculations hereunder.
- 8.11 **Legal Restrictions** . If at any time legal restrictions prevent the remittance by Merck of all or any part of royalties due on Net Sales in any country, Merck shall have the right and option to make such payment either by depositing the amount thereof in local currency to an account in the name of Licensor in a bank or other depository selected by Licensor in such country.
- 8.12 **Late Payments** . All payments under this Agreement shall earn interest from the date due until paid at a per annum rate equal to the lesser of (a) the maximum rate permissible under Law and (b) *** percent (***%) above the monthly Reuters 01 EURIBOR, measured at 2 p.m. Frankfurt/Germany time on the date payment is due. Interest will be calculated on a 365/360 basis. An example of the interest rate calculation follows, assuming that the Reuters interest rate is 0.25% and a payment of \$10,000,000 is thirty (30) days overdue:

Step 1: applicable annual interest rate on a 365/360 basis = ***% + 0.25% = ***%

Step 2: applicable interest rate for the period of delay = $30/360 \times \text{***\%} = \text{***\%}$

Step 3: total interest due = $10,000,000 \times \text{***\%} = \$\text{***}$

8.13 Audits .

- (a) **Audits Generally** . During the Royalty Term and for *** thereafter, and not more than once in each Calendar Year, Merck shall permit, and shall cause its Affiliates or Sublicensees to permit, an independent certified public accounting firm of nationally recognized standing selected by Licensor, and reasonably acceptable to Merck or such Affiliate or Sublicensee, to have access to and to review, during normal business hours upon reasonable prior written notice, the applicable records of Merck and its Affiliates or Sublicensees to verify the accuracy of the royalty reports and payments under this ARTICLE 8. Such review may cover the records for sales made in any Calendar Year ending not more than *** prior to the date of such request. The accounting firm shall disclose to Licensor and Merck only whether the royalty reports are correct or incorrect and the specific details concerning any discrepancies. No other information shall be provided to Licensor.
- (b) **Audit-Based Reconciliation** . If such accounting firm concludes that additional royalties were owed during such period, and Merck agrees with such calculation, Merck shall pay the additional undisputed royalties within *** after the date Licensor delivers to Merck such accounting firm's written report. If such accounting firm concludes that an overpayment was made, such overpayment shall be fully creditable against amounts payable in subsequent payment periods or, at Merck's request, shall be promptly reimbursed to Merck. If Merck disagrees with such calculation, it may retain its own independent certified public accounting firm of recognized standing and reasonably acceptable to Licensor, to conduct a review at Merck's expense, and if such firm concurs with the other accounting firm, Merck shall make the required payment within *** after the date Merck receives the report of its accounting firm. If Merck's accounting firm does not concur, Merck and Licensor shall meet and negotiate in good faith a resolution of the discrepancies between the two firms. Licensor shall pay for the cost of any audit requested by Licensor, unless Merck has underpaid Licensor by the greater of (i) *** percent (***) or more or (ii) *** USD (\$***), in which case Merck shall pay for the costs of audit.
- (c) **Audit Confidentiality** . Each Party shall treat all information that it receives under this Section 8.13 in accordance with the confidentiality provisions of ARTICLE 10, and shall cause its accounting firm to enter into an acceptable confidentiality agreement with the other Party obligating such firm to retain all such financial information in confidence pursuant to such confidentiality agreement, except to the extent necessary for such Party to enforce its rights under this Agreement.

8.14 Taxes .

- (a) **Withholding Tax** . Licensor shall be responsible for the payment of any and all Taxes levied on account of the royalties and other payments paid to Licensor by Merck or its Affiliates or Sublicensees under this Agreement. If Law requires that Taxes be deducted and withheld from royalties or other payments paid under this Agreement, Merck shall: (i) deduct those Taxes and interests and penalties assessed thereon from the payment or from any other payment owed by Merck hereunder; (ii) pay the Taxes to the proper Governmental Body; (iii) send evidence of the obligation together with proof of Tax payment to Licensor within *** days following such payment; (iv) remit the net amount, after deductions or withholding made under this Section 5.13(a); and (v) cooperate with Licensor in any way reasonably requested by Licensor, to obtain available reductions, credits or refunds of such Taxes; provided, however, that Licensor shall reimburse Merck for Merck's Out-of-Pocket Expenses incurred in providing such assistance.

(b) **Value Added Tax** . It is understood and agreed between the Parties that any payments made by Merck under this Agreement are inclusive of any value added or similar Tax imposed upon such payment and that Licensor shall be responsible for the payment of any and all Taxes levied on account of any payments paid to Licensor by Merck. Merck is entitled to receive a proper tax invoice where any Value Added Tax amount is shown separately.

ARTICLE 9 INVENTIONS AND PATENTS

- 9.1 **Patent Listing under Public Health Services Act** . Each Party shall immediately give written notice to the other Party of any certification of which they become aware filed pursuant to 42 USC. §262(1)(3) (or any amendment or successor statute thereto) claiming that any Licensor Patents Covering or claiming Product, or the manufacture of Product, are invalid or unenforceable, or that infringement will not arise from the manufacture, use or sale of a product by a Third Party.
- 9.2 **Further Assurances** . Licensor shall require all of its employees, agents, and independent contractors and any Affiliates and Third Parties working on its behalf under this Agreement (and their respective employees, and independent contractors), to assign to Licensor any Licensor Technology.
- 9.3 **Ownership of Inventions**. Each Party shall own any inventions made solely by its own employees, agents, or independent contractors in the course of conducting its activities under this Agreement, together with all intellectual property rights therein (“ **Sole Inventions** ”). Patent Rights claiming any inventions that are made jointly by employees, agents, or independent contractors of each Party in the course of performing activities under this Agreement, together with all intellectual property rights therein (“ **Joint Inventions** ”) shall be jointly owned by the Parties. Inventorship shall be determined in accordance with U.S. patent laws.
- 9.4 **Patent Prosecution and Maintenance** . The following terms and conditions shall become effective as of the Option Exercise Date:
- (a) **Licensor Patents** . Licensor shall have the first right to file, prosecute and maintain Licensor Patents in the Territory, and Licensor shall bear the costs and expenses of such activities. Licensor shall keep Merck informed of the status of the filing and prosecution of Licensor Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications) in the Territory in a timely manner, and will take into consideration the advice and recommendations of Merck. At Licensor’s request, Merck will provide Licensor with reasonable, free-of-charge assistance in prosecuting Licensor Patents to the extent possible, including providing such data in Merck’s Control that is, in Licensor’s reasonable judgment, needed to support the prosecution of a Licensor Patent.

(b) **Election Not to File and Prosecute Licensor Patents** . If Licensor elects not to file or to continue to prosecute or maintain a Licensor Patent in the Territory, then it shall notify Merck in writing at least *** days before any final deadline applicable to the filing, prosecution or maintenance of such Licensor Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Licensor Patent in such country or possession. In such case, Merck shall have the right to pursue the filing or support the continued prosecution or maintenance of such Licensor Patent. If Merck fails to continue prosecution or maintenance of any of the Licensor Patents, then such abandoned Licensor Patents shall not extend the Royalty Term (i.e., no royalty payments shall be due under this Agreement on account of such abandoned Licensor Patents). In the event Merck provides written notice expressing its interest in obtaining such Licensor Patent(s), Licensor shall, free-of-charge, assign and transfer to Merck the ownership of, and interest in, such Licensor Patent(s) and Licensor shall cooperate with Merck for assignment and transfer of such Licensor Patent(s). With respect to any such assigned and transferred Patent Rights(s): (i) Merck shall bear all costs of preparation, filing, prosecution and maintenance thereof; (ii) such Patent Rights shall cease to be Licensor Patents; (iii) Merck hereby agrees not to exercise rights under such Patent Rights with respect to Product outside of the Field; and (iv) Merck hereby covenants not to sue Licensor or its licensees, successors or assigns (which licensees, successors or assigns are the beneficiaries of a contemporaneous license under, or assignment of, other intellectual property rights Controlled by Licensor) for infringement of such Patent Rights on account of Licensor's (or such licensees, successors or assigns) activities outside of the Field.

(c) **Joint Patents** . Merck shall have the first right and authority to prepare, file, prosecute and maintain Patent Rights (“ **Joint Patents** ”) covering or claiming Joint Inventions on a worldwide basis as an equally shared cost and expense of such Patent Rights. Merck shall keep Licensor informed of the status of the filing and prosecution of Joint Patents or related proceedings (e.g. interferences, oppositions, reexaminations, reissues, revocations or nullifications), and will take into consideration the advice and recommendations of Licensor. At Merck's request, Licensor will provide Merck with reasonable free-of-charge assistance in prosecuting Joint Patents to the extent possible, including providing such data in Licensor's Control that is, in Merck's reasonable judgment, needed to support the prosecution of a Joint Patent. Merck shall invoice Licensor from time-to-time for Licensor's portion of the costs associated with Merck's preparation, filing, prosecution and maintenance of the Joint Patents, which invoices Licensor shall pay within *** days of receipt; provided, that, if Licensor does not pay such invoices when due, then Merck may offset any amounts due to Licensor against such unpaid invoice(s).

