Registration No. 333-

UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

Confidential Draft Submission No. 2

FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Minerva Neurosciences, Inc.

(Exact name of registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

2834

(Primary Standard Industrial Classification Code Number)

26-0784194

(I.R.S. Employer Identification Number)

245 First Street Suite 1800 Cambridge, MA 02142 (617) 444-8444

(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Rogerio Vivaldi Coelho Chief Executive Officer 245 First Street Suite 1800 Cambridge, MA 02142 (617) 444-8444

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

David W. Pollak Denis Segota Morgan Lewis & Bockius LLP 101 Park Avenue New York, NY 10178 (212) 309-6000 Nicole Brookshire
Darren K. DeStefano
Charles S. Kim
Cooley LLP
500 Boylston Street, 14th Floor
Boston, MA 02116
(617) 937-2300

Approximate date of commencement of proposed sale to the public: As soon as practicable after the effective date of this Registration Statement.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

CALCULATION OF REGISTRATION FEE

Proposed Maximum				
Title of Each Class of Securities to be Registered	Aggregate Offering Price ⁽¹⁾	Amount of Registration Fee ⁽²⁾		
Common Stock, \$0.0001 par value per share	\$	\$		

⁽¹⁾ Estimated solely for the purpose of calculating the registration fee pursuant to Rule 457(o) under the Securities Act of 1933. Includes the offering price of any additional shares that the underwriters have the option to purchase.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

⁽²⁾ Calculated pursuant to Rule 457(o) based on an estimate of the proposed maximum aggregate offering price.

EXPLANATORY NOTE

This Confidential Draft Submission No.2 (Submission No.2) to the Registration Statement on Form S-1 of Minerva Neurosciences, Inc. (Registration Statement) is being submitted solely for the purpose of submitting certain exhibits indicated in Part II of this Submission No.2. This Submission No. 2 does not modify any provision of the prospectus that forms a part of the Registration Statement. Accordingly, a preliminary prospectus has been omitted.

PART II INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by the Registrant in connection with the sale and distribution of the common stock being registered. All amounts are estimates except for the SEC registration fee, the FINRA filing fee, and the NASDAQ Global Market listing fee.

SEC registration fee	\$ *
FINRA filing fee	*
NASDAQ Global Select Market listing fee	*
Legal fees and expenses	*
Accounting fees and expenses	*
Printing and engraving expenses	*
Transfer agent and registrar fees and expenses	*
Blue sky fees and expenses	*
Miscellaneous fees and expenses	*
Total	\$ *

^{*} To be filed by amendment.

em 14. Indemnification of Directors and Officers

The Registrant is incorporated under the laws of the State of Delaware. Section 145 of the Delaware General Corporation Law (referred to as the "DGCL") authorizes a court to award, or a corporation's board of directors to grant, indemnity to directors and officers in terms sufficiently broad to permit such indemnification under certain circumstances for liabilities, including reimbursement for expenses incurred, arising under the Securities Act of 1933, as amended.

The certificate of incorporation of the Registrant that will be in effect at the closing of this offering provides for indemnification of the Registrant's directors, officers, team members, and other agents to the maximum extent permitted by the DGCL, and the bylaws that will be in effect at the closing of this offering provide for indemnification of the directors, officers, team members, and other agents to the maximum extent permitted by the DGCL.

In addition, the Registrant has entered into indemnification agreements with its directors and officers containing provisions which are in some respects broader than the specific indemnification provisions contained in the DGCL. The indemnification agreements require the Registrant, among other things, to indemnify its directors against certain liabilities that may arise by reason of their status or service as directors and to advance their expenses incurred as a result of any proceeding against them as to which they could be indemnified.

The Registrant maintains insurance policies that indemnify its directors and officers against various liabilities arising under the Securities Act of 1933, as amended, and the Securities Exchange Act of 1934, and amended, that might be incurred by any director or officer in his capacity as such.

The underwriters are obligated, under certain circumstances, pursuant to the underwriting agreement to be filed as Exhibit 1.1 hereto, to indemnify the Registrant, its officers, and directors against liabilities under the Securities Act of 1933, as amended.

Item 15. Recent Sales of Unregistered Securities

Since January 1, 2011, we issued the following unregistered securities:

Common Stock Issuances

Since January 1, 2011, we sold an aggregate of 3,150,000 shares of common stock to six accredited investors at a purchase price of \$1.00 per share for total proceeds of \$3,150,000.

In February and April 2012, we issued in exchange for services an aggregate of 368,590 shares of common stock to one of our consultants for an aggregate purchase price at par value for total proceeds of \$36.85.

In April 2012, we issued 2,875,000 shares of common stock to an accredited investor in exchange for a note payable of approximately \$3.1 million (or approximately \$1.06 per share). In December 2013, we issued 97,737 shares of common stock to the same investor in exchange for a note payable of \$97,737 (or approximately \$1.00 per share).

In December 2013, we issued in exchange for services 85,806 shares of common stock to one of our consultants for an aggregate purchase price at par value for total proceeds of \$8.58.

Option Issuances

Since January 1, 2011, we granted to our directors, officers and a consultant options to purchase an aggregate of 2,263,661 shares of our common stock under our equity compensation plans at an exercise price of \$2.71 per share.

Convertible Debt

During November 2013, we issued convertible promissory notes with a stated interest rate of 8% per annum for approximately \$1.3 million in aggregate to six accredited investors.

Warrants

During 2011 and 2012, we issued warrants to purchase 175,000 shares of our common stock to an accredited investor at an exercise price of \$1.06 per share.

Shares Issued in Connection with Acquisitions

Since January 1, 2011, we issued an aggregate of 13,667,316 shares of our common stock in connection with our acquisitions of certain companies or their assets.

None of the foregoing transactions involved any underwriters, underwriting discounts or commissions, or any public offering. We believe the offers, sales and issuances of the above securities were exempt from registration under the Securities Act by virtue of Section 4(2) or Regulation S of the Securities Act because the issuance of securities to the recipients did not involve a public offering, or in reliance on Rule 701 because the transactions were pursuant to compensatory benefit plans or contracts relating to compensation as provided under such rule. The recipients of the securities in each of these transactions represented their intentions to acquire the securities for investment only and not with a view to or for sale in connection with any distribution thereof, and appropriate legends were placed upon the stock certificates issued in these transactions. All recipients had adequate access, through their relationships with us, to information about us. The sales of these securities were made without any general solicitation or advertising.

Item 16. Exhibits and Financial Statement Schedules

(a) Exhibits

Exhibit No. Description of Exhibit

1.1* Form of Underwriting Agreement

3.1* Form of Amended and Restated Certificate of Incorporation of the Registrant to be in effect upon the closing of this offering

- 10.7[#] Co-Development and License Agreement between Janssen Pharmaceutica, N.V. and the Registrant, dated as of February 12, 2014
- 10.8^{†^} Employment Agreement between Rogerio Vivaldi Coelho and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of October 4, 2013, and amendment thereto dated as of December 30, 2013
- 10.9^{†^} Employment Agreement between Joseph Reilly and the Registrant, dated as of December 23, 2013
- 10.10^{†^} Letter Agreement between Marc D. Beer and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of October 16, 2013

Exhibit No. 21.1^	Description of Exhibit List of subsidiaries
21.1	LIST OF SUBSIDIATIES
23.1*	Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1)
23.2*	Consent of Deloitte & Touche LLP, independent registered public accounting firm
23.3*	Consent of Deloitte & Touche LLP, independent auditors
23.4*	Consent of PricewaterhouseCoopers SA, independent auditors
24.1*	Power of Attorney
A Durantes	

- Previously filed
- * To be filed by amendment
- # Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit is being submitted separately to the SEC.
- † Indicates a management contract or compensatory plan

(b) Financial Statement Schedules

Schedules have been omitted because the information required to be set forth therein is not applicable or is included in the financial statements or related notes.

Item 17. Undertakings

The undersigned Registrant hereby undertakes to provide to the underwriters at the closing specified in the underwriting agreement, certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

The undersigned Registrant hereby undertakes that:

- (1) For purposes of determining any liability under the Securities Act, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.
- (2) For the purpose of determining any liability under the Securities Act, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of Boston, State of Massachusetts, on , 2014.

Ву:	
	Rogerio Vivaldi Coelho President. Chief Executive Officer and Director

MINERVA NEUROSCIENCES, INC.

POWER OF ATTORNEY

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Rogerio Vivaldi and Geoff Race, and each one of them, as his true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him and in his name, place, and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this registration statement, and to sign any registration statement for the same offering covered by this registration statement that is to be effective upon filing pursuant to Rule 462(b) under the Securities Act, and all post-effective amendments thereto, and to file the same, with all exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents or any of them, or his or their substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	<u>Title</u>	Date
Rogerio Vivaldi Coelho	President, Chief Executive Officer and Director (Principal Executive Officer)	, 2014
Geoff Race	Chief Financial Officer - (Principal Financial and Accounting Officer)	, 2014
	Director	, 2014
Marc Beer	-	
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<u>Signature</u>	<u>Title</u>	Date
Francesco de Rubertis	Director	, 2014
Michèle Ollier	Director	, 2014
Lorenzo Pellegrini	Director	, 2014
Robert Seltzer	Director	, 2014
Robert Sellzei	II-6	

	EXHIBIT INDEX
Exhibit No.	Description of Exhibit
1.1*	Form of Underwriting Agreement
3.1*	Form of Amended and Restated Certificate of Incorporation of the Registrant to be in effect upon the closing of this offering
3.2 [*]	Form of Bylaws of the Registrant to be in effect upon the closing of this offering
3.3^	Amended and Restated Certificate of Incorporation of the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc. currently in effect
3.4^	Certificate of Merger Merging Sonkei Pharmaceuticals, Inc. with and into Cyrenaic Pharmaceuticals, Inc., dated as of November 12, 2013
3.5^	Bylaws of the Registrant (f/k/a Cyrenaic Pharmaceuticals, Inc.) currently in effect
4.1*	Form of Common Stock Certificate
4.2^	Investor Rights Agreement among the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc. and certain of its security holders, dated as of August 29, 2007
4.3^	Amendment No. 1 to Investor Rights Agreement among the Registrant and certain of its security holders, dated as of December 20, 2013
4.4^	Promissory Note between Wint2felden Holding SA and the Registrant as successor in interest to Sonke Pharmaceuticals, Inc., dated as of March 30, 2012
4.5^	Promissory Note between Wint2felden Holding SA and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of April 26, 2012
4.6^	Promissory Note between Wint2felden Holding SA and the Registrant, dated as of December 20, 2013
5.1*	Opinion of Morgan, Lewis & Bockius LLP
10.1*	Form of the Indemnification Agreement between the Registrant and each of its directors and executive officers
10.2#	License Agreement between Mitsubishi Pharma Corporation and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of August 30, 2007
10.3#	Amendment to License Agreement between Mitsubishi Pharma Corporation and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of June 16, 2011
10.4#	Second Amendment to License Agreement between Mitsubishi Pharma Corporation and the Registrant, dated as of January 20, 2014
10.5#	License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant as successor in interest to Sonkei Pharmaceuticals, Inc., dated as of September 1, 2008
10.6 [#]	Amendment to License Agreement between Mitsubishi Tanabe Pharma Corporation and the Registrant, dated as of January 20, 2014
10.7#	Co-Development and License Agreement between Janssen Pharmaceutica, N.V. and the Registrant, dated as of February 12, 2014
10.8†^	Employment Agreement between Rogerio Vivaldi Coelho and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of October 4, 2013, and amendment thereto dated as of December 30, 2013