(d) **Election Not to File and Prosecute Joint Patents or to Share in Joint Patent-Related Costs .**

(i) If Merck elects not to file or to continue to prosecute or maintain a Joint Patent in the Territory, then it shall notify Licensor in writing at least *** days before any final deadline applicable to the filing, prosecution or maintenance of such Joint Patent, as the case may be, or any other date by which an action must be taken to establish or preserve such Joint Patent in such country or possession. In such case, Licensor shall have the right to pursue the filing or support the continued prosecution or maintenance of such Joint Patent at its sole cost and expense and, in the event Licensor provides written notice expressing its interest in obtaining such Joint Patent(s), Merck shall, free-of-charge, assign and transfer to Licensor its ownership of, and interest in, such Joint Patent(s); provided, that, for purposes of this Agreement any such Joint Patent(s) shall not be Licensor Patent(s).

(ii) If Licensor does not desire to share in the expense of prosecuting or maintaining any given Joint Patent(s) it shall so advise Merck in writing and shall, free-of-charge, assign and transfer to Merck its ownership of, and interest in, such Joint Patent(s), and from and after such assignment Merck shall be solely responsible for the cost and expense of maintaining such Patent Rights.

(e) **Patent Term Extension .**

(i) Licensor shall be responsible for obtaining patent term extensions wherever available for Licensor Patents.

(ii) Merck shall be responsible for obtaining patent term extensions wherever available for Joint Patents.

(iii) The non-obtaining Party shall provide the obtaining Party, free-of-charge, with all relevant information, documentation and assistance as may reasonably be requested by the obtaining Party. Any such assistance, supply of information and consultation shall be provided promptly and in a manner that will ensure that all patent term extensions for the subject Patents are obtained wherever legally permissible, and to the maximum extent available. In the event that any election with respect to obtaining patent term extensions is to be made, Merck shall have the right to make such elections, and Licensor shall abide by all such elections.

(f) **Merck Patents .** Merck shall own any Know-How constituting a Sole Invention developed by Merck or any of its Affiliates or a Third Party on behalf of Merck and shall have the right, but not the obligation, to file, prosecute and maintain Patent Rights covering or claiming any such Know-How (“ **Merck Patent** ”). Merck shall bear all costs and expenses of filing, prosecuting and maintaining Merck Patents and Licensor shall have no particular rights with respect thereto.

9.5 **Enforcement of Patents and Know-How .** The following terms and conditions shall become effective as of the Option Exercise Date:

(a) **Notice .**

(i) If either Party believes that an infringement, unauthorized use, misappropriation or ownership claim or threatened infringement or other such activity by a Third Party with respect to any Licensor Technology or Joint Invention, or if a Third Party claims that any Licensor Patent or Joint Patent is invalid or unenforceable, then: (1) the Party possessing such knowledge or belief shall notify the other Party, (2) the Parties (and any relevant Third Party licensees or sublicensees of the Parties) shall promptly execute a common interest agreement for the purpose of maintaining privilege and otherwise specifically addressing the exchange of information under such circumstances (“ **Common Interest Agreement** ”), and (3) the Parties shall provide, under such Common Interest Agreement, each other with details of such infringement or claim that are known by such Party. All exchanges of information under this Section 9.5 shall be conducted under the auspices of the Common Interest Agreement.

(ii) In the event that Licensor believes that a Merck Patent, if any, is being infringed by a Third Party or if a Third Party claims that any Merck Patent is invalid or unenforceable, Licensor shall notify Merck and provide it with details of such infringement or claim.

(b) **Right to Bring an Action .** Merck shall have the first right to attempt to resolve any infringement or claim, including by filing an infringement suit, defending against such claim or taking other similar action, with respect to a Licensor Patent or Joint Patent (each, an “ **Action** ”) and to compromise or settle any such infringement or claim; provided, that if such Action relates to a product covered by such Licensor Patent outside of the Field and such Action does not relate to, and the outcome of such action is not reasonably likely to adversely affect, the Product in the Field, then, Merck will not have the right to resolve such infringement or claim. At Merck’s request, Licensor shall immediately provide Merck with all relevant documentation (as may be requested by Merck) evidencing that Merck is validly empowered by Licensor to take such an Action. Licensor is obligated to join Merck in such Action if Merck determines that it is necessary to demonstrate “standing to sue”. If Merck does not intend to prosecute or defend an Action, Merck shall promptly inform Licensor and Licensor may undertake the prosecution or defense of such Action.

(c) **Costs of an Action .** Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 12, *** an Action under 9.5(b) shall pay *** costs associated with such Action, other than *** the expenses of *** if the *** elects to ***. Each Party shall have the right to join an Action relating to a Licensor Patent***.

(d) **Settlement .** Neither Party shall settle or otherwise compromise any Action by admitting that any Licensor Patent or Joint Patent is invalid or unenforceable without the other Party’s prior written consent with such consent not to be unreasonably withheld, conditioned or delayed, and, in the case of Licensor, Licensor may not settle or otherwise compromise an Action in a way that adversely affects or would be reasonably expected to adversely affect Merck’s rights or benefits hereunder, without Merck’s prior written consent with such consent not to be unreasonably withheld, conditioned or delayed.

(e) **Reasonable Assistance** . The Party not enforcing or defending Licensor Patents or Joint Patents shall provide reasonable assistance to the other Party, including providing access to relevant documents and other evidence and making its employees available, subject to *** of any *** on an *** by the *** or *** in providing such assistance.

(f) **Distribution of Amounts Recovered** . Any amounts recovered by the Party taking an Action pursuant to this Section 9.5, whether by settlement or judgment, shall be allocated in the following order: (i) to reimburse the Party taking such Action for any costs incurred; (ii) to reimburse the Party not taking such Action for its costs incurred in such Action, if it joins or is joined in such Action; and (iii) the remaining amount of such recovery shall be (x) ***the ***if ***is the *** and (y) ***to ***and ***for the ***in which the ***is ***and ***to ***a ***on such ***based on the ***if ***is the ***the ***.

(g) **Merck Patents** . Merck shall have the sole right and authority, but not the obligation, to enforce Merck Patents against any Third Party infringer; provided, that Licensor shall provide reasonable assistance to Merck with respect thereto, including providing access to relevant documents and other evidence and making its employees available, subject to Merck's reimbursement of any Out-of-Pocket Expenses incurred on an on-going basis in providing such assistance.

9.6 **Third Party Actions Claiming Infringement** . The following terms and conditions shall become effective as of the Option Exercise Date:

(a) **Notice** . If a Party becomes aware of any Third Party Action, then (1) such Party shall promptly notify the other Party, (2) the Parties shall, if one has not already been entered into, enter into a Common Interest Agreement, and (3) the Parties shall provide, under such Common Interest Agreement, each other all details regarding such claim or action that is reasonably available to such Party.

(b) **Right to Defend** . Merck shall have the right, at its sole expense, but not the obligation, to defend a Third Party Action described in Section 9.6(a) and to compromise or settle such Third Party Action to the extent that (i) Merck is a named party in such Third Party Action or (ii) such action relates to ***. If Merck declines or fails to assert its intention to defend such Third Party Action within *** days of after sending (in the event that Licensor is the notifying Party) or receipt (in the event that Merck is the notifying Party) of notice under Section 9.6(a), then Licensor shall have the right to defend such Third Party Action. In the event that Merck elects to defend the Third Party Action according to this Section 9.6(b) and such Third Party Action also concerns allegations of infringement or misappropriation outside of the Field or the Territory, Merck shall reasonably cooperate with Licensor regarding the defense of the Third Party Action to the extent that it so concerns allegations of infringement or misappropriation outside of the Field or the Territory.

(c) **Consultation** . The Party defending a Third Party Action pursuant to Section 9.6(b) shall be the “ **Controlling Party** .” The Controlling Party shall consult with the non-Controlling Party on all material aspects of the defense. The non-Controlling Party shall have a reasonable opportunity for meaningful participation in decision-making and formulation of defense strategy. The Parties shall reasonably cooperate with each other in all such actions or proceedings. The non-Controlling Party will be entitled to be represented by independent counsel of its own choice at its own expense.

(d) **Appeal** . In the event that a judgment in a Third Party Action is entered against the Controlling Party and an appeal is available, the Controlling Party shall have the first right, but not the obligation, to file such appeal. In the event the Controlling Party does not desire to file such an appeal, it will promptly, in a reasonable time period (i.e., with sufficient time for the non-Controlling Party to take whatever action may be necessary) prior to the date on which such right to appeal will lapse or otherwise diminish, permit the non-Controlling Party to pursue such appeal at such non-Controlling Party's own cost and expense. If Law requires the other Party's involvement in an appeal, the other Party shall be a nominal party of the appeal and shall provide reasonable cooperation to such Party at such Party's expense.

(e) **Costs of an Action** . Subject to the respective indemnity obligations of the Parties set forth in ARTICLE 12, the *** shall pay *** costs associated with such Third Party Action other than the expenses ***if the ***elects to ***; provided, that, if Merck is ***, then Merck shall have the right to deduct from any amount payable to Licensor under *** or under *** *** an amount equal to *** percent (***%) of any amounts paid by Merck in connection with such Third Party Action; provided, that such deductions***, may not reduce the amount of *** and *** payable by Merck to Licensor for any *** by more than *** percent (***%) of the amount that would otherwise be due. Excess amounts that Merck is not allowed to deduct pursuant to the foregoing proviso will be carried forward into future ***. Each Party shall have the right to join a Third Party Action defended by the other Party, at its own expense.

(f) **No Settlement Without Consent** . Neither Party shall settle or otherwise compromise any Third Party Action (i) by admitting that any Licensor Patent or Joint Patent is invalid or unenforceable without the other Party's prior written consent, or (ii) in a way that adversely affects or would be reasonably expected to adversely affect the other Party's rights and benefits hereunder, without such other Party's prior written consent.

ARTICLE 10 CONFIDENTIALITY

10.1 **Confidentiality Obligations** . Each Party agrees that, for the Term and for *** years thereafter, such Party shall, and shall ensure that its Representatives, hold in confidence all Confidential Information disclosed to it by the other Party pursuant to this Agreement, unless such information:

- (i) is or becomes generally available to the public other than as a result of disclosure by the recipient;

- (ii) is already known by or in the possession of the recipient at the time of disclosure by the disclosing Party;
 - (iii) is independently developed by recipient without use of or reference to the disclosing Party's Confidential Information;
- or
- (iv) is obtained by recipient from a Third Party that has not breached any obligations of confidentiality.

The recipient shall not disclose any of the Confidential Information, except to Representatives of the recipient who need to know the Confidential Information for the purpose of performing the recipient's obligations, or exercise its rights, under this Agreement and who are bound by obligations of non-use and non-disclosure substantially similar to those set forth herein. The recipient shall be responsible for any disclosure or use of the Confidential Information by such Representatives. The recipient shall protect Confidential Information using not less than the same care with which it treats its own confidential information, but at all times shall use at least reasonable care. Each Party shall: (a) implement and maintain appropriate security measures to prevent unauthorized access to, or disclosure of, the other Party's Confidential Information; (b) promptly notify the other Party of any unauthorized access or disclosure of such other Party's Confidential Information; and (c) cooperate with such other Party in the investigation and remediation of any such unauthorized access or disclosure.

10.2 **Use .** Notwithstanding Section 10.1, a Party may use the Confidential Information of the other Party for the purpose of performing its obligations, or exercising its rights, under this Agreement, including for purposes of:

- (i) filing or prosecuting patent applications, subject to the terms of ARTICLE 9;
- (ii) prosecuting or defending litigation;
- (iii) conducting pre-clinical studies or Clinical Trials pursuant to this Agreement;
- (iv) seeking or maintaining Regulatory Approval for Product; or
- (v) complying with Law, including securities Law and the rules of any securities exchange or market on which a Party's securities are listed or traded.

In addition to the foregoing, Merck may, in furtherance of its rights under this Agreement, disclose Confidential Information of Licensor to any Third Party, provided that such Third Party is bound by obligations of confidentiality at least as stringent as the ones herein.

In making any disclosures set forth in clauses (i) through (v) above, the disclosing Party shall, where reasonably practicable, give such advance notice to the other Party of such disclosure requirement as is reasonable under the circumstances and will use its reasonable efforts to cooperate with the other Party in order to secure confidential treatment of such Confidential Information required to be disclosed. In addition, in connection with any permitted filing by either Party of this Agreement with any Governmental Body the filing Party shall endeavor to obtain confidential treatment of economic, trade secret information and such other information as may be requested by the other Party, and shall provide the other Party with the proposed confidential treatment request with reasonable time for such other Party to provide comments, and shall include in such confidential treatment request all reasonable comments of the other Party.

- 10.3 **Required Disclosure** . The recipient may disclose the Confidential Information to the extent required by Law or court order; provided, however, that the recipient promptly provides to the disclosing party prior written notice of such disclosure and provides reasonable assistance in obtaining an order or other remedy protecting the Confidential Information from public disclosure.
- 10.4 **Publications** . Following the Option Exercise Date, (i) Licensor shall not publish any information relating to Product without the prior written consent of Merck (which consent may be withheld or given in Merck's sole discretion), unless such information has already been publicly disclosed either prior to the Effective Date or after the Effective Date through no fault of Licensor or otherwise not in violation of this Agreement; (ii) Merck shall have the right to make such publications as it chooses, in its sole discretion, without the approval of Licensor; and (iii) Licensor shall submit to Merck for Merck's written approval (which approval be granted or denied in Merck's sole discretion) any publication or presentation (including in any seminars, symposia or otherwise) of information related directly or indirectly to Product for review and approval at least ninety (90) days prior to submission for the proposed date of publication or presentation.
- 10.5 **Press Releases and Disclosure** .
- (a) **Initial Press Release** . The Parties' joint public announcement regarding the execution of this Agreement is set forth on Schedule 10.5(a) hereto.
- (b) **Subsequent Public Disclosures By Licensor** . Licensor may not make any subsequent press release or public announcements or public disclosure regarding this Agreement beyond the scope of the public announcement set forth on Schedule 10.5(a) hereto or, subsequent to the Option Exercise Date, any matter covered by this Agreement, including the Development or Commercialization of Product, without the prior written consent of Merck, except that, in the event that Licensor is, in the opinion of its counsel, required under applicable Laws or stock market listing requirements as a publicly-traded company to make a public announcement or make a particular disclosure in its periodic filings or registration statements filed with the U.S. Securities and Exchange Commission, Licensor may do so but shall provide the text of such planned disclosure to Merck as far in advance as is reasonably practicable (and to the extent possible no less than *** days prior to disclosure) so as to provide a reasonable opportunity to comment thereon and Licensor shall incorporate all reasonable comments of Merck regarding such disclosure.

(c) **Public Disclosures by Merck .**

(i) Prior to the Option Exercise Date: (i) Merck may not make any subsequent press release or public announcements regarding this Agreement beyond the scope of the public announcement set forth on Schedule 10.5(a) hereto or any matter covered by this Agreement, including the Development or Commercialization of Product, without the prior written consent of Licensor, and (ii) in the event that Merck is, in the opinion of its counsel, required under applicable Laws as a publicly-traded company to make a public announcement or make a particular disclosure to investors or potential investors, Merck shall provide the text of such planned disclosure to Licensor as far in advance as is reasonably practicable (and to the extent possible no less than seven (7) days prior to disclosure) so as to provide a reasonable opportunity to comment thereon and incorporate all reasonable comments of Licensor regarding such disclosure.

(ii) Following the Option Exercise Date, Merck shall have the right to make such press releases or other public announcements as it chooses, in its sole discretion, without the approval of Licensor.

- 10.6 **Agreement Filing .** The Parties acknowledge that Licensor may be obligated to file a copy of this Agreement with the SEC or other applicable entity having regulatory authority over Licensor securities or the exchange thereof. Licensor shall be entitled to make such a required filing; provided, that it requests confidential treatment of certain commercial terms and sensitive technical terms hereof as agreed to by the Parties pursuant to a separate written agreement (which agreement may be documented by an email exchange confirming the Parties' agreement regarding the redactions to be sought through such confidential treatment).

**ARTICLE 11
REPRESENTATIONS, WARRANTIES AND COVENANTS**

- 11.1 **Representations and Warranties .** Each Party represents and warrants to the other Party that, as of the Effective Date and the Option Exercise Date:

- (i) such Party is duly organized and validly existing under the Laws of the jurisdiction of its incorporation or organization;
- (ii) such Party has taken all action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement;
- (iii) this Agreement is a legal and valid obligation of such Party, binding upon such Party and enforceable against such Party in accordance with the terms of this Agreement, except as enforcement may be limited by applicable bankruptcy, fraudulent conveyance, insolvency, reorganization, moratorium and other laws relating to or affecting creditors' rights generally and by general equitable principles. The execution, delivery and performance of this Agreement by such Party does not conflict with, breach or create in any Third Party the right to accelerate, terminate or modify any agreement or instrument to which such Party is a party or by which such Party is bound, and does not violate any Law of any Governmental Body having authority over such Party; and

(iv) such Party has all right, power and authority to enter into this Agreement, to perform its obligations under this Agreement.

11.2 **Additional Representations and Warranties of Licensor** . Licensor represents and warrants to Merck that, as of the Effective Date, subject to the disclosures on Schedule 11.2, and as of the Option Exercise Date, subject to an updated Schedule 11.2 provided in accordance with, and subject to, Section 2.1:

(i) no consent by any Third Party or Governmental Body is required with respect to the execution and delivery of this Agreement by Licensor or the consummation by Licensor of the transactions contemplated hereby;

(ii) no claims have been asserted, or, to Licensor's Knowledge, threatened by any Person, nor to Licensor's Knowledge are there any valid grounds for any claim of any such kind (a) challenging the validity, effectiveness, or ownership of the Licensor Technology, and/or (b) to the effect that the use, reproduction, modification, manufacturing, distribution, licensing, sublicensing, sale or any other exercise of rights in any of the Licensor Technology infringes, will infringe, misappropriates or will misappropriate any intellectual property right of any Person. No such claims have been asserted or, to the Knowledge of Licensor, are threatened;

(iii) to the Knowledge of Licensor, there is no unauthorized use, infringement or misappropriation of any of Licensor Technology by any employee or former employee of Licensor, or any other Third Party;

(iv) the Licensor Patents (a) owned by Licensor are subsisting and are not the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute, and (b) in-licensed by Licensor are subsisting and are not to Licensor's Knowledge the subject of any litigation procedure, discovery process, interference, reissue, reexamination, opposition, appeal proceedings or any other legal dispute;