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- $10.10^{\uparrow \land}$ Letter Agreement between Marc D. Beer and the Registrant f/k/a Cyrenaic Pharmaceuticals, Inc., dated as of October 16, 2013
 - 21.1[^] List of subsidiaries
 - 23.1* Consent of Morgan, Lewis & Bockius LLP (included in Exhibit 5.1)
 - 23.2* Consent of Deloitte & Touche LLP, independent registered public accounting firm
 - 23.3* Consent of Deloitte & Touche LLP, independent auditors
 - 23.4* Consent of PricewaterhouseCoopers SA, independent auditors
 - 24.1* Power of Attorney
- ^ Previously filed
- * To be filed by amendment
- # Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit is being submitted separately to the SEC.
- † Indicates a management contract or compensatory plan

QuickLinks

EXPLANATORY NOTE PART II INFORMATION NOT REQUIRED IN PROSPECTUS

<u>Item 13. Other Expenses of Issuance and Distribution</u> <u>Item 14. Indemnification of Directors and Officers</u>

Item 15. Recent Sales of Unregistered Securities
Item 16. Exhibits and Financial Statement Schedules
Item 17. Undertakings

SIGNATURES POWER OF ATTORNEY **EXHIBIT INDEX**

LICENSE AGREEMENT

THIS LICENSE AGREEMENT (hereinafter referred to as "<u>Agreement</u>") dated as of 30 August, 2007 (hereinafter referred to as "<u>Effective Date</u>"), is entered into between Cyrenaic Pharmaceuticals, Inc., a Delaware corporation, having a place of business located at 47 Hulfish Street, Suite 310 Princeton NJ 08542, the U.S. (hereinafter referred to as "<u>LICENSEE</u>") and Mitsubishi Pharma Corporation, a Japanese corporation, having a place of business located at 6-9, Hiranomachi 2-chome, Chuo-ku, Osaka 541-0046, Japan (hereinafter referred to as "<u>MPC</u>").

WITNESSETH:

WHEREAS, MPC is the owner of the patents, patent applications and other intellectual property relating to a certain pharmaceutical compound coded as MT-210;

WHEREAS, LICENSEE desires to obtain an exclusive license, with a right to grant sublicenses, under the MPC Intellectual Property (hereinafter defined); and

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

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the terms defined in this Article 1 shall have the respective meanings set forth below, it being understood that words in the singular include the plural and vice versa:

1.1 "Affiliate" shall mean any person, corporation, joint venture or business entity of such party which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such party, as the case may be. As used herein, "control" means (a) to possess, the power to direct the management or policies of such company

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A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

or other business entity, through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital in such company or other business entity.

- 1.2 "Allocable Overhead" shall mean costs incurred by a Party or for its account (and not reimbursed by a Third Party) which are attributable to its supervisory, services, occupancy costs, payroll, information systems, human relations or purchasing functions and which are allocated to company departments involved in and relevant to the subject matter of this Agreement, based on space occupied, headcount, or activity-based method, in all cases as determined by such Party in accordance with GAAP (hereinafter defined). "Allocable Overhead" shall not include any costs attributable to general corporate activities including, by way of example only, executive management, investor relations, business development, legal, finance and government affairs, and shall not include any costs or expenses which are reimbursed by the other Party or any Third Party.
 - 1.3 "Alternate Compound" shall mean a Back-Up Compound or a Metabolite.
- 1.4 "Application" shall mean a New Drug Application ("NDA") submitted (and the submission of which has been accepted) with the Food and Drug Administration ("FDA") in the United States or a corresponding application for commercial sales which has been submitted (and the submission of which has been accepted for review) with a regulatory agency in a country of the LICENSEE Territory other than the United States, in each case for the Product in the Field.
- 1.5 "<u>Back-Up Compound</u>" shall mean (i) compounds described in the examples and included in the Valid Claim of MPC's patent (U.S. patent No. 7166617) except for the MT-210

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Compound (hereinafter defined) and (ii) compound coded as BFB-484 which chemical structure is set forth in Schedule 1.5.

- 1.6 "Bulk Drug Substance" shall mean the Compound in bulk form, which if appropriately formulated and finished, would constitute the Product.
- 1.7 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.

- 1.8 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
- 1.9 "Clinical Studies" shall mean Phase I Studies, Phase II(a) Studies, Phase II(b) Studies, and Phase III Studies.
- 1.10 "CNS Indication" shall mean Schizophrenia and all other CNS diseases including, but not limited to, psychotic disorders, depression, anxiety, sleep disorders, pain, dementia, Alzheimer disease, cognitive disorders and attention disorders (ADHD).
- 1.11 "Commercially Reasonable Efforts" shall mean efforts and resources normally used by a Party for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors.
- 1.12 "Competing Product" shall mean any prescription pharmaceutical product of which shall have the same indication of the Product and the same sigma-2 mechanism of action.
- 1.13 "Compound" shall mean (i) compound known as MT-210 with the chemical name [*] having the molecular structure set forth in Schedule 1.13 (hereinafter referred to as the "MT-

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210 Compound"), (ii) any solvate, salt form, enantiomers, racemate, w-crystal, anhydride, hydrate, polymorph or amorphous of the MT-210 Compound (an "MT-210 Back-Up"), (iii) any Back-Up Compound, and (iv) any Metabolite.

- 1.14 "<u>Development Work</u>" shall mean all works to be performed by or on behalf of LICENSEE, its Affiliates and/or sublicensees, under appropriate support, if requested by LICENSEE, its Affiliates and/or sublicensees, to be provided by FORENAP, to obtain the data and information necessary or useful for the Registration and future commercial operation of the Product, including all necessary pre-clinical, clinical studies and formulation development and manufacturing of the Compound and/or Product.
- 1.15 "Development Plan" shall mean LICENSEE's and/or Affiliate's and/or its sublicensee's development plan for the Compound and Product with timeline. The initial Development Plan is set forth on Schedule 1.15.
 - 1.16 "Effective Date" shall have the meaning set forth in the introductory paragraph of this Agreement.
- 1.17 "<u>European Country</u>" shall mean a country which is a member of the European Union as of the Effective Date, or which join the European Union after the Effective Date.
- 1.18 "Excluded Compounds" shall mean the following compounds: BFB-484, BFB-687, BFB-512, BFB-462 which chemical structures are set forth in Schedule 1.18, and M1, M2, M3 and M4 as defined in Section 1.33.
- 1.19 "Field" shall mean the use of the Product in humans to treat, manage or prevent CNS Indications. Non-systemic ophthalmic use of the Product shall be specifically excluded from the Field.

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- 1.20 "<u>FORENAP</u>" shall mean FORENAP PHARMA EURL, having its registered offices at 27 rue du 4^{ème} RSM B.P. 27, 68250 Rouffach, France.
- 1.21 "Fully Burdened Manufacturing Cost" shall mean the cost of production of the Compound or the Product, comprised of the sum of: (a) the manufacturing cost of goods produced as determined in accordance with GAAP as applied by the manufacturer of such Compound or Product including, without limitation, direct labor, material and product testing costs incurred in connection with the manufacture or quality control testing of such product, as well as Allocable Overhead and shipping containers, (b) the manufacturer's allocable intellectual property licensing and acquisition costs paid to Third Parties which are necessary for the manufacture of such Compound or Product and (c) any other costs borne by the manufacturer for the transport, customs clearance and storage of such Compound or Product (if necessary) at the request of LICENSEE or its Affiliates or sublicensees (i.e., freight, duty, insurance, and warehousing).
 - 1.22 "GAAP" shall mean generally accepted accounting principles in the United States.
- 1.23 "Generic Competition" shall mean, with respect to a particular country in the LICENSEE Territory where LICENSEE, its Affiliate or its sublicensee is selling Product, a Third Party, other than a sublicensee of LICENSEE, is selling a Generic Drug in such country and the average Net Sales in such country for two (2) consecutive Calendar Quarters immediately or at any time after the launch of such Generic Drug in such country is [*] or less than the average Net Sales for the two (2) consecutive Calendar Quarters immediately prior to the launch of such Generic Drug in such country, despite LICENSEE, its Affiliate and/or its

sublicensee using Commercially Reasonable Efforts to market and sell the Product in such country.

- 1.24 "Generic Drug(s)" shall mean any product containing Compound for which Registration is obtained by an abbreviated NDA ("ANDA") or other abridged procedure in the United States or a corresponding application in any country of the LICENSEE Territory, other than a Product introduced in such country by LICENSEE, its Affiliates or its sublicensees.
- 1.25 "IND" shall mean an Investigational New Drug filed with FDA in the United States or a corresponding application filed with a regulatory agency with respect to development of a Product in the Field.
- 1.26 "Know-How" shall mean any proprietary, non-public information or materials, relating to the research, development, registration, manufacture, marketing, use or sale of the Compound and/or Product which prior to or during the term of this Agreement are developed by or is in a Party's possession or control through license or otherwise (provided that such Party is permitted to make disclosure thereof to the other Party without violating the terms of any Third Party agreement). Know-How may include, without limitation: (i) all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety and quality control data and information related to the Compound and/or Product; (ii) compositions of matter, assays and biological materials, necessary or useful for development, manufacture, use or sale of the Compound and/or Product; (iii) data and information necessary for manufacturing the Compound and/or Product; and (iv) all applications, registrations licenses, authorizations, approvals and correspondences submitted to or received from any regulatory authorities with jurisdiction over an investigational drug containing the Compound and/or Product.

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- 1.27 "<u>Launch</u>" shall mean, with respect to any Product after Registration, the first sale to a Third Party by LICENSEE, its Affiliate or its sublicensees of that Product in such country. Sales for test marketing, clinical study purposes or compassionate, named patient or similar use shall not constitute a sale.
- 1.28 "<u>LICENSEE Intellectual Property</u>" shall mean all intellectual property and proprietary rights in (i) all LICENSEE Patents and (ii) all LICENSEE Know-How.
- 1.29 "<u>LICENSEE Know-How</u>" shall mean any Know-How owned or controlled by LICENSEE and/or its Affiliates that is developed by LICENSEE or its Affiliates after the Effective Date in connection with its performance of its activities under this Agreement.
- 1.30 "<u>LICENSEE Patents</u>" shall mean any Patent Right owned or controlled by LICENSEE or its Affiliate, to the extent such Patent Right both (a) covers a Compound or Product and (b) the underlying invention of which was conceived and reduced to practice after the Effective Date by LICENSEE in connection with its performance of its activities under this Agreement.
 - 1.31 "LICENSEE Territory." shall mean all countries in the world, excluding the MPC Territory.
 - 1.32 "Major Countries" shall mean the United States, Canada, the United Kingdom, Germany, France, Italy and Spain.
- 1.33 "<u>Metabolite</u>" shall mean the following metabolites of the MT-210 Compound: (a) M1 coded as BFB-520; (b) M2 coded as BFB-999; (c) M3; and (d) M4 which chemical structures are set forth in <u>Schedule 1.33</u>.
 - 1.34 "MPC Intellectual Property." shall mean all intellectual property and proprietary rights in (i) all MPC Patents and (ii) all MPC Know-How.

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- 1.35 "MPC Know-How" shall mean Know-How owned or controlled by MPC and/or its Affiliates.
- 1.36 "MPC Patents" shall mean any Patent Right owned or controlled by MPC and/or its Affiliates during the term of this Agreement which relates to Compound or Product, and, absent rights hereunder, would be infringed by the research, development, manufacture, use, importation, sale or offer for sale of the Compound and/or Product, including the Patent Rights listed on Schedule 1.36, and any patents that may issue from, or claim priority to or through, the applications listed on Schedule 1.36.
- 1.37 "MPC Territory" shall mean Bangladesh, Brunei, India, Indonesia, Japan, Malaysia, Pakistan, People's Republic of China (including Hong Kong), Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand and Vietnam.
- 1.38 "Net Sales" shall mean, with respect to any Product, the aggregate gross amount invoiced by LICENSEE or its Affiliates or sublicensees on all sales of such Product in the LICENSEE Territory to an unaffiliated Third Party, less reasonable and customary deductions from such gross amounts, including:

- 1.38.2 credits or allowances for damaged goods, returns or rejections or recalls of Product and shelf stock and other retroactive price adjustments;
 1.38.3 normal and customary trade, cash, quantity and volume based discounts, allowances and credits;

1.38.1 bad debts actually written off which are attributable to sales of the Product;

- 1.38.4 sales or similar taxes (other than income taxes);
- 1.38.5 freight, postage, shipping, insurance charges;

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- 1.38.6 chargebacks and rebates to managed healthcare organizations or to federal, state and local governments, their agencies, or to trade customers, including without limitation, wholesalers and chain pharmacy buying groups;
 - 1.38.7 inventory management, distribution, warehousing, and related services fees, and
- 1.38.8 any other reduction or specifically identifiable amounts included in the invoice price that should be credited for any reasons substantially equivalent to those listed above.

Each of the deductions set forth above shall be determined on an accrual basis in accordance with GAAP. To the extent that any discounts or other similar deductions that are based on sales to the customer of multiple products are included in determining Net Sales of the Product, such discounts or deductions shall be allocated to the Product and the other relevant products on a pro rata basis.

- 1.39 "Onset" shall mean the first dosing of the first patient in a Clinical Study.
- 1.40 "Party" shall mean one of MPC and LICENSEE, as appropriate. Where used in the plural, "Parties" shall mean MPC and LICENSEE.
- 1.41 "Patent Rights" shall mean (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any

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and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.

- 1.42 "Person" shall mean an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.
- 1.43 "Phase I Studies" shall mean that portion of the clinical development program which provides for the first introduction into humans of a Product including small scale clinical studies conducted in normal volunteers or patients to get information on Product safety.
- 1.44 "Phase II(a) Studies" shall mean that portion of the clinical development program which provides for the initial trials of a Product on a limited number of patients for the purpose of determining whether the Product affects a surrogate marker or indicator of pharmacological or clinical activity in the proposed disease state/therapeutic indication.
- 1.45 "Phase II(b) Studies" shall mean that portion of the clinical development program carried out either post-Phase II(a) Studies or concurrently with Phase II(a) Studies and which provides information for the definitive, well controlled clinical trials of a Product in patients, including clinical studies conducted in patients and designed to indicate clinical efficacy for the Product for one or more indications and its safety, as well as to obtain an indication of the dosage regimen required.

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- 1.47 "Phase III Studies" shall mean large scale clinical studies conducted in a sufficient number of patients to establish the Product clinical efficacy in the Field and its safety.
- 1.48 "Proprietary Information" shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and/or under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.
- 1.49 "Product" shall mean a pharmaceutical preparation containing Compound which has been manufactured into an oral dosage form (including sustained release formulation), injectable formulation or any other formulation, packaged and labeled for administration in the Field. Combination product may be included in this defined term of "Product", provided, however, that calculation method of Net Sales of the combination product shall be separately agreed upon between the Parties.
- 1.50 "Royalty Period" shall mean the period, on a country-by-country and Product-by-Product basis, until the later of: (a) the expiration of the last-to-expire Valid Claim covering such Product in such country or; (b) twelve (12) years from the Launch of such Product in such country of the LICENSEE Territory.
- 1.51 "<u>Royalty Year</u>" shall mean (i) for the year in which the Launch occurs (the "<u>First Royalty Year</u>"), the period commencing with the first day of the Calendar Quarter in which the Launch occurs and expiring on the last day of the Calendar Year in which the Launch occurs and (ii) for each subsequent year, each successive Calendar Year.

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- 1.52 "Registration(s)" shall mean, in relation to any Product, such authorizations of the regulatory authorities in a given country (including marketing, marking and pricing approvals) as may be legally required before such Product may be commercialized or sold in such country.
- 1.53 "<u>Steering Committee</u>" shall mean a committee established by the Parties subject to Section 4.3.1 to coordinate, review and assess the development of Product, to harmonize worldwide objectives for Product and, after MPC decides to initiate clinical development in the MPC Territory, to facilitate the transfer of data and regulatory communications, including the handling and reporting of adverse events, between the Parties.
 - 1.54 "Territory" shall mean the LICENSEE Territory or the MPC Territory, as applicable.
 - 1.55 "Third Party." shall mean any person or entity other than MPC, LICENSEE, or an Affiliate of either Party.
- 1.56 "<u>Valid Claim</u>" shall mean a claim within the MPC Patents (a) in an unexpired and issued patent that has not been revoked, held invalid, declared unpatentable or unenforceable by a body of competent jurisdiction and (b) that has not been rendered unenforceable through disclaimer or otherwise.

ARTICLE 2 GRANT OF LICENSE

2.1 <u>License Grant to LICENSEE</u>. MPC hereby grants to LICENSEE and its Affiliate an exclusive license (even as to MPC) under the MPC Intellectual Property to develop, have developed, register, have registered, make, have made, use, have used, sell, offer for sale, have sold, import and have imported Product in the Field for purposes of commercialization in the LICENSEE Territory.

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- 2.2 <u>Compound Manufacturing Right</u>. MPC hereby grants to LICENSEE and its Affiliate under the MPC Intellectual Property (a) a semi-exclusive license, with the right to sublicense, to make and have made Compound in the LICENSEE Territory solely for purposes of researching, developing and/or commercializing Product in the LICENSEE Territory; it being understood that such semi-exclusive license will allow MPC the right to make and have made Compound in the LICENSEE Territory solely for purposes of researching, developing and/or commercializing Product in the MPC TERRITORY and (b) a non-exclusive license, with the right to sublicense, to make and have made Compound in the MPC Territory solely for the purposes of researching, developing and/or commercializing Product in the LICENSEE TERRITORY.
- 2.3 <u>Sublicense Rights</u>. LICENSEE and its Affiliate shall have the right to grant sublicenses under all or part of the licenses granted under Sections 2.1 and 2.2; provided, however, prior to sublicensing such rights, LICENSEE shall provide MPC with the opportunity to negotiate terms under which MPC would collaborate in or obtain a license for research, development and/or commercialization of the Compound and/or Product in the LICENSEE Territory (a "Right of First Negotiation"). A Right of First Negotiation shall operate as follows:
- 2.3.1 LICENSEE shall promptly notify MPC in writing (the "<u>Right of First Negotiation Notification</u>") of its intention to enter into a sublicensing arrangement for the research, development and/or commercialization of the relevant Compound and/or Product and shall provide to MPC a reasonably detailed written description of such proposed sublicense, together with any data, results materials or information related to such Compound and/or Product which LICENSEE reasonably believes is necessary and useful for evaluation of an interest in participating in such proposed sublicense by MPC and has not previously been provided to MPC.

- 2.3.2 Within ten (10) business days of its receipt of the Right of First Negotiation Notification (the "Response Period"), MPC shall notify LICENSEE of its interest, if any, in initiating discussions regarding such proposed sublicense.
- 2.3.3 In the event that MPC notifies LICENSEE prior to the termination of the Response Period that it has an interest in participating in such proposed sublicense (an "Expression of Interest"), then the Parties shall negotiate in good faith in an effort to reach a definitive agreement regarding such sublicense for a period of up to sixty (60) days from the date of LICENSEE's receipt of the Expression of Interest; provided that, at MPC's option, the negotiation period may be extended one time for an additional sixty (60) days.
- 2.3.4 In the event that (a) MPC fails to notify LICENSEE prior to the termination of the Response Period that it has an interest in participating in such proposed sublicense, or (b) MPC notifies the LICENSEE prior to the termination of the Response Period that it has no interest in such sublicense, or (c) MPC timely provides LICENSEE with an Expression of Interest but MPC decides and notifies LICENSEE not to continue negotiation regarding such sublicense within the period specified in Section 2.3.3, then LICENSEE shall be free to enter into a sublicense with a Third Party with respect to such Compound and/or Product and the terms of any such sublicense agreement shall not be inconsistent with terms and conditions set forth in this Agreement.
- 2.3.5 For the duration of the Response Period, and if MPC timely delivers the Expression of Interest, the sixty (60) day period specified in Section 2.3.3, and additional sixty (60) days period specified in Section 2.3.3 if the Parties continue the negotiation regarding such sublicense, LICENSEE shall not negotiate such sublicense arrangement with a Third Party, nor enter into any agreements with such Third Party or propose terms to such Third Party.