(v) the Licensor Patents (a) constitute all Patent Rights owned or Controlled by Licensor as of the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date), that are directly related to, or necessary or useful for, the research, Development, manufacture, use or Commercialization of Product and (b) listed on Schedule 1.40 hereto constitute all Patent Rights that are, to Licensor's Knowledge, necessary for, the research, Development, manufacture, use or Commercialization of Product as proposed or conducted by Licensor as of the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date);

(vi) the Licensors Know-How (a) constitutes all Know-How owned or Controlled by Licensors as of the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date) that is directly related to, or necessary or useful for, the research, Development, manufacture, use or Commercialization of the Product and (b) constitutes all Know-How that is, to Licensors Knowledge, necessary for, the research, Development, manufacture, use or Commercialization of Product as proposed or conducted by Licensors as of the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date);

(vii) Licensors has not developed, subcontracted or licensed to a Third Party the right to develop a Competing Product;

(viii) to Licensors Knowledge, no Third Party has filed, pursued or maintained or threatened in writing to file, pursue or maintain any claim, lawsuit, charge, complaint or other action alleging that any Licensors Patent is invalid or unenforceable;

(ix) to Licensors Knowledge, Mercks and its Affiliates' and Sublicensees' practice and use of the inventions claimed in, or covered by, the Licensors Patents as the Product has been Developed by Licensors prior to the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date), will not infringe any intellectual property rights of any Third Party;

(x) all Representatives of Licensors who have performed any activities on its behalf in connection with research regarding the Product have assigned to Licensors the whole of their rights in any intellectual property made, discovered or developed by them as a result of such research, and no Third Party has any rights to any such intellectual property except as provided in an Existing Third Party Agreement;

(xi) Licensors has all right, title and interest in and to the Licensors Technology and Licensors Technology is free and clear of any liens, charges, encumbrances or rights of others to possession or use, except for those existing liens for secured creditors that are identified on Schedule 11.2;

(xii) Licensors has not previously licensed, assigned, transferred, or otherwise conveyed any right, title or interest in and to the Licensors Technology to any Third Party, including any rights with respect to Product, in conflict with the option or license rights granted herein;

(xiii) the Licensors Technology constitutes all of the intellectual property of Licensors, which, to the Knowledge of Licensors as of the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date) could reasonably be expected to be necessary or useful in the research, Development, manufacture, import, export, use or Commercialization of Product in the Field;

(xiv) Licensors has the right, power and authority to grant to Merck the rights granted to Merck hereunder with respect to the Existing Third Party Agreements. In particular, the grant of such sublicense requires no consent, waiver or other action by any party to the Existing Third Party Agreements and the rights and obligations of Merck set forth in this Agreement do not contravene nor are they inconsistent with or in conflict with the terms of any Existing Third Party Agreement;

(xv) The Existing Third Party Agreements constitute all agreements with Third Parties pursuant to which Licensor has licensed, or otherwise obtained rights, with respect to the Product. Licensor has provided to Merck an accurate, true and complete copy of each of the Existing Third Party Agreements, as amended to date and each of the Existing Third Party Agreements is in full force and effect and Licensor is not in breach or default in the performance of its obligations under any of the Existing Third Party Agreements. Licensor has not received any notice from any Third Party of any breach, default or non-compliance of Licensor under the terms of any of the Existing Third Party Agreements. There have been no amendments or other modification to any Existing Third Party Agreements, except as have been disclosed to Merck in writing;

(xvi) except as set forth on Schedule 11.2(xvi), Licensor is not aware of any additional Third Party licenses that have to be taken now or in the future to guarantee freedom-to-operate to Develop, manufacture and Commercialize Products without any limitation;

(xvii) all tangible information and data provided by or on behalf of Licensor to Merck on or before, on the Effective Date, the Effective Date, and on the Option Exercise Date, the Option Exercise Date, in contemplation of entering into this Agreement as of the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date) was and is true, accurate and complete in all material respects, and Licensor has not failed to disclose, or cause to be disclosed, any information or data that would cause the information and data that has been disclosed to be misleading in any material respect;

(xviii) Licensor (and its Affiliates) has not employed or otherwise used in any capacity, and will not employ or otherwise use in any capacity, the services of any Person debarred under United States law, including under Section 21 USC 335a or any foreign equivalent thereof, with respect to the Product (including in the context of performing the Abili-T Trial);

(xix) all research and development (including non-clinical studies, Clinical Studies and the Abili-T Trial) related to the Product prior to the Effective Date (and, in conjunction with the exercise of the Option, the Option Exercise Date), has been conducted in accordance with all Laws;

(xx) no Governmental Authority has notified Licensor or its Affiliates, and Licensor is not otherwise aware, that the Development, manufacture, use or Commercialization of Product was or is in violation of any Law or the subject of any investigation;

(xxi) Licensor has not received notice from any Regulatory Authority and is not otherwise aware that there are any circumstances currently existing which would reasonably be expected to lead to: (1) any loss of or refusal to renew any Regulatory Approvals relating to Product; (2) renewal on terms less advantageous to Licensor or any of its Affiliates, if applicable, or any subsequent holder thereof, than the terms of those Regulatory Approvals currently in force; (iii) recall, withdrawal, suspensions or seizure of Product; or (iv) an action to enjoin production of Product;

(xxii) Licensors have delivered to Merck copies of all: (1) reports of FDA Form 483 inspection observations, or any equivalent report by inspectors or officials from any other Regulatory Authority of any situation requiring attention or correction or of conditions or circumstances that are objectionable or otherwise in contrary to Law; (2) FDA Notices of Adverse Findings or any equivalent correspondence, notice or communication from any other Regulatory Authority indicating a failure to comply with Law or other requirements; (3) establishment inspection reports; (4) warning letters or untitled letters; and (v) other documents that assert ongoing lack of compliance in any material respect with any Law or regulatory requirements (including those of the FDA), in each case received by Licensors from the FDA or any other Regulatory Authority relating to Product or arising out of the conduct of Licensors' business relating to Product; and

(xxiii) Licensors and each of its Affiliates, as applicable, has made all necessary filings and received all necessary approvals and consents for the conduct of all Clinical Trials performed by it or them with respect to Product from the necessary Regulatory Authorities and: (1) Licensors are not aware of any proceedings or actions threatened or taken by any Regulatory Authorities to suspend or terminate any ongoing Clinical Trials for Product; (2) Licensors have not received any notice, charge, subpoena or other request for information, which has not been complied with or withdrawn, by a Regulatory Authority asserting any material breach of the conditions for approval of any ongoing Clinical Trials; and (3) Licensors and its Affiliates, as applicable, have conducted all Clinical Trials for Product pursuant to valid protocols, and have received no notice or indication, in writing or orally, from any Regulatory Authority to the effect that any such protocol is not sufficient to support approval of Product or any Indications for Product.

11.3 Licensors Covenants . Licensors covenants to Merck that:

(i) Licensors shall fulfill all of its obligations, including but not limited to its payment obligations, under any Existing Third Party Agreement or any Third Party License Agreement; and

(ii) Licensors shall not amend or waive, or take any action or omit to taking any action that would alter, any of Licensors' rights under any Existing Third Party Agreement or any Third Party License Agreement in any manner that adversely affects, or would reasonably be expected to adversely affect, Merck's rights and benefits under this Agreement. Licensors shall promptly notify Merck of any default under, termination or amendment of, any Existing Third Party Agreement or Third Party License Agreement.

ARTICLE 12

INDEMNIFICATION AND INSURANCE

- 12.1 **Indemnification by Merck** . Merck shall indemnify, defend and hold Licensor and its Affiliates and each of their respective employees, officers, directors and agents (the “ **Licensor Indemnitees** ”) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorneys’ fees) to the extent arising out of Third Party claims or suits related to: (a) Merck’s negligence or willful misconduct; (b) Merck’s performance of its obligations under this Agreement; (c) Merck’s Development or Commercialization of Product; or (d) breach by Merck of its representations or warranties set forth in ARTICLE 11; provided, however, that Merck’s obligations pursuant to this Section 12.1 shall not apply (i) to the extent such claims or suits result from the negligence or willful misconduct of any of the Licensor Indemnitees, or (ii) with respect to claims or suits arising out of breach by Licensor of its representations, warranties or covenants set forth in ARTICLE 11.
- 12.2 **Indemnification by Licensor** . Licensor shall indemnify, defend and hold Merck and its Affiliates and each of their respective agents, employees, officers and directors (the “ **Merck Indemnitees** ”) harmless from and against any and all liability, damage, loss, cost or expense (including reasonable attorney’s fees) to the extent arising out of Third Party claims or suits related to: (a) the Abili-T Trial; (b) Licensor’s negligence or willful misconduct; (c) Licensor’s performance of its obligations under this Agreement; or (d) breach by Licensor of its representations, warranties or covenants set forth in ARTICLE 11; provided, however, that Licensor’s obligations pursuant to this Section 12.2 shall not apply (i) to the extent that such claims or suits result from the negligence or willful misconduct of any of the Merck Indemnitees or (ii) with respect to claims or suits arising out of a breach by Merck of its representations or warranties set forth in ARTICLE 11.
- 12.3 **No Consequential Damages** . EXCEPT WITH RESPECT TO EACH PARTY’S INDEMNIFICATION OBLIGATIONS UNDER SECTION 12.1 OR SECTION 12.2, AS APPLICABLE, IN NO EVENT SHALL EITHER PARTY OR ANY OF ITS AFFILIATES BE LIABLE TO THE OTHER PARTY OR ANY OF ITS AFFILIATES FOR SPECIAL, INDIRECT, INCIDENTAL, CONSEQUENTIAL OR PUNITIVE DAMAGES, INCLUDING LOSS OF PROFITS, WHETHER IN CONTRACT, WARRANTY, TORT, NEGLIGENCE, STRICT LIABILITY OR OTHERWISE ARISING OUT OF OR RELATING TO THIS AGREEMENT, THE TRANSACTIONS CONTEMPLATED HEREIN OR ANY BREACH HEREOF. ***
- 12.4 **Notification of Claims; Conditions to Indemnification Obligations** . As a condition to a Party’s right to receive indemnification under this ARTICLE 12, it shall: (a) promptly notify the other Party as soon as it becomes aware of a claim or suit for which indemnification may be sought pursuant hereto; (b) cooperate, and cause the individual indemnitees to cooperate, with the indemnifying Party in the defense, settlement or compromise of such claim or suit; and (c) permit the indemnifying Party to control the defense, settlement or compromise of such claim or suit, including the right to select defense counsel. In no event, however, may the indemnifying Party compromise or settle any claim or suit in a manner which admits fault or negligence on the part of the indemnified Party or any indemnitee without the prior written consent of the indemnified Party. Each Party shall reasonably cooperate with the other Party and its counsel in the course of the defense of any such suit, claim or demand, such cooperation to include without limitation using reasonable efforts to provide or make available documents, information and witnesses. The indemnifying Party shall have no liability under this ARTICLE 12 with respect to claims or suits settled or compromised without its prior written consent.