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- 2.4 <u>License Grant to MPC</u>. LICENSEE or its Affiliate shall grant to MPC and its Affiliate a non-exclusive and royalty-free license, with the right to grant sublicenses, under LICENSEE Intellectual Property for the purpose of developing and commercializing the Compound and/or the Product in the MPC Territory. LICENSEE or its Affiliate shall use its Commercially Reasonable Efforts to cause its sublicensees to grant to MPC and its Affiliate a non-exclusive and royalty-free license, with the right to grant sublicenses, under such sublicensee's intellectual property for the purpose of developing or commercializing the Compound and/or the Product in the MPC Territory.
- 2.5 <u>First Offer to LICENSEE</u>. For an exclusive period of sixty (60) days, MPC will first offer to and discuss with LICENSEE the licensing terms and conditions of the Compound and/or Product before entering into discussion with any Third Party in the MPC Territory. After the expiration of such 60-day period, MPC shall be free to enter into a license with a Third Party with respect to the Compound and/or Product for the MPC Territory.
- 2.6 Outside the Field. Neither LICENSEE nor any of its Affiliates or sublicensees shall be entitled to develop, have developed, register, have registered, make, have made, use, have used, sell, offer for sale, have sold, import or have imported Compound or Product outside the Field in the LICENSEE Territory. MPC and its respective Affiliates and sublicensees shall be free to develop, have developed, register, have registered, make, have made, use, have used, sell, offer for sale, have sold, import and have imported Compound and Product for use outside the Field in the LICENSEE Territory; provided, however, that such Compound and/or Product must be formulated in a dosage and administration form that does not lead to systemic absorption.
- 2.6.1 For each individual Compound, MPC will grant to LICENSEE exclusivity for evaluation of its interest for outside the Field applications of such Compound in the

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LICENSEE Territory for a period of time until the later to occur of (a) the second anniversary of the Effective Date or (b) the six month anniversary of the completion by LICENSEE of the Phase II(a) Studies with such Compound (the "<u>Grace Period</u>"). For the avoidance of doubt, such initial exclusivity will apply to each Compound taken individually. LICENSEE will keep MPC informed about its progress of the evaluation.

- 2.6.2 During the Grace Period, MPC will be free to engage Third Parties in discussions regarding use of such Compound outside the Field and/or to plan and conduct research, including clinical research, in the MPC Territory only; provided that in no event during the Grace Period shall MPC be entitled to enter into a license, collaboration or similar agreement with a Third Party for such Compound. No later than thirty (30) days before the end of the Grace Period, MPC will disclose to LICENSEE the results of research and/or licensing activities conducted during the Grace Period, if any such activities were conducted. The Grace Period will continue until thirty (30) days after such disclosure has been made by MPC.
- 2.6.3 For each individual Compound, LICENSEE will be granted a second period of exclusivity as follows when an Outside the Field Event occurs ("Second Exclusivity Period"). Upon the occurrence of an Outside the Field Event, MPC shall immediately notify LICENSEE of such event. An "Outside the Field Event" is one of the following:
- (a) Second Exclusivity Period of one hundred twenty (120) days will be granted upon receipt by LICENSEE of a written communication by MPC informing LICENSEE that MPC has received a fully-negotiated term sheet from a qualified Third Party concerning the use of such Compound outside the Field; or

communication by MPC to LICENSEE informing LICENSEE that MPC has conducted or has plans to conduct research for use of the Compound outside the Field.

- 2.6.4 If an Outside the Field Event occurs during the Grace Period, then the Second Exclusivity Period shall begin, in the case of Outside the Field Event (a) above, immediately upon LICENSEE's receipt of written communication by MPC of the Outside the Field Event, and in the case of Outside the Field Event (b) above, after the Grace Period and upon LICENSEE's receipt of written communication by MPC of the Outside the Field Event. MPC will provide LICENSEE with all data and information that LICENSEE will require to complete its assessment, including the Third Party term sheet (if one exists), MPC development plans and/or results obtained through such time.
- 2.6.5 During the Second Exclusivity Period, LICENSEE will evaluate the information provided by MPC. At the end of the Second Exclusivity Period:
- (a) LICENSEE will have the right to purchase perpetual and exclusive evaluation rights for any use of such Compound outside the Field by paying to MPC an initial milestone of [*] before the expiration of the Second Exclusivity Period;
- (b) LICENSEE may decide that it needs more time to evaluate the potential risk, and in such an event, LICENSEE may purchase a two-year period of exclusivity for use of such Compound outside the Field by paying to MPC a milestone of [*] before the expiration of the Second Exclusivity Period. For the purpose of determining rights and obligations of both Parties during this additional exclusivity period, the two-year extension will be considered identical to the Grace Period; or
- (c) If LICENSEE notifies MPC of its commercial interest in such Compound for use outside the Field before the expiration of the Second Exclusivity Period, then

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the Parties shall discuss in good faith the licensing terms and conditions for use of such Compound outside the Field in the LICENSEE Territory; or

- (d) If LICENSEE fails to make the intended payment pursuant to either Section 2.6.5(a) or 2.6.5(b) and fails to notify MPC of its intention to enter into licensing discussions pursuant to Section 2.6.5(c) before the expiration of the Second Exclusivity Period, MPC shall be free to pursue use of such Compound outside the Field in the LICENSEE Territory for which it was presented to LICENSEE but not for other uses outside the Field.
- 2.6.6 Notwithstanding the foregoing, if LICENSEE has made payments to MPC pursuant to Sections 2.6.5(a) and 2.6.5(b), collectively, four times, then from and after such fourth payment, LICENSEE will automatically receive perpetual and exclusive evaluation rights for all Compounds and for all use outside the Field.

ARTICLE 3 DISCLOSURE

- 3.1 <u>Disclosure by MPC</u>. Within thirty (30) days after the Effective Date, and throughout the term of this Agreement as new MPC Intellectual Property is developed, MPC shall disclose to LICENSEE any and all then-available MPC Intellectual Property, including without limitation, any regulatory filings or information related thereto, which has not already been disclosed and made available to LICENSEE or its Affiliate, on an "as-is" basis.
- 3.2 <u>Technical Assistance by MPC</u>. Upon specific request from LICENSEE, MPC shall cooperate with LICENSEE and provide LICENSEE with technical assistance, to the extent such technical assistance is reasonably available to MPC, with respect to the MPC Know-How in order to enable LICENSEE to use such MPC Know-How to manufacture and produce the Compound or Product. If LICENSEE requests and MPC accepts in its sole discretion that MPC technical personnel shall be dispatched to the facilities of LICENSEE or its Affiliate or Third

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Party contractor for the purposes of providing such technical assistance, LICENSEE shall pay to MPC a reasonable per diem or hourly rate fee for such assistance in an amount to be negotiated in good faith by the Parties and shall reimburse MPC for the actual out-of-pocket costs incurred in providing such technical assistance.

3.3 <u>Disclosure by LICENSEE</u>. During the term of this Agreement, LICENSEE shall disclose to MPC any and all then available LICENSEE Intellectual Property, including without limitation relevant information contained in any IND and NDA. If MPC requests and LICENSEE accepts in its sole discretion to conduct certain study or experiment to obtain certain additional data and information relating to LICENSEE Intellectual Property solely for the

purpose of development and/or Application of the Product in MPC Territory specifically but such additional data and information will not be useful for the purpose of development and/or Application of the Product in LICENSEE Territory, MPC shall pay to LICENSEE a reasonable per diem or hourly rate fee for obtaining such additional data and information in an amount to be negotiated in good faith by the Parties and shall reimburse LICENSEE for the actual out-of-pocket costs incurred in providing such additional data and information.

3.4 <u>Technical Assistance by LICENSEE</u>. Upon specific request from MPC, LICENSEE shall reasonably cooperate with MPC and provide MPC with technical assistance with respect to the LICENSEE Know-How in order to enable MPC to use such LICENSEE Know-How to manufacture and produce the Compound or Product. If MPC requests and LICENSEE accepts in its sole discretion that LICENSEE's technical personnel shall be dispatched to the facilities of MPC, its Affiliate, its licensee or Third Party contractor for the purposes of providing such technical assistance, MPC shall pay to LICENSEE a reasonable per diem or hourly rate fee for such assistance in an amount to be negotiated in good faith by the

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Parties and shall reimburse LICENSEE for the actual out-of-pocket costs incurred in providing such technical assistance.

3.5 Technical Transfer. Within sixty (60) days of the Effective Date, MPC shall provide to LICENSEE copies in English of all substantive or material information (in electronic format where available), relating to the following: (1) pre-clinical and clinical data and other know-how compiled as of the Effective Date with respect to the Compounds, including any and all data which MPC reasonably considers necessary for LICENSEE to file an IND with the FDA, and (2) all prior correspondence with the FDA or other regulatory equivalent for countries in the LICENSEE Territory other than the United States related to the Compound. MPC acknowledges and agrees that timing shall be of the essence in complying with its obligations under this Section 3.5.

Notwithstanding anything to the contrary contained herein, if FDA or equivalent regulatory agency outside the US makes a specific request for information, MPC, as soon as practical but in no event later than 15 days after such request, must provide to LICENSEE such information, to the extent that it is or was in MPC's possession or control at any time, and to the extent such information has not already been transferred to LICENSEE.

ARTICLE 4 DEVELOPMENT; REGULATORY MATTERS; POST REGISTRATION ACTIVITIES

4.1 <u>Development</u>.

4.1.1 <u>Development Work</u>. In accordance with the Development Plan, LICENSEE, its Affiliates and its sublicensees shall, at their own expense, use Commercially Reasonable Efforts to conduct the Development Work and shall pursue Registrations for the Product in the Field in the LICENSEE Territory, including the preparation and filing of regulatory submissions. In conducting the Development Work, LICENSEE and/or its Affiliates or sublicensees may utilize FORENAP for support in conducting the Development Work which

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shall include the services set forth in the Services Agreement dated June 25, 2007 between LICENSEE and FORENAP, a copy of which is attached as Schedule 4.1.1 (hereinafter referred to as "Services Agreement"). Further, LICENSEE may subcontract portions of the Development Work to any other Third Party having enough knowledge, experience and capability for pre-clinical and/or Clinical Studies; provided, however, that such subcontracted Third Party shall be subject to an agreement with LICENSEE consistent with the confidentiality obligations in accordance with Article 8 below. LICENSEE shall be responsible for the Development Work to be performed by FORENAP and any other subcontracted Third Party.

- 4.1.2 <u>Development Plan</u>. For each Compound and Product, LICENSEE shall prepare a Development Plan that describes the significant development activities to be undertaken by LICENSEE, its Affiliates and/or its sublicensees with respect to the Compound and Product in the Field in the LICENSEE Territory. As part of the Services Agreement, LICENSEE, and/or its Affiliates shall prepare the initial Development Plan for the MT-210 Compound in consultation with FORENAP. The initial Development Plan for the MT-210 Compound shall take into consideration the following strategies for development;
- (a) Characterize the clinical trial subjects for their hepatic metabolic status, particularly by looking to CYP2D6 polymorphism (genotyping and if necessary phenotyping) and probably excluding CYP2D6 poor metabolisers from the initial Phase II(a) Study;
 - (b) Exclude from the clinical trials subjects who are at risk for cardiovascular side effects;
 - (c) Explore low doses of MT-210 Compound that have been considered clinically safe as far as QTc prolongation is

considered;

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(d) Titrate the doses of MT-210 up in a very conservative titration regimen to find the maximum safe dose with respect to

- (e) For the initial Phase II(a) Study, clinical study subjects shall be inpatients during the first two weeks, or longer, if no clinical efficacy is objectively demonstrated;
 - (f) Frequently perform ECG recordings, including at Tmax, and before each dose increase;
- (g) Regularly monitor plasma levels of Compound and active metabolites in a manner similar to the monitoring conducted by MPC in the Phase I Studies with MT-210 Compound; and
 - (h) Use only clinical sites that are experienced in conducting clinical studies with antipsychotic compounds.

The Development Plan may be modified from time to time as LICENSEE, its Affiliates and/or sublicensees deem necessary, and with respect to the MT-210 Compound, within the scope of the development strategy set forth in this Section 4.1.2; provided, however, LICENSEE, to the extent it is aware of such revisions, shall promptly inform MPC of any material revision of such Development Plan and will use good faith efforts to inform MPC of any other revision of such Development Plan. If the Development Plan for the MT-210 Compound is modified by LICENSEE, and/or its Affiliates beyond the development strategy considerations set forth in Section 4.1.2(a) — (h), LICENSEE shall promptly inform MPC of such revision of such Development Plan and MPC shall provide any comments it may have on such modifications within eight (8) days and LICENSEE shall consider in good faith any such comments.

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LICENSEE shall be responsible for preparing and implementing any modifications or amendments to the Development Plan.

4.1.3 <u>Back-Up Compounds & Metabolites</u>. If during the course of the Development Work, LICENSEE or its Affiliate or its sublicensee decides (a) that it desires to develop the Product containing an Alternate Compound at the same time as the Development Work on the Product containing MT-210 Compound or (b) that it no longer desires to continue the Development Work of the Product containing MT-210 Compound based on its reasonable judgment of internal scientific and/or economic evaluation, such as safety, efficacy or commercial viability of the Product containing the MT-210 Compound, and, in substitute of the MT-210 Compound, desires to commence Development Work of the Product containing a Back-Up Compound, a MT-210 Back-Up or Metabolite selected by LICENSEE as a back-up Compound, LICENSEE shall notify MPC of such intention and the Development Plan for the Product containing such back-up Compound. LICENSEE shall be free to commence such simultaneous or alternate Development Work unless MPC notifies LICENSEE within thirty (30) days after receipt of notice from LICENSEE that MPC, its Affiliate and/or its licensee is then conducting any research, development and/or commercialization activities for such back-up Compound outside the Field; provided, however, that none of MPC, its Affiliates and/or its licensee shall be permitted to restrict LICENSEE from commencing Development Work on the Excluded Compounds. Upon the Onset of a Phase I Study of the Product containing such back-up Compound, LICENSEE shall notify MPC of such Development Work. For the avoidance of doubt, the development diligence set forth in Section 5.2 (but subject to Section 5.2) and the royalties set forth in Section 5.3 shall be applied

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to the Product containing such back-up Compound to the extent such back-up Compound is an Alternate Compound.

- 4.1.4 <u>Clinical Studies Protocol</u>. Before commencement of any Clinical Studies conducted by LICENSEE and its Affiliates in accordance with the Development Plan, LICENSEE or its Affiliate shall provide to MPC the final draft of the protocol for such Clinical Study. MPC may comment within fifteen (15) business days on such protocol and LICENSEE or its Affiliate shall consider in good faith any MPC comments; provided, however, the final decision with respect to any such protocol shall be taken by LICENSEE at its sole discretion.
- 4.1.5 <u>Development Diligence</u>. Without prejudice to any other remedies available at law or otherwise provided for in this Agreement, MPC shall have the right to terminate this Agreement in the event that LICENSEE, its Affiliate or its sublicensee fails to meet any of the following milestones for the Product containing the MT-210 Compound:
 - (a) Filing of the first IND in one of the Major Countries within [*] months after the Effective Date;
 - (b) Onset of the first Phase II(b) Study within [*] months after the first IND filing;
 - (c) Onset of the first Phase III Study within [*] months after completion of the last Phase II(b) Study; and
 - (d) Filing of the first NDA within [*] years and [*] months after the first IND filing;

Provided, however, that MPC shall not have the right to terminate this Agreement if the failure of LICENSEE, its Affiliate or its sublicensee to meet any of the milestones set forth above is due to or caused by any of the following:

- (1) Reason(s) beyond the reasonable control of LICENSEE, its Affiliate or its sublicensee. For the avoidance of doubt and without prejudice to other reasons, the following reasons will be deemed beyond the reasonable control of LICENSEE, its Affiliate or its sublicensee: a requirement by the FDA or other applicable regulatory agency that LICENSEE, its Affiliate or its sublicensee (i) perform additional studies or trials, (ii) reformulate or alter the manufacturing process of any Product, (iii) cease any clinical trial or redesign any clinical trial, or (iv) perform any other action or cease to perform any action that otherwise delays the clinical development of any Product. LICENSEE, its Affiliate or its sublicensee will present to MPC evidence of such FDA or other applicable regulatory agency action.
- Activities performed in the best interest of the Product as reasonably determined by LICENSEE, its Affiliate or its sublicensee, subject to MPC's approval, not to be unreasonably withheld. For the avoidance of doubt and without prejudice to other activities, the following activities will be deemed in the best interest of the Product: (i) an expanded clinical program scope; (ii) additional safety studies, including drugdrug interaction studies and special population studies; (iii) reformulation efforts; or (iv) business development efforts following initiation of a Phase II(b) Study. Plan of such activities will be communicated to MPC by LICENSEE, its Affiliate or its sublicensee.
- (3) LICENSEE's decision to discontinue development of the Product containing the MT-210 Compound, pursuant to Section 4.1.3(b) or 10.3.

The Steering Committee will review the overall progress of the Development Plan and will agree on reasonable time extensions or milestone adjustments to accommodate delays due to clause (1) or (2) set forth above based on information presented by LICENSEE, its Affiliate or its sublicensee.

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In the event that LICENSEE, its Affiliate or its sublicensee commence alternate Development Work of the Product containing a Back-Up Compound or Metabolite selected by LICENSEE as a back-up Compound pursuant to Section 4.1.3(b), the Parties shall discuss and agree in good faith revisions to the respective timeline for the back-up Compound in consideration of the Development Plan for the Product containing such back-up Compound proposed by LICENSEE pursuant to Section 4.1.3(b).

Notwithstanding the foregoing, LICENSEE may extend the time to achieve any of the milestones set forth in Section 4.1.5(a) through (d) set forth above for one (1) year, at its sole discretion, by making a payment of [*] to MPC before the date on which such milestone was to have been originally achieved (the "Extension Payment"). If such Extension Payment is made, all following milestones will be concomitantly extended by one (1) year. LICENSEE will have the right to make an unlimited number of Extension Payments in conjunction with the development of Product containing the MT-210 or of a Product containing a Back-Up Compound pursuant to Section 4.1.3(b), provided that the payment amount will increase to [*] beginning with the third Extension Payment. For the avoidance of doubt, Extension Payments will be in addition to any milestone that is otherwise payable to MPC as set forth in Section 5 of this Agreement.

4.1.6 <u>Progress Reports.</u> Every six (6) months until the Registration is obtained in any country in the LICENSEE Territory, LICENSEE shall use its Commercially Reasonable Efforts to prepare and deliver to MPC a written report summarizing LICENSEE's, its Affiliates' and/or sublicensees' significant activities of the Development Work, including all pre-clinical tests and Clinical Studies, with respect to the Compound and Product in the Field in the LICENSEE Territory performed by LICENSEE, its Affiliates and/or sublicensees. MPC may

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comment on the progress of the Development Work when reviewing such process reports and LICENSEE or its Affiliates, shall, in its or their sole discretion, consider in good faith any such comments; provided, however, the final decision as to the Development Work shall be taken by the LICENSEE or its Affiliates or sublicensees at its or their sole discretion.

- 4.1.7 <u>Regulatory Matters</u>. LICENSEE and/or its Affiliates or sublicensees shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Registration of Product in the LICENSEE Territory in the Field.
- 4.1.8 <u>Supply of Samples of Compound</u>. Upon request of LICENSEE, MPC will make, at its sole discretion, its reasonable effort to supply LICENSEE with samples of Compound if such samples of Compound are available to MPC at the time.
- 4.1.9 Reporting of Adverse Events and Adverse Drug Reactions. LICENSEE and its Affiliates and sublicensees and MPC and its Affiliates and licensees shall cooperate with respect to the exchange of adverse event and safety information associated with the Product. Details of the cooperation in the handling of adverse event and safety information related to the Product shall be included in a separate agreement to be negotiated in good faith between the Parties at the time MPC, its Affiliates, its licensee or its sublicensee initiates development of the Product in the MPC Territory. Such agreement shall set forth a standard operating procedure governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions/experiences sufficient to permit each Party to comply with its legal obligations in its respective Territory. Each Party will designate a regulatory affairs or pharmacovigilance liaison to be responsible for communicating with the other Party regarding

the reporting of adverse event and safety information associated with the Compound and Product.

4.2 <u>Launch and Marketing Efforts</u>. LICENSEE, its Affiliates or its sublicensees shall use Commercially Reasonable Efforts to launch and market the Product in the LICENSEE Territory.

4.3 <u>Coordination of Development Efforts.</u>

- 4.3.1 <u>Steering Committee</u>. MPC, LICENSEE and their respective Affiliates, agree to establish a Steering Committee on the Effective Date to facilitate the disclosure described in Article 3. The specific composition, role and responsibility of the Steering Committee, and details relating to meetings and decision-making, shall be negotiated in good faith in a separate agreement to be entered into between the Parties within thirty (30) days after the Effective Date.
- 4.3.2 <u>Development in the MPC Territory.</u> MPC shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Registration of Product in the MPC Territory. LICENSEE will be allowed to comment on development program for development of the Product in MPC Territory in the Steering Committee.
- 4.3.3 <u>Supply of the Bulk Drug Substance and Product for Development in the MPC Territory.</u> Upon the reasonable request from MPC, LICENSEE shall discuss in good faith with MPC terms and conditions under which LICENSEE would be willing to supply the Bulk Drug Substance and/or the Product to MPC, its Affiliates or its licensee for development in the MPC Territory. The price of such Bulk Drug Substance and/or the Product shall be equal to the amount of the Fully Burdened Manufacturing Cost plus two percent (2%). The detailed terms

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and conditions of such supply shall be discussed in good faith and agreed upon between the Parties.

4.4 <u>Supply of the Bulk Drug Substance and Product for Commercialization in the MPC Territory</u>. Upon the reasonable request from MPC, LICENSEE shall discuss in good faith with MPC terms and conditions under which LICENSEE would be willing to supply the Bulk Drug Substance and/or the Product to MPC, its Affiliate or its licensee for commercialization in the MPC Territory. The detailed terms and conditions of such supply (including supply price) shall be discussed in good faith and agreed upon between the Parties.