- 12.5 **Insurance** . During the Term, each Party shall obtain and maintain, at its sole cost and expense, insurance (including any self-insured arrangements) in types and amounts, that are reasonable and customary in the United States pharmaceutical and biotechnology industry for companies engaged in comparable activities. It is understood and agreed that this insurance shall not be construed to limit either Party's liability with respect to its indemnification obligations hereunder. Each Party will, except to the extent self insured, provide to the other Party upon request a certificate evidencing the insurance such Party is required to obtain and keep in force under this Section 12.5.

ARTICLE 13 TERM AND TERMINATION

- 13.1 **Term and Expiration** . The term of this Agreement (the "**Term**") shall commence on the Effective Date and, unless earlier terminated as provided in this ARTICLE 13, shall continue in full force and effect, on a country-by-country basis until the date on which the Royalty Term in such country expires, at which time this Agreement shall expire in its entirety with respect to Product in such country and the terms of Section 13.4(b)(i) shall apply. Notwithstanding the foregoing, the Term will automatically expire contemporaneously with the expiration of the Option Period if Merck has not exercised the Option.
- 13.2 **Termination of the Agreement for Convenience** . At any time during the Term, Merck may, at its convenience, terminate this Agreement in its entirety, or on a country-by-country basis, upon *** days' prior written notice to Licensor. In the event a country is terminated, the Territory shall thereafter exclude such country for all purposes under the Agreement.
- 13.3 **Termination upon Material Breach** .
- (a) **Material Breach** . If a Party breaches any of its material obligations under this Agreement, the Party not in default may give to the breaching Party a written notice specifying the nature of the default, requiring it to cure such breach, and stating its intention to terminate this Agreement if such breach is not cured within *** days. If such breach is not cured within *** days after the receipt of such notice and such breach remains uncured, the Party not in default shall be entitled to terminate this Agreement immediately by written notice to the other Party. For clarity, such material obligations may apply to the performance of either: (i) this Agreement in its entirety, in which case this provision shall apply to the entire Agreement; or (ii) a specific Product or Product(s), in which case this provision shall apply only to such affected Product or Product(s). Notwithstanding the foregoing, Licensor shall not have the right to terminate this Agreement under this Section 13.3 as a result of, or in connection with, any breach by Merck of the covenant in Section 4.1.

(b) **Sole Remedy** . In the event that Merck fails to fulfill its obligations under Section 5.4 (and (1) such failure constitutes a material breach and (2) Merck does not cure such failure as provided in Section 13.3(a)), Licensor's sole and exclusive remedy shall be to terminate this Agreement as provided in Section 13.3(a) on a Product-by-Product basis.

(c) **Material Breach Dispute** . Any dispute regarding an alleged material breach of this Agreement shall be resolved in accordance with ARTICLE 14.

13.4 **Effects of Expiration or Termination** .

(a) **Survival** .

(i) Notwithstanding the expiration or termination of this Agreement, the following provisions shall survive: ARTICLE 1 and Sections 5.7 (only in the case of expiration), 8.12, 8.13 (for the period set forth therein), 8.14, 9.3, 9.4(b) (last sentence), 9.4(d)(i), 10.1 through 10.3 (inclusive; for the period set forth in Section 10.1), 12.1 through 12.4 (inclusive), 13.4 (as applicable), 15.1, 15.3, 15.9 through 15.11 (inclusive), and 15.13 through 15.18 (inclusive).

(ii) Expiration or termination of this Agreement shall not relieve the Parties of any liability that accrued hereunder prior to the effective date of such termination. In addition, except for the termination events addressed in Section 13.3(b), termination of this Agreement shall not preclude either Party from pursuing all rights and remedies it may have hereunder or at Law or in equity with respect to any breach of this Agreement nor prejudice either Party's right to obtain performance of any obligation.

(b) **Licenses**.

(i) As of the effective date of expiration of the Royalty Term with respect to a given country, the license from Licensor to Merck under Section 4.1 shall convert to a fully paid, royalty free, irrevocable, perpetual, exclusive, and sublicensable license under the Licensor Technology to research, develop, manufacture, have manufactured, use and Commercialize Product in the Field in such country.

(ii) Upon termination of this Agreement by Merck pursuant to Section 13.2 or by Licensor pursuant to Section 13.3(a), the following terms and conditions shall apply with respect to such Product(s) and country(ies) as are the subject of such termination:

(1) all licenses granted to Merck under Section 4.1 shall terminate;

(2) Merck shall, upon written request by Licensor and subject to Licensor assuming legal responsibility for any Clinical Trials of such Product(s) then ongoing, transfer to Licensor, at *** cost and expense (except in the case of termination by *** pursuant to Section ***, at *** cost and expense), all regulatory documentation and Regulatory Approvals prepared or obtained by or on behalf of Merck prior to the date of such termination, to the extent solely related to such Product(s) and country(ies) and transferable, and Merck shall have the right to retain one copy of such transferred documentation and Regulatory Approvals for record-keeping purposes;

- (3) Subject to the provisions of Section 13.4(b)(ii) (2), Merck shall, upon written request of Licensor, return to Licensor or, at ***'s option, destroy, at ***'s cost and expense (except in the case of termination by *** pursuant to Section ***, at ***'s cost and expense), all relevant records and materials in its possession or control containing or comprising the Licensor Know-How, or such other Confidential Information of Licensor, to the extent solely related to such Product(s) and country(ies); provided, however, that Merck shall have the right to retain one copy of such Licensor Know-How and such other Confidential Information of Licensor.
- (4) Merck shall, at ***'s sole option and discretion (except in the case of termination by *** pursuant to Section ***, at ***'s sole option and discretion), (i) subject to Licensor reimbursing Merck for its costs of good thereof, destroy or retain any and all chemical, biological or physical materials relating to or comprising such Product(s), including clinical supplies of such Product(s), that are Controlled by Merck, or (ii) sell such materials (in whole or in part) to Licensor at a price equal to Merck's costs of goods (transportation and transfer costs will be Licensor's cost and expense), plus a *** percent (***) mark-up. Any clinical supplies of such Product(s) or other materials purchased by Licensor from Merck shall be purchased on an "as is" basis with no representations or warranties.
- (5) To the extent not prohibited by Law, Merck shall wind down any ongoing Clinical Trials with respect to such Product(s), or at Licensor's option, transfer such Clinical Trials to Licensor at ***'s cost and expense (except in the case of termination by *** pursuant to Section ***, at ***'s cost and expense), in which case Licensor shall purchase from Merck the relevant clinical trial supplies of the Product at Merck's costs of goods, plus a *** percent (***) mark-up.
- (6) Merck and its Affiliates and Sublicensees shall be entitled, during the *** period following such termination, to sell any commercial inventory of such Product(s) which remains on hand as of the date of the termination, so long as Merck pays to Licensor the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement. Any commercial inventory remaining following *** period shall be offered for sale to Licensor at a price equal to Merck's costs of goods, plus *** percent (**%).