ARTICLE 5 PAYMENTS AND ROYALTIES

Initial License Fee. In consideration of the licenses granted by MPC to LICENSEE, LICENSEE shall pay to MPC the total amount of One Million United States Dollars (US\$1,000,000) as the initial license fee within thirty (30) days after the Effective Date. Further, in the event that LICENSEE, its Affiliate or its sublicensee commence the clinical development of the Product containing an Alternate Compound pursuant to Section 4.1.3.(a), LICENSEE shall pay to MPC the additional license fee set forth in Schedule 5.2(b) within thirty (30) days after the Onset of the first Phase I Study for such Alternate Compound; provided, however, that certain costs and expenses for certain preclinical pharmacological efficacy test of such Back-Up Compound agreed upon by MPC could be deducted from such additional license fee but any and all costs and expenses for certain preclinical pharmacological efficacy test of such Metabolite shall not be deducted from such additional license fee. If LICENSEE, its Affiliate or its sublicensee commence alternate Development Work of the Product containing a Back-Up Compound or Metabolite selected by LICENSEE as a back-up Compound pursuant to Section 4.1.3.(b), LICENSEE shall have no obligation to make such additional license fee payment with

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respect to the replacement Alternate Compound for which it commences Development Work after the discontinuation of the Development Work on the MT-210 Compound. For the avoidance of doubt, LICENSEE shall have no obligation to pay the additional licensee fee set forth in Schedule 5.2(b) for preclinical development work performed on or with an Alternate Compound. For the further avoidance of doubt, the initial license fee set forth in this Section 5.1 shall not be creditable against future milestone payments or royalties.

5.2 <u>Milestone Payments</u>.

5.2.1 <u>Milestone Payments</u>. In addition to the initial license fee, in consideration of the licenses granted by MPC to LICENSEE, LICENSEE, shall pay to MPC the milestone payments set forth in <u>Schedule 5.2(a)</u> for Product containing the MT-210 Compound. Further, in the event that LICENSEE, its Affiliates or sublicensees clinically develop and commercialize the Product containing an Alternate Compound in LICENSEE Territory pursuant to Section 4.1.3.(a), in consideration of the licenses granted by MPC to LICENSEE, LICENSEE shall pay to MPC the milestone payments set forth in <u>Schedule 5.2(b)</u>. If LICENSEE, its Affiliates or sublicensees clinically develop and commercialize the Product containing a Back-Up Compound or Metabolite selected by LICENSEE as a back-up Compound pursuant to Section 4.1.3.(b) and has made any of the milestone payments set forth in <u>Schedule 5.2(a)</u> for the Product containing the MT-210 Compound, then LICENSEE shall not have to make the same milestone payments for the substituted Product containing such back-up Compound set forth in <u>Schedule 5.2(b)</u>. For example, if LICENSEE, its Affiliates or sublicensees discontinues Development Work

that it develops to replace the Product containing MT-210 Compound unless and until there is an Onset of a Phase III Study utilizing the Product containing such back-up Compound.

5.2.2 Reports and Payments. The milestone payments shall be made no more than once with respect to the achievement of each milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such milestones (but payable on the first achievement of such milestone). LICENSEE shall notify MPC in writing within thirty (30) days after the achievement of the milestones specified on Schedule 5.2 and each such notice shall be accompanied by the appropriate milestone payment. For the avoidance of doubt, the milestone payments pursuant to this Section 5.2 shall not be creditable against future milestone payments or royalties.

5.3 <u>Royalties Payable by LICENSEE</u>.

5.3.1 In addition, in consideration of the licenses granted by MPC to LICENSEE herein, LICENSEE shall pay to MPC a royalty on Net Sales in each Royalty Year in the LICENSEE Territory, on a Product-by-Product, as follows:

Annual Net Sales in the LICENSEE Territory		Royalty Rate
[*]		[*]
[*]		[*]
[*]		[*]
[*]		[*]
	("M" means "million".)	

As an example, for Net Sales of [*] in the LICENSEE Territory, the royalties payable by LICENSEE to MPC will represent [*].

5.3.2 Royalties set forth in this Section 5.3 shall accrue from the date of Launch of Product in each country and shall continue and accrue on Net Sales until the end of the Royalty Period in such country.

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- 5.3.3 One Royalty. No more than one royalty payment shall be due with respect to a sale of a particular Product. No multiple royalties shall be payable because any Product, or its manufacture, sale or use is covered by more than one Valid Claim. No royalty shall be payable under this Section 5.3 with respect to sales of the Products among LICENSEE and its Affiliates or sublicensees for resale, nor shall a royalty be payable under this Section 5.3 with respect to the Products distributed for use in research and/or development, in clinical trials, as donations to non-profit institutions or government agencies or as promotional free samples.
- 5.3.4 <u>Generic Competition</u>. At any time after Generic Competition exists in a country of the LICENSEE Territory, in each Calendar Quarter during the Royalty Period, Net Sales from such country shall be reduced by [*] before including same into Net Sales in all countries in the LICENSEE Territory for the purpose of calculating the applicable royalty rates set forth in Section 5.3.1.
- 5.4 Third Party's New Formulation Technology. LICENSEE may, at its discretion, introduce any third party formulation technology for the development and commercialization of the Product. LICENSEE shall bear the costs and expenses for the development of such third party new formulation technology. If MPC becomes interested in the Product using such third party's new formulation technology, LICENSEE, to the extent it has the right and ability to do so, shall provide MPC with any and all data and information with regard to such third party's new formulation technology (hereinafter referred to as "Third Party Technology") as a part of the LICENSEE Intellectual Property. Further, if MPC decides to develop and commercialize the Product in MPC Territory using such Third Party Technology, LICENSEE, to the extent it has the right and ability to do so, shall grant or have such third party granted MPC to make, have made, use, sell, offer for sale, have sold and import the Product in MPC Territory using such

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Third Party Technology as a part of the LICENSEE Intellectual Property. In such case, in consideration of the license granted to MPC herein, MPC shall pay to such third party royalties for commercialization of the Product using such Third Party Technology in the MPC Territory which rate is equivalent to the royalties for such license granted to LICENSEE.

Reports. During the Royalty Period, LICENSEE shall furnish to MPC a written report for the Calendar Quarter showing, on a country by country and Product by Product basis, (a) the gross sales of all Products sold by LICENSEE and its Affiliates and sublicensees during such Calendar Quarter, (b) the Net Sales, (c) the royalties, payable in United States Dollars, which shall have accrued hereunder based upon Net Sales of Products, (d) the withholding taxes, if any, required by law to be deducted in respect of such royalties, (e) the date of the Launch of each Product in each country in the LICENSEE Territory and (f) the exchange rates used in determining the amount of United States Dollars, as more specifically provided in Section 7.2. Reports shall be due sixty (60) days following the close of each Calendar Quarter. LICENSEE shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined in accordance with Section 6.2.

6.2 Audit.

6.2.1 Audit Rights. Upon the reasonable written request of MPC and not more than once in each Calendar Year, LICENSEE shall permit MPC and/or an independent certified public accounting firm of nationally recognized standing, selected by MPC and reasonably acceptable to LICENSEE, at MPC's expense, to have access during normal business hours on at least ten (10) days' prior written notice, to such of the records of LICENSEE and its Affiliates as

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may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request; provided that MPC shall not be entitled to audit the same period of time more than once.

- 6.2.2 Audit Results. If such accounting firm concludes that additional royalties were owed during such period, LICENSEE shall remit to MPC within thirty (30) days of the date MPC delivers to LICENSEE such accounting firm's written report so concluding: (a) the amount of such additional royalties; and (b) interest on the amounts overdue of such underpayment which shall be calculated pursuant to Section 7.4. In the event such accounting firm concludes that amounts were overpaid by LICENSEE during such period, LICENSEE shall have a credit against future royalties payable to MPC in the amount of such overpayment; provided, however, that LICENSEE may have an independent certified public accounting firm of nationally recognized standing, selected by LICENSEE and reasonably acceptable to MPC, at LICENSEE's expense, confirm the results of the audit conducted by MPC's accounting firm. The fees charged by MPC's accounting firm shall be paid by MPC; provided, however, if an error in favor of MPC of more than five percent (5%) of the royalties due hereunder for the period being reviewed is discovered, then LICENSEE shall pay the reasonable fees and expenses charged by such accounting firm.
- 6.2.3 <u>Confidential Financial Information</u>. MPC shall treat all financial information subject to review under this Article 6 as confidential, and shall cause its accounting firm to retain all such financial information in confidence.

ARTICLE 7 PAYMENTS

7.1 <u>Payments Terms</u>. Royalties shown to have accrued by each royalty report provided for under Section 6.1 shall be due and payable on the date such royalty report is due.

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- 7.2 <u>Payment Method</u>. All payments by LICENSEE to MPC under this Agreement shall be paid in United States Dollars. If any currency conversion shall be required in connection with the payment of any royalties hereunder, such conversion shall be made by using the average of the exchange rates for the purchase and sale of United States Dollars reported by the Bank of Tokyo Mitsubishi UFJ on the last business day of the Calendar Quarter to which such royalty payments relate.
- 7.3 <u>Exchange Control</u>. If at any time legal restrictions prevent the prompt remittance of part or all of the royalties with respect to any country in the LICENSEE Territory where the Product is sold, LICENSEE shall have the right, at its option, to make such payments by depositing the amount thereof in local currency to MPC's account in a bank or other depository designated by MPC in such country.
- 7.4 Overdue Payments. In the event the initial payment, any milestone payment or any royalty payment is not made when due, such outstanding payment shall accrue interest (from the date such payments is due through and including the date upon which full payment is made) at the annual rate of [*].
- 7.5 <u>Withholding Taxes</u>. LICENSEE shall be entitled to deduct from any payment due MPC under this Agreement the amount of any withholding taxes payable by LICENSEE or its Affiliates, or any taxes required to be withheld by LICENSEE or its Affiliates, to the extent LICENSEE or its Affiliates pay to the appropriate governmental authority on behalf of MPC such taxes, levies or charges. LICENSEE shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of MPC by LICENSEE or its Affiliates. LICENSEE promptly shall deliver to MPC proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental

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authority with respect thereto. Upon reasonable request from MPC, LICENSEE shall cooperate with MPC to supply forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit.

ARTICLE 8 CONFIDENTIALITY

- 8.1 <u>Nondisclosure Obligations</u>. Except as otherwise provided in this Article 8, during the term of this Agreement and for a period of five (5) years thereafter, both Parties shall maintain in confidence and use only for purposes of this Agreement the Proprietary Information supplied by the other Party.
- 8.2 Permitted Disclosures. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, a Party (including its Affiliates and sublicensees) may disclose Proprietary Information of the other Party which it is otherwise obligated under this Article 8 not to disclose (a) to its Affiliates, its sublicensees, its consultants, outside contractors and clinical investigators, on a need-to-know basis on condition that such Persons agree to keep the Proprietary Information confidential for the same time periods and to the same extent as such Party is required to keep the Proprietary Information confidential; and (b) to government or other regulatory authorities to the extent that such disclosure is required by applicable law (including without limitation all applicable securities laws), regulation, agency or court order, or is reasonably necessary to obtain patents or authorizations to conduct clinical trials with, and to commercially market the Product, provided that, with respect to clause (b) the disclosing Party shall provide written notice to the other Party and sufficient opportunity to object to such disclosure or to request confidential treatment thereof. The obligation not to disclose or use Proprietary Information received from the other Party shall not apply to any part of such Proprietary Information that (i) is or becomes patented, published or otherwise part of the

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public domain other than by acts of the Party obligated not to disclose such Proprietary Information in contravention of this Agreement; (ii) is disclosed to the receiving Party by a Third Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party on a confidential basis; (iii) prior to disclosure under this Agreement, was already in the possession of the receiving Party, provided such Proprietary Information was not obtained directly or indirectly from the other Party; (iv) is subsequently and independently developed by the receiving Party without the knowledge of the Proprietary Information or (v) is disclosed in a press release agreed to by both Parties, which agreement shall not be unreasonably withheld.

- 8.3 <u>SEC Filings</u>. The Parties will consult with each other on the provisions of this Agreement to be redacted in filings, if any, made by the Parties with the Securities and Exchange Commission or as otherwise required by law. The Parties agree that either Party may make such disclosures pursuant to Form 8-K or otherwise as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure, with the prior written consent by the other Party. The Parties shall consult with one another before any such filing, and shall seek protection for any Proprietary Information (including any terms and conditions of this Agreement).
 - 8.4 Press Release and Publication.
- 8.4.1 <u>Press Release</u>. In the event that either Party desires to issue a press release relating to this Agreement, the Parties shall discuss in good faith and agree upon the contents and timing of such press release.
- 8.4.2 <u>Scientific Publication</u>. In the event that LICENSEE, its Affiliate or its sublicensee(s) is willing, required or obliged to make any publication in a scientific journal or at

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the conference in any academic society on the information obtained from its Development Work on the Compound and/or the Product, LICENSEE, to the extent LICENSEE has a right to review any such publication or presentation, shall endeavor in good faith to submit to MPC the full text of such publication, at least thirty (30) days before the date of such publication and to consult with MPC and to solicit comments with respect to such publication or presentation; provided, however, that MPC shall not prevent LICENSEE from complying with regulatory requirements.

ARTICLE 9 INTELLECTUAL PROPERTY

9.1 Ownership of Improvements. Each Party shall solely own, and such Party alone shall have the right to apply for, any patents within and outside its Territory for any improvements made solely by such Party's employees in the course of the performance of any work under this Agreement. Improvements made jointly by employees of MPC and LICENSEE, its Affiliates or its sublicensees shall be owned jointly by MPC and LICENSEE, its Affiliates or its sublicensees and shall be included in the licenses described in Article 2 hereof.

9.2 <u>Patents Prosecution and Maintenance</u>.

9.2.1 MPC Patents. MPC shall have the initial right to control the filing, prosecution and maintenance of the MPC Patents in the LICENSEE Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the MPC Patents in the LICENSEE Territory. MPC shall be responsible for the payment of all such patent prosecution and maintenance costs of the MPC Patents in the Major Countries and LICENSEE shall be responsible for the payment of all such patent prosecution and maintenance costs of the MPC Patents in the remaining

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LICENSEE Territory and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and MPC takes into account LICENSEE's reasonable comments related thereto. MPC, taking such LICENSEE's request into consideration but at its sole discretion, shall file patent claims related to the Compound or Product proposed by LICENSEE in any MPC Patent or a continuation or divisional of the foregoing. MPC shall inform LICENSEE of any significant developments in the prosecution of pending patent applications included in the MPC Patents in the LICENSEE Territory, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If MPC decides not to file, prosecute or maintain a MPC Patent in any country in the LICENSEE Territory, MPC shall provide LICENSEE with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) days notice), and LICENSEE shall have the right but not the obligation, at its sole expense, to file, prosecute or maintain such MPC Patent in such country, and MPC shall assign to LICENSEE a right, title and interest in and to such MPC Patent in such country and such MPC Patent shall no longer be deemed MPC Patent.

9.2.2 <u>LICENSEE Patents</u>. LICENSEE shall have the right to control the filing, prosecution, and maintenance of the LICENSEE Patents in the respective Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the LICENSEE Patents. LICENSEE shall be responsible for the payment of all such patent prosecution and maintenance costs. LICENSEE shall solicit MPC's review of the nature and text of any such patent applications in the MPC Territory and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and LICENSEE shall take into account MPC's reasonable comments related thereto. LICENSEE shall inform MPC of any

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significant developments in the prosecution of pending patent applications included in the LICENSEE Patents in the MPC Territory, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If LICENSEE decides not to file, prosecute or maintain a Patent Right included in the LICENSEE Patents in any country in the MPC Territory, it shall provide MPC with written advance notice sufficient to avoid any loss or forfeiture (but in any event at least sixty (60) days notice), and MPC shall have the right but not the obligation, at its sole expense, to file, prosecute or maintain such LICENSEE Patent in such country, and LICENSEE shall assign to MPC a right, title and interest in and to such LICENSEE Patent in such country and such LICENSEE Patent shall no longer be deemed LICENSEE Patent.

9.3 <u>Cooperation</u>. Each Party shall make available as far as possible to the other Party or to the other Party's authorized attorneys, agents, representatives, employees or consultants any documents necessary or appropriate to enable the other Party to file, prosecute and maintain patent applications and resulting patents, as set forth in Section 9.2, for a period of time sufficient for the other Party to obtain the assistance it needs from the first Party. Where appropriate, each Party shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other Party.

9.4 <u>Enforcement of Patents</u>.

9.4.1 <u>Excluding Action</u>. Each of the Parties shall notify the other of any activity or product which it reasonably believes constitutes an infringement or misappropriation of the MPC Patents or MPC Know-How in the LICENSEE Territory or of any claim of invalidity in respect of a MPC Patent. LICENSEE shall have the right, in the first instance, to enforce the MPC Patents against such infringing technology or to defend any such claim of invalidity within

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the LICENSEE Territory. In the event LICENSEE declines to prosecute such infringing technology or to defend such claim within ninety (90) days (or twenty-one (21) days from the receipt of paragraph IV certificate or aware of the ANDA application) of becoming aware thereof, MPC shall have the right to so enforce or defend. The Parties agree that the costs of such prosecution or defense of validity, in connection with an infringement in the LICENSEE Territory shall be borne by the Party who prosecutes or defends the action.

- 9.4.2 <u>Settlements, Allocation of Monetary Award</u>. The Party controlling the action may not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, MPC and LICENSEE shall cooperate with each other in the planning and execution of any action to enforce the MPC Patents. Any recovery and proceeds of any awards, judgments or settlements obtained by LICENSEE or MPC shall be shared as follows, whether the recovery is by settlement or otherwise:
- (a) the enforcing or defending Party shall first be entitled to recoup all of its out-of-pocket costs and expenses (including reasonable attorneys' fees) incurred in connection with the action;
- (b) the other Party, if joined or cooperating in the action, shall then be entitled to recover its out-of-pocket costs and expenses (including reasonable attorneys' fees) incurred in connection with the action, not already reimbursed by the enforcing or defending Party;

- (c) any recovery remaining shall be allocated between the Parties on a pro rata basis based upon the respective lost profits of the Parties as a result of the infringing activities, which allocation ratio shall be separately agreed upon in writing by the Parties.
- 9.4.3 Each Party agrees to furnish the other with such cooperation, including consenting to act as a Party to litigation if required, and exchange of information as the other Party may reasonably request in connection with the prosecution of any such action and the Party prosecuting an infringement or defending a claim of invalidity shall consult periodically with the other Party in connection with any such action. Neither Party shall take any action which would admit the invalidity of a MPC Patent without the consent of the other Party, which consent shall not be unreasonably withheld.
- 9.5 Patent Term Restoration. The Parties, their Affiliates or their sublicensees shall cooperate with each other, execute all documents and take all actions that may be necessary to pursue patent term extensions, supplemental protection certificates or their future equivalents applicable to the LICENSEE Patents or the MPC Patents, under appropriate laws and/or regulations in the LICENSEE Territory and/or MPC Territory. MPC and LICENSEE shall discuss and determine which patents shall be extended in respective Territory. All filings for such patent term extension or supplemental protection certificates shall be made by the Party who owns the patent at its sole cost and expense.
- 9.6 <u>Infringement of Third Party Rights.</u> LICENSEE or its Affiliate shall promptly notify MPC in writing of any allegation by a Third Party that the manufacture, development, importation, use, offer for sale or sale of a Compound or Product covered by the MPC Intellectual Property, infringes or may infringe the intellectual property rights of such Third Party in any country of the LICENSEE Territory. LICENSEE or its Affiliate or sublicensee shall

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have the first right to control the defense of any claim alleging that the manufacture, development, importation, use, offer for sale or sale of such Compound or Product in the LICENSEE Territory infringes any such Third Party rights or may settle on terms that it deems advisable in its sole discretion, provided that any final disposition of the litigation that will restrict the claims in or admit any invalidity of any MPC Patent shall not be made without full consultation with and approval by MPC, not to be unreasonably withheld. If LICENSEE or its Affiliate or sublicensee fails to proceed in a timely manner with respect to such defense, MPC shall have the right to control the defense of such claim. The Parties shall consult and cooperate fully to determine a course of action. If, finally, LICENSEE or its Affiliate or sublicensee is required by order or judgment of any court in any jurisdiction, or LICENSEE or its Affiliate or sublicensee in its sole discretion after having obtained an outside legal opinion, believes it necessary to obtain a license, obtains a license under such intellectual property right from such Third Party, and makes payments to such Third Party to avoid alleged infringement, then [*] of the royalty or other payments required to be paid by LICENSEE or its Affiliate or sublicensee to such Third Party as the result of a judgment or settlement under this Section 9.6 ("Third Party Payment") shall be creditable against the royalties payable to MPC be reduced to less than [*] of the amount due under this Agreement, and provided further any remaining portion the [*] of the Third Party Payment not credited pursuant to this Section 9.6 may be carried over against the royalties payable to MPC for the subsequent period in which the royalties are due. Each Party shall have the right to participate in the defense of any such claim with counsel of its choice at its own expense.

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ARTICLE 10 TERM AND TERMINATION

10.1 <u>Expiration</u>. This Agreement shall come into effect on the Effective Date and, unless earlier terminated, shall continue in effect until the expiration of LICENSEE's obligations to pay royalties. After the expiration of this Agreement, on a country-by-country basis, in such country in the Territory, LICENSEE will have a fully paid-up, non-exclusive, perpetual, irrevocable license, with the right to grant and authorize sublicenses, with respect to the MPC Patents and MPC Know-How in such country in the LICENSEE Territory or in the case of the manufacture of Compound, anywhere in the world for the purpose of manufacturing the Product to be sold in the LICENSEE Territory.

10.2 <u>Termination for Cause</u>.