(iii) Upon termination of this Agreement by Merck pursuant to Section 13.3(a), the following terms and conditions shall apply with respect to such Product(s) and country(ies) as are the subject of such termination:

- (1) all licenses granted to Merck under Section 4.1 shall terminate;
- (2) To the extent not prohibited by Law, Merck shall wind down any ongoing Clinical Trials with respect to such Product(s); and
- (3) Merck and its Affiliates and Sublicensees shall be entitled, during the *** period following such termination, to sell any commercial inventory of such Product(s) which remains on hand as of the date of the termination, so long as Merck pays to Licensor the royalties applicable to said subsequent sales in accordance with the terms and conditions set forth in this Agreement.
- (4) Upon any termination of this Agreement, at Licensor's election, either (1) each of Merck's Sublicensees shall continue to have the rights and licenses set forth in its respective sublicense agreement, which agreements shall be automatically assigned to Licensor, or (2) each of Merck's Sublicensees shall be offered a right of first negotiation, on commercially reasonable terms and for a commercially reasonable period of time, with respect to the rights and licenses set forth in this Agreement that pertain to the respective sublicense agreement for which such Sublicensee is a party; provided, however, that such Sublicensee is not then in breach of any of its respective material obligations under its sublicense agreement.
- (5) Immediately following Merck's notification of termination to Licensor pursuant to Sections 13.2 or 13.3(a), the diligence obligations in Section 5.5 shall no longer apply and Merck shall have the right to wind-down all then on-going Development, manufacturing and/or Commercialization activities.

13.5 Termination on Bankruptcy or Insolvency; Right of First Negotiation .

- (a) **Bankruptcy Code** . All rights and licenses granted under or pursuant to this Agreement by Licensor are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, if applicable, licenses of right to "intellectual property" as defined under Section 101 of the U.S. Bankruptcy Code.
- (b) **Continuing Rights** . The Parties agree that Merck, as licensor of such rights under this Agreement, shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code. The Parties further agree that, in the event of Licensor Bankruptcy Event, Merck shall be entitled to a complete duplicate of (or complete access to, as appropriate) any such intellectual property and all embodiments of such intellectual property, which, if not already in Merck's possession, shall be promptly delivered to it (a) following any such commencement of a bankruptcy proceeding upon Merck's written request therefor, unless Licensor elects to continue to perform all of its obligations under this Agreement or (b) if not delivered under clause (a), following the rejection of this Agreement by Licensor upon written request therefor by Merck.

(c) **Right of First Refusal** . In addition to the foregoing, in the event of a Licensor Bankruptcy Event, Merck shall, to the extent allowed by Law, have a right of first refusal to purchase all of Licensor's interest in the Product and the Licensor Technology (the "**Right of First Refusal** "). The Right of First Refusal shall operate as follows:

(i) Licensor (or other authorized representative of Licensor, including a bankruptcy trustee) shall promptly send to Merck a reasonably detailed written notification of any Licensor Bankruptcy Event.

(ii) Licensor (or other authorized representative of Licensor, including a bankruptcy trustee) shall promptly send to Merck a written notification of any Third Party offer made on the Product or Licensor Technology. For a period of up to *** days after Merck receives such notice (such period, the "**Right of First Refusal Notice Period** "), it shall notify Licensor of its intention to exercise its Rights of First Refusal. In the event Merck exercises its Right of First Refusal, the terms of the Third Party offer shall become binding upon Merck and Licensor. For the avoidance of doubt, Licensor shall not enter into any agreement with a Third Party relating to Licensor's interest in the Products or Licensor Technology during the Right of First Refusal Notice Period.

13.6 **Other Remedies** . Termination of this Agreement for any reason shall not release either Party from any liability or obligation that already has accrued prior to such termination. Termination of this Agreement for any reason shall not constitute a waiver or release of, or otherwise be deemed to prejudice or adversely affect or limit, any rights or remedies that otherwise may be available at Law or in equity.

ARTICLE 14 DISPUTE RESOLUTION

14.1 **Disputes** . The Parties recognize that disputes as to certain matters may from time to time arise during the Term which relate to either Party's rights and/or obligations hereunder. It is the objective of the Parties to establish under this ARTICLE 14 procedures to facilitate the resolution of disputes arising under this Agreement in an expedient manner by mutual cooperation and, subject to Section 14.3, unless the dispute resolution provisions provided herein are unsuccessful, without resort to litigation. All disputes shall be referred to the JSC for discussion and resolution; provided, however, that any JSC Discussion Dispute not resolved at the JSC shall be resolved pursuant to Section 14.2.

14.2 **JSC Discussion Disputes** . Either Party may, by written notice to the other Party, request that a JSC Discussion Dispute that remains unresolved by the JSC for a period of ***) days be resolved by the Executive Officers, within *** days after referral of such dispute to them . If the Executive Officers cannot resolve such dispute within *** days after referral of such dispute to them, then, at any time after such *** day period, either Party may proceed to enforce any and all of its rights with respect to such dispute.

- 14.3 **Injunctive Relief** . Subject to Section 13.3(b), no provision herein shall be construed as precluding a Party from bringing an action for injunctive relief or other equitable relief prior to the initiation or completion of the above procedure.

ARTICLE 15 MISCELLANEOUS PROVISIONS

- 15.1 **Relationship of the Parties** . Nothing in this Agreement is intended or shall be deemed, for financial, tax, legal or other purposes, to constitute a partnership, agency, joint venture or employer-employee relationship between the Parties.

15.2 **Assignment** .

(a) **Assignment Generally** . Except as expressly provided herein, neither this Agreement nor any interest hereunder shall be assignable, nor any other obligation delegable, by Licensor without the prior written consent of Merck (not to be unreasonably withheld or delayed), except that no consent of Merck shall be required with respect to a Change of Control of Licensor or the sale to a Third Party of substantially all of the assets of Licensor to which this Agreement relates.

(b) **Assignment by Merck** . Merck may assign this Agreement, in whole or in part, to any Affiliate or Third Party without the consent of Licensor. Merck shall give written notice to Licensor promptly following any such assignment.

(c) **Continuing Obligations** . No assignment under this Section 15.2 shall relieve the assigning Party of any of its responsibilities or obligations hereunder and, as a condition of such assignment, the assignee shall agree in writing to be bound by all obligations of the assigning Party hereunder. This Agreement shall be binding upon the successors and permitted assigns of the Parties.

(d) **Void Assignments** . Any assignment not in accordance with this Section 15.2 shall be void.

(e) **Assignment of Licensor Technology** . Licensor shall not assign or transfer any Licensor Technology to any of its Affiliates without the prior written consent of Merck.

(f) **Exclusion of Certain Affiliates** . The rights to Know-How and Patent Rights***

- 15.3 **Performance and Exercise by Affiliates** . Merck shall have the right to have any of its obligations hereunder performed, or its rights hereunder exercised, by, any of its Affiliates and the performance of such obligations by any such Affiliate(s) shall be deemed to be performance by Merck; provided, however, that Merck shall be responsible for ensuring the performance of its obligations under this Agreement and that any failure of any Affiliate performing obligations of Merck hereunder shall be deemed to be a failure by Merck to perform such obligations. For clarity, the foregoing means that Merck may designate an Affiliate to perform its obligations hereunder or to be the recipient of Licensor's performance obligations hereunder (e.g., with respect to Manufacturing Technology Transfer, Merck may designate an Affiliate to be the recipient of such transfer).

- 15.4 **Change of Control** . In the event of a Change of Control of Licensor in which a Merck Competitor acquires control (as defined in Section 1.3) of Licensor, then, from the later of (a) the date of any public announcement by Opexa of an agreement by Opexa to enter into a Change of Control transaction and (b) the Option Exercise Date:
- (i) Merck shall, subject to compliance with any legally required safety reporting requirements of applicable Governmental Bodies, cease to have any reporting or information or data sharing obligations hereunder toward Licensor or its successor entity (other than under Articles 8-10, 12-15) including, but not limited to, the obligations of Merck under Sections 4.4(a) and 5.8;
 - (ii) the JSC shall be permanently disbanded;
 - (iii) notwithstanding the provisions of Section 7.1, the determination whether or to what extent the Parties shall enter into (or, if then already entered into, continue to bound by) the Supply Agreement shall be in Merck's sole discretion. If the Parties have already entered in to the Supply Agreement prior to the occurrence of the announcement of the potential Change of Control transaction, Merck may, upon *** days' prior written notice to Licensor, terminate the Supply Agreement. If Merck notifies Licensor that it does not wish to enter into the Supply Agreement or provides notice of termination of the Supply Agreement, then, as between Licensor and Merck, Merck shall during the Term have the sole right to manufacture the Product for use in the Field in the Territory following the Option Exercise Date; and
 - (iv) With respect to Licensor Patents that are *** related to Product, Merck shall have the first right to perform the activities delegated to Licensor in Section *** and *** Section ***, with Section *** and *** Section *** thereafter applying mutatis mutandis (i.e., references in parts of Section *** to "Licensor" shall be deemed references to "Merck" and references to "Merck" shall be deemed references to "Licensor").
- 15.5 **Further Actions** . Each Party agrees to execute, acknowledge and deliver such further instruments and to do all such other acts as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 15.6 **Accounting Procedures** . Each Party shall calculate all amounts, and perform other accounting procedures required, under this Agreement and applicable to it in accordance with IFRS.

- 15.7 **Force Majeure** . Neither Party shall be liable to the other Party or be deemed to have breached or defaulted under this Agreement for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by or results from acts of God, earthquake, riot, civil commotion, terrorism, war, strikes or other labor disputes, fire, flood, failure or delay of transportation, omissions or delays in acting by a governmental authority, acts of a government or an agency thereof or judicial orders or decrees or restrictions or any other reason which is beyond the control of the respective Party. The Party affected by force majeure shall provide the other Party with full particulars thereof as soon as it becomes aware of the same (including its best estimate of the likely extent and duration of the interference with its activities), and will use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations hereunder as soon as practicable.
- 15.8 **No Trademark Rights** . Except as set forth in Sections 4.1 and 5.7, no right, express or implied, is granted by this Agreement to a Party to use in any manner the name or any other trade name or trademark of the other Party in connection with the performance of this Agreement or otherwise.
- 15.9 **Entire Agreement of the Parties; Amendments** . This Agreement and the Schedules hereto, together with the CDA, constitute and contain the entire understanding and agreement of the Parties respecting the subject matter hereof and cancel and supersede any and all prior negotiations, correspondence, understandings and agreements between the Parties, whether oral or written, regarding such subject matter. No waiver, modification or amendment of any provision of this Agreement shall be valid or effective unless made in a writing referencing this Agreement and signed by a duly authorized officer of each Party.
- 15.10 **Captions** . The captions to this Agreement are for convenience only, and are to be of no force or effect in construing or interpreting any of the provisions of this Agreement.
- 15.11 **Governing Law** . This Agreement shall be governed by and interpreted in accordance with the laws of England, excluding application of any conflict of laws principles that would require application of the Law of a jurisdiction outside of England, and will be subject to the exclusive jurisdiction of the courts of competent jurisdiction located in London, England.
- 15.12 **Non-Solicitation of Employees** . During the Term, each Party agrees that it shall not, directly or indirectly, for itself or any other party, urge, induce, or in any manner whatsoever solicit any employee of the other Party without the prior written consent of the other Party. This provision shall not be construed to prohibit the advertisement of employment opportunities or job openings so long as such advertisements are not customized for, directed at or targeted at specific employees of the other Party.
- 15.13 **Notices and Deliveries** . Any notice, request, approval or consent required or permitted to be given under this Agreement shall be in writing and shall be deemed to have been sufficiently given if delivered in person, transmitted by facsimile (receipt verified) or by express courier service (signature required) to the Party to which it is directed at its address or facsimile number shown below or such other address or facsimile number as such Party shall have last given by notice to the other Party.

If to Merck, addressed to:

Ares Trading SA
Zone industrielle de l'Ouriettaz
1170 Aubonne, Switzerland
Attn: General Manager
Facsimile:

With a copy to:

Merck KGaA
Frankfurter Strasse 250
64293 Darmstadt
Germany
Attn: General Counsel
Facsimile: ***

With a further copy to:

Morgan, Lewis & Bockius LLP
502 Carnegie Center
Princeton, New Jersey, USA 08540
USA
Attn: Randall B. Sunberg

If to Licensor, addressed to:

Opexa Therapeutics, Inc.
2635 Technology Forest Boulevard
The Woodlands, TX 77381
USA
Attn: Chief Executive Officer
Facsimile:

With a copy to:

Pillsbury Winthrop Shaw Pittman, LLP
12255 El Camino Real, Suite 300
San Diego, CA 92130
USA
Attn: Mike Hird

- 15.14 **Waiver** . A waiver by either Party of any of the terms and conditions of this Agreement in any instance shall not be deemed or construed to be a waiver of such term or condition for the future, or of any other term or condition hereof. All rights, remedies, undertakings, obligations and agreements contained in this Agreement shall be cumulative and none of them shall be in limitation of any other remedy, right, undertaking, obligation or agreement of either Party.

- 15.15 **Severability** . When possible, each provision of this Agreement will be interpreted in such manner as to be effective and valid under Law, but if any provision of this Agreement is held to be prohibited by or invalid under Law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. The Parties shall make a good faith effort to replace the invalid or unenforceable provision with a valid one which in its economic effect is most consistent with the invalid or unenforceable provision.
- 15.16 **No Implied License** . No right or license is granted to Licensor hereunder by implication, estoppel, or otherwise to any know-how, patent or other intellectual property right owned or controlled by Merck or its Affiliates.
- 15.17 **Interpretation** . The words “include,” “includes” and “including” shall be deemed to be followed by the phrase “without limitation.” All references herein to ARTICLES, Sections, and Schedules shall be deemed references to ARTICLES and Sections of, and Schedules to, this Agreement unless the context shall otherwise require. Except as otherwise expressly provided herein, all terms of an accounting or financial nature shall be construed in accordance with IFRS, as in effect from time to time. Unless the context otherwise requires, countries shall include territories.
- 15.18 **Counterparts** . This Agreement may be executed in counterparts, each of which will be deemed an original, and all of which together will be deemed to be one and the same instrument. A facsimile or a portable document format (PDF) copy of this Agreement, including the signature pages, will be deemed an original.

[SIGNATURE PAGE FOLLOWS]

IN WITNESS WHEREOF , the Parties have caused this Agreement to be executed and delivered by their respective duly authorized officers as of the Effective Date.

OPEXA THERAPEUTICS, INC.

ARES TRADING SA

By: /s/ Neil K. Warma
Name: Neil K. Warma
Title: President & CEO

By: /s/ Cedric Hyde
Name: Cedric Hyde
Title: Authorized Representative

By: /s/ James B. Singleton
Name: James B. Singleton
Title: Authorized Representative

SIGNATURE PAGE TO OPTION AND LICENSE AGREEMENT

*** Confidential material redacted and filed separately with the Commission.

SCHEDULE 1.25

*** Confidential material redacted and filed separately with the Commission.

SCHEDULE 1.40
Licensors Patents

SCHEDULE 1.42

Licensor Trademarks

Tcelna™

Schedule 10.5(a)
Joint Public Announcement



OPEXA THERAPEUTICS

Company Contact:

Opexa Therapeutics, Inc.
Neil K. Warma
281.775.0600
nwarma@opexatherapeutics.com

Vida Strategic Partners
Tim Brons
415-675-7400
tbrons@vidasp.com

DRAFT – NOT FOR RELEASE – DRAFT – NOT FOR RELEASE

Merck Serono and Opexa Therapeutics Enter into Option and License Agreement for Development of Tcelna™ (imilecleucel-T) for Treatment of Multiple Sclerosis

Merck Serono granted option for exclusive license from Opexa to develop and commercialize Tcelna (imilecleucel-T), an investigational T-cell therapy for patients suffering from multiple sclerosis (MS)

THE WOODLANDS, TEXAS - February 2, 2013 – Opexa Therapeutics, Inc. (NASDAQ:OPXA) today announced the execution of an agreement with Merck Serono, a division of Merck, Darmstadt, Germany, for the development and commercialization of Tcelna™ (imilecleucel-T), a potential first-in-class personalized T-cell therapy for patients suffering from multiple sclerosis (MS). Tcelna (imilecleucel-T) is being developed by Opexa and currently is in a Phase IIb clinical trial in patients with Secondary Progressive MS (SPMS). Potential payments to Opexa from the option and license agreement could total \$225 million based upon the successful development and commercialization of Tcelna for MS.

Tcelna (imilecleucel-T) is being developed as a personalized therapy specifically tailored to each patient's individual disease profile and has been evaluated in Phase I and II clinical studies in MS that included SPMS patients. Tcelna (imilecleucel-T) has received Fast Track Designation from the United States Food and Drug Administration as a potential treatment for SPMS.

Under the terms of the agreement, Opexa will receive an upfront payment of \$5 million for granting an option to Merck Serono for the exclusive license of the Tcelna (imilecleucel-T) program for the treatment of MS. The option may be exercised prior to or upon completion of Opexa's ongoing Phase IIb clinical trial in patients with SPMS. Upon exercising this licensing option, Merck Serono would pay an upfront license fee of either \$25 million or \$15 million (depending upon whether certain conditions are met), and in return receive worldwide development and commercial rights to Tcelna (imilecleucel-T) in MS, excluding Japan. After exercising the option Merck Serono would be wholly responsible for funding clinical development, subject to Opexa's co-funding option, as well as regulatory and commercialization activities for the MS program. Additional financial considerations of the agreement include development and commercial milestone payments to Opexa of up to \$195 million and a tiered royalty rate from the high single digits to the mid-teens based on net sales payable to Opexa. The potential payments to Opexa could, therefore, total \$225 million excluding royalty payments.

Under the agreement, Opexa will have an option right to co-fund development, under which the Company would participate in economic support for future clinical development of the program in exchange for additional royalty consideration. In addition to retaining all rights outside of MS as well as retaining the ability to commercialize Tcelna (imilecleucel-T) in Japan, Opexa also retains certain manufacturing rights related to the program. Further details of the transaction are included in a Form 8-K that was filed this morning by Opexa with the United States Securities and Exchange Commission.

“Merck Serono is strongly committed to developing innovative drug candidates like Tcelna (imilecleucel-T), a potential first-in-class personalized cell therapy for patients with multiple sclerosis,” said Susan Herbert, Head of Global Business Development and Strategy at Merck Serono. “This agreement illustrates Merck Serono’s commitment to employ creative ways of accessing external innovation to develop potential next generation multiple sclerosis treatments, especially in secondary progressive multiple sclerosis, an area of high unmet need.”

Neil K. Warma, President and Chief Executive Officer of Opexa, commented, “Opexa is pleased to partner with Merck Serono and given Merck Serono’s long-term strategic commitment to, and existing franchise position in the field of multiple sclerosis, we could not ask for a more experienced partner to carry Tcelna (imilecleucel-T) through development and hopefully to the market and to patients. We also are pleased to retain important rights through this transaction, such as certain manufacturing rights, commercialization rights to the Japanese market and a co-funding of development option, as well as rights for all indications outside of MS, all of which are intended to enhance Opexa shareholder value.”

Conference Call

The management of Opexa will host a conference call today, _____, February __, 2013, at X:XX a.m. EST to discuss the agreement. To participate in the live conference call, please dial (XXX) XXX-XXXX (U.S.) or (XXX) XXX-XXXX (International), and provide passcode XXXXXXXX. A live webcast of the call will also be available on the investor relations section of the Company's website, www.opexatherapeutics.com. A replay of the call will be available through XXXXXXXXXXXX XX, 2013. To access the replay, please dial (XXX) XXX-XXXX (U.S.) or (XXX) XXX-XXXX (International), and provide passcode XXXXXXXX. An online archive of the webcast will be available on Opexa’s website for XX days following the call.

About Multiple Sclerosis (MS)

MS is a chronic, inflammatory condition of the central nervous system and is the most common, non-traumatic, disabling neurological disease in young adults. It is estimated that approximately two million people have MS worldwide.

While symptoms can vary, the most common symptoms of MS include blurred vision, numbness or tingling in the limbs and problems with strength and coordination. The relapsing forms of MS are the most common.

About Tcelna

Tcelna is a potential personalized therapy that is under development to be specifically tailored to each patient's disease profile. Tcelna is manufactured using ImmPath™, Opexa's proprietary method for the production of a patient-specific T-cell immunotherapy, which encompasses the collection of blood from the MS patient, isolation of peripheral blood mononuclear cells, generation of an autologous pool of myelin-reactive T-cells (MRTCs) raised against selected peptides from myelin basic protein (MBP), myelin oligodendrocyte glycoprotein (MOG) and proteolipid protein (PLP), and the return of these expanded, irradiated T-cells back to the patient. These attenuated T-cells are reintroduced into the patient via subcutaneous injection to trigger a therapeutic immune system response.

Opexa is currently conducting a Phase IIb study of Tcelna. Named Abili-T, the trial is a randomized, double-blind, placebo-controlled clinical study in patients who demonstrate evidence of disease progression without associated relapses. The trial is expected to enroll 180 patients at approximately 30 leading clinical sites in the U.S. and Canada with each patient receiving two annual courses of Tcelna treatment consisting of five subcutaneous injections per year. The trial’s primary efficacy outcome is the percentage of brain volume change (atrophy) at 24 months. Study investigators will also measure several important secondary outcomes commonly associated with MS, including disease progression as measured by the Expanded Disability Status Scale (EDSS), annualized relapse rate and changes in disability as measured by EDSS and the MS Functional Composite.

About Opexa

Opexa Therapeutics, Inc. (NASDAQ:OPXA) is dedicated to the development of patient-specific cellular therapies for the treatment of autoimmune diseases such as MS. The Company's leading therapy candidate, Tcelna™, is a personalized cellular immunotherapy that is in phase IIb clinical development for MS. Tcelna 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.

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

About Merck Serono

Merck Serono is the biopharmaceutical division of Merck.. With headquarters in Darmstadt, Germany, Merck Serono offers leading brands in 150 countries to help patients with cancer, multiple sclerosis, infertility, endocrine and metabolic disorders as well as cardiovascular diseases . In the United States and Canada, EMD Serono operates as a separately incorporated subsidiary of Merck Serono.

Merck Serono discovers, develops, manufactures and markets prescription medicines of both chemical and biological origin in specialist indications. We have an enduring commitment to deliver novel therapies in our core focus areas of oncology, neurology and immunology.

For more information, please visit www.merckserono.com or www.merckgroup.com

About Merck

Merck is a global pharmaceutical and chemical company with total revenues of €10.3 billion in 2011, a history that began in 1668, and a future shaped by approx. 40,000 employees in 67 countries. Its success is characterized by innovations from entrepreneurial employees. Merck's operating activities come under the umbrella of Merck KGaA, in which the Merck family holds an approximately 70% interest and free shareholders own the remaining approximately 30%. In 1917 the U.S. subsidiary Merck & Co. was expropriated and has been an independent company ever since.

For more information, please visit www.merckserono.com or www.merckgroup.com

Cautionary Statement Relating to Forward-Looking Information for the Purpose of "Safe Harbor" Provisions of the Private Securities Litigation Reform Act of 1995

This press release contains forward-looking statements which are made pursuant to the safe harbor provisions of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. The words "expects," "believes," "may," "could," and similar expressions are intended to identify forward-looking statements. The forward-looking statements in this release do not constitute guarantees of future performance. Investors are cautioned that statements in this press release which are not strictly historical statements, including, without limitation, statements regarding the development of the Company's product candidate, Tcelna (imilecleucel-T) , constitute forward-looking statements. Such forward-looking statements are subject to a number of risks and uncertainties that could cause actual results to differ materially from those anticipated, including, without limitation, risks associated with: the success of our clinical trials (including the phase 2b trial for Tcelna (imilecleucel-T) in SPMS which, depending upon results, may determine whether Merck Serono elects to exercise its option pursuant to the option and development agreement), whether Merck Serono exercises its option and, if so, whether the Company receives any development or commercialization milestone payments or royalties from Merck Serono pursuant to the option and development agreement, our dependence (if Merck Serono exercises its option) on the resources and abilities of Merck Serono for the further development of Tcelna (imilecleucel-T) , our ability to raise additional capital to continue our development programs (including to undertake and complete any ongoing or further clinical studies for Tcelna (imilecleucel-T)), the efficacy of Tcelna (imilecleucel-T) for any particular indication, such as for relapsing remitting MS or secondary progressive MS, our compliance with all Food and Drug Administration regulations, our ability to obtain, maintain and protect intellectual property rights (including for Tcelna), and other risks detailed in our filings with the Securities and Exchange Commission. These forward-looking statements speak only as of the date made. We assume no obligation or undertaking to update any forward-looking statements to reflect any changes in expectations with regard thereto or any change in events, conditions or circumstances on which any such statement is based. You should, however, review additional disclosures we make in our reports filed with the Securities and Exchange Commission, including our Annual Report on Form 10-K for the year ended December 31, 2011 and our Quarterly Report on Form 10-Q for the quarter ended September 30, 2012.

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Schedule 11.2

Disclosure Schedule

Merck Serono and Opexa Therapeutics Enter into Option and License Agreement for Development of Tcelna[™] (imilecleucel-T) for Treatment of Multiple Sclerosis

Merck Serono granted option for exclusive license from Opexa to develop and commercialize Tcelna (imilecleucel-T), an investigational T-cell therapy for patients suffering from multiple sclerosis (MS)

THE WOODLANDS, Texas--(BUSINESS WIRE)--February 1, 2013--Opexa Therapeutics, Inc. (NASDAQ: OPXA) today announced the execution of an agreement with Merck Serono, a division of Merck, Darmstadt, Germany, for the development and commercialization of Tcelna[™] (imilecleucel-T), a potential first-in-class personalized T-cell therapy for patients suffering from multiple sclerosis (MS). Tcelna (imilecleucel-T) is being developed by Opexa and currently is in a Phase IIb clinical trial in patients with Secondary Progressive MS (SPMS). Potential payments to Opexa from the option and license agreement could total \$225 million based upon the successful development and commercialization of Tcelna for MS.

Tcelna (imilecleucel-T) is being developed as a personalized therapy specifically tailored to each patient's individual disease profile and has been evaluated in Phase I and II clinical studies in MS that included SPMS patients. Tcelna (imilecleucel-T) has received Fast Track Designation from the United States Food and Drug Administration as a potential treatment for SPMS.

Under the terms of the agreement, Opexa will receive an upfront payment of \$5 million for granting an option to Merck Serono for the exclusive license of the Tcelna (imilecleucel-T) program for the treatment of MS. The option may be exercised prior to or upon completion of Opexa's ongoing Phase IIb clinical trial in patients with SPMS. Upon exercising this licensing option, Merck Serono would pay an upfront license fee of either \$25 million or \$15 million (depending upon whether certain conditions are met), and in return receive worldwide development and commercial rights to Tcelna (imilecleucel-T) in MS, excluding Japan. After exercising the option Merck Serono would be wholly responsible for funding clinical development, subject to Opexa's co-funding option, as well as regulatory and commercialization activities for the MS program. Additional financial considerations of the agreement include development and commercial milestone payments to Opexa of up to \$195 million and a tiered royalty rate from the high single digits to the mid-teens based on net sales payable to Opexa. The potential payments to Opexa could, therefore, total \$225 million excluding royalty payments.

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“Merck Serono is strongly committed to developing innovative drug candidates like Tcelna (imilecleucel-T), a potential first-in-class personalized cell therapy for patients with multiple sclerosis,” said Susan Herbert, Head of Global Business Development and Strategy at Merck Serono. “This agreement illustrates Merck Serono’s commitment to employ creative ways of accessing external innovation to develop potential next generation multiple sclerosis treatments, especially in secondary progressive multiple sclerosis, an area of high unmet need.”

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Conference Call

The management of Opexa will host a conference call today, Tuesday, February 5, 2013, at 8:30 a.m. EST to discuss the agreement. To participate in the live conference call, please dial (877) 372-0867 (U.S.) or (253) 237-1170 (International). A live webcast of the call will also be available on the investor relations section of the Company's website, www.opexatherapeutics.com. An online archive of the webcast will be available on Opexa’s website for one year following the call.

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