- 10.2.1 Either Party may terminate this Agreement upon or after the breach of any material provision of this Agreement by the other Party, if the breaching Party has not cured such breach within sixty (60) days after notice thereof from the non-breaching Party. This Agreement shall terminate, at the option of the non-breaching Party, at the expiration of such sixty (60) day cure period; provided, however, that if the breach is not capable of being cured within sixty (60) days of such written notice, this Agreement may not be terminated so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable.
- 10.2.2 Either Party may terminate this Agreement upon giving notice to the other Party, which termination notice shall have immediate effect, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against the other Party.

- 10.2.3 Notwithstanding anything to the contrary contained in Section 10.2.1, 10.2.2 or 13.2, in the event that MPC is entitled to terminate this Agreement pursuant to Section 10.2.1 or 10.2.2, prior to exercising such termination right, MPC shall offer LICENSEE's sublicensees the ability to assume LICENSEE's rights and obligations under this Agreement and to continue this Agreement in full force and effect between MPC and such sublicensee.
- Other LICENSEE Termination. In the event that LICENSEE believes that (1) certain data and information with regard to safety or efficacy of the Compound or Product obtained through the Development Work does not justify continued development of the Product by LICENSEE, its Affiliate and/or sublicensee or (2) LICENSEE believes that commercial considerations or other factors for marketing of the Product do not justify continued development, commercialization or marketing of the Product by LICENSEE, its Affiliate and/or its sublicensees, LICENSEE may terminate this Agreement in its sole discretion at any time during the term hereof in its entirety, or on a country-by-country, Compound-by-Compound or Product-by-Product basis (a) on not less than ninety (90) days prior written notice to MPC if such termination occurs prior to Launch of such Product in such country, or (b) on not less than one hundred eighty (180) days prior written notice to MPC if such termination occurs after the Launch of such Product in such country, informing MPC of and discussing with MPC the reasonable reason for which it is terminating all or part of this Agreement; provided however that if LICENSEE desires to terminate this Agreement in the cases safety problems caused by prolongation of heart repolarisation as measured by the QTc, LICENSEE shall explain MPC the reasonable reason why such safety problems could not be avoided despite of LICENSEE's clinical development plan to decrease the risk of such safety problems. In which case LICENSEE's obligation to perform any further work under this Agreement shall cease in such

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country or for such Compound or for such Product as of the date of the end of the period set forth in Section 10.3.(a) or 10.3.(b).

- Effect of Expiration and Termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing on or prior to such expiration or termination. LICENSEE and its Affiliates and sublicensees shall have the right to sell or otherwise dispose of the stock of any Product subject to this Agreement then on hand or in process of manufacture, subject to Articles 5, 6 and 7. In addition to any other provisions of this Agreement which shall by their terms continue after the expiration of this Agreement, the provisions of Article 8 shall survive the expiration or termination of this Agreement and shall continue in effect during the term set forth in Section 8.1. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.
- 10.5 Effect of Termination Without MPC's Cause. In the event that this Agreement shall be terminated by MPC pursuant to Section 4.1.5, 10.2 or by LICENSEE pursuant to Section 10.3, LICENSEE or its Affiliate shall return to MPC all written MPC Know-How and all copies thereof and furnish MPC with all of LICENSEE, its Affiliates or its sublicensee Know-How not already provided to MPC with a royalty-free worldwide right to use all LICENSEE Patents and LICENSEE Know-How. LICENSEE or its Affiliate shall further transfer free of charge to MPC or its nominee any IND, Application or other documents filed with any government agency in

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LICENSEE Territory and any Registration obtained in LICENSEE Territory. LICENSEE shall, at the request of MPC, cooperate with MPC or its nominee for the smooth transfer of them.

ARTICLE 11 REPRESENTATIONS AND WARRANTIES

- 11.1 <u>Mutual Representations</u>. The Parties hereby represent and warrant as follows:
- 11.1.1 <u>Corporate Existence and Power</u>. Such Party (a) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is incorporated, and (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted;
- 11.1.2 <u>Authorization and Enforcement of Obligations</u>. Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;
- 11.1.3 Consents. All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained; and

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- 11.2 <u>Representations and Warranties of MPC</u>. MPC additionally represents and warrants to LICENSEE as of the Effective Date that:
- 11.2.1 the MPC Intellectual Property is owned or controlled by MPC free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental or university entity or subdivision thereof, has any valid claim of ownership with respect to the MPC Intellectual Property, whatsoever;
- 11.2.2 MPC has not previously granted, and will not grant during the term of this Agreement, any right, license or interest in and to the MPC Intellectual Property, or any portion thereof, inconsistent with the licenses granted to LICENSEE herein;
- 11.2.3 MPC does not have any knowledge of the existence of any references or conduct that would bring into question the validity or enforceability of the MPC Intellectual Property in the Field;
- 11.2.4 there are no pending or, to the knowledge of MPC, threatened actions, suits, investigations, claims or proceedings in any way relating to the MPC Intellectual Property;
- 11.2.5 MPC has disclosed to FORENAP or LICENSEE all material scientific and technical information known to MPC or its Affiliates relating to the safety and efficacy of the MT-210 Compound and Product containing the MT-210 Compound;
- 11.2.6 MPC has disclosed to FORENAP or LICENSEE all information which MPC reasonably considers necessary for LICENSEE to file an IND with the FDA;
- 11.2.7 <u>Schedule 1.36</u> contains a complete and accurate list of all Patents relating to the MT-210 Compound or the Product containing the MT-210 Compound owned or controlled by MPC in the LICENSEE Territory;

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- 11.2.8 to the knowledge of MPC, the patents encompassed within the MPC Patents, are, or, upon issuance, will be, valid and enforceable patents.
- 11.2.9 to the knowledge of MPC, the manufacture, use, sale, offer for sale, supply or importation by LICENSEE (or its Affiliates or sublicensees) of the MT-210 Compound or Product containing the MT-210 Compound does not and will not infringe any issued patent of any Third Party or, if and when issued, any claim within any published patent application of any Third Party;
- 11.2.10 MPC has heretofore disclosed to LICENSEE or FORENAP, all material filings, notices, reports and other correspondence and contact information between MPC and the FDA or any other regulatory authority regarding the MT-210 Compound or the Product containing the MT-210 Compound;
- 11.2.11 Schedule 11.2.11 sets forth a complete and accurate listing of all pre-clinical and clinical studies and trials, together with the dates and titles of such studies and trials, previously or currently undertaken or sponsored by MPC or its Affiliates with respect to the Compounds and Products. True, complete and accurate copies of all data and reports with respect to the studies and trials listed on Schedule 11.2.11 have been provided for review to LICENSEE or FORENAP, and MPC has otherwise provided for review to LICENSEE or FORENAP all material preclinical and clinical studies and trials of all Compounds and Products; and
- 11.2.12 MT-210 Compound and Product containing the MT-210 Compound are being developed, manufactured, stored, labeled, distributed and tested by MPC or its Affiliates or any Third Party acting on behalf of MPC in compliance in all applicable laws, rules and regulations at that time.

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- 11.3 Representations of LICENSEE. LICENSEE additionally represents and warrants to MPC that:
 - 11.3.1 LICENSEE is a corporation duly organized and validly existing and in good standing under the laws of the State of Delaware,

- 11.3.2 upon request by LICENSEE, LICENSEE will be funded in accordance with the terms and conditions of a Securities Purchase Agreement by and among Care Capital, LLC, Index Ventures (or other respective Affiliates) and the LICENSEE, a copy of which is attached as Schedule 11.3.2; and
- 11.3.3 LICENSEE has an ability to conduct the Development Work and to prepare the Development Plan in consultation with FORENAP.
- 11.4 <u>Disclaimer of Representations</u>. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF ANY PATENTS ISSUED OR PENDING.

ARTICLE 12 INDEMNIFICATION

12.1 <u>LICENSEE's Obligation</u>. LICENSEE shall defend, indemnify, and hold harmless MPC, its Affiliates and their respective directors, officers, shareholders, employees and agents ("MPC Indemnitees"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, but not limited to reasonable attorney's fees (collectively "MPC Damages") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against an MPC Indemnitee that is due to or based upon:

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- 12.1.1 any breach of a representation, warranty, covenant or agreement of LICENSEE under this Agreement,
- 12.1.2 any negligent or more culpable act of LICENSEE, its Affiliates or its sublicensees under this Agreement, or
- 12.1.3 development, manufacture, use, sale or labeling of Compound, Bulk Drug Substance or Product by LICENSEE, its Affiliates or its sublicensees.

However, LICENSEE shall not indemnify or hold harmless MPC Indemnitees from MPC Damages to the extent that such MPC Damages are finally determined to have resulted from an item for which MPC is obligated to indemnify LICENSEE pursuant to Section 12.2. LICENSEE's obligations under this Section shall survive the expiration or termination of this Agreement for any reason.

- MPC's Obligation. MPC shall defend, indemnify, and hold harmless LICENSEE, its Affiliates and their respective directors, officers, shareholders, employees and agents ("LICENSEE Indemnitees"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, but not limited to reasonable attorney's fees (collectively "LICENSEE Damages") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against an LICENSEE Indemnitee that is due to or based upon:
 - 12.2.1 any breach of a representation, warranty, covenant or agreement of MPC under this Agreement,
 - 12.2.2 any negligent or more culpable act of MPC, its Affiliates or its sublicensees under this Agreement; or

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12.2.3 development, manufacture, use, sale or labeling of Compound, Bulk Drug Substance or Product by MPC, its Affiliates or its sublicensees.

However, MPC shall not indemnify or hold harmless LICENSEE Indemnitees from LICENSEE Damages to the extent that such LICENSEE Damages are finally determined to have resulted from an item for which LICENSEE is obligated to indemnify MPC pursuant to Section 12.1. MPC's obligations under this Section shall survive the expiration or termination of this Agreement for any reason.

12.3 <u>Insurance</u>. LICENSEE, its Affiliates and/or its sublicensees shall maintain and keep in force for the term of this Agreement comprehensive general liability insurance including Products/Completed Operations, Contractual and Broad Form Property Damage covering its indemnification obligations hereunder combined single limit for Bodily Injury and Property Damage. It is understood that such insurance shall not be construed to limit LICENSEE's liability with respect to such indemnification obligations.

ARTICLE 13 MISCELLANEOUS

13.1 <u>Force Majeure</u>. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, power shortage or failure, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party.

- 13.2 <u>Assignment</u>. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned or transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either MPC or LICENSEE may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger or consolidation or change in control or similar transaction. Any permitted assignee shall assume all obligations of its assignor under this Agreement.
- 13.3 Severability. Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In case such provisions cannot be agreed upon, the invalidity of one or several provisions of the Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without such invalid provisions.
- 13.4 <u>Notices</u>. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered personally

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or by facsimile (and promptly confirmed by personal delivery, first class mail or courier), first class mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated in the Section 13.4, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

To MPC: Mitsubishi Pharma Corporation

2-6, Nihonbashi-Honcho 2-chome, Chuo-ku, Tokyo 103-8405,

Japan

Attn: Head of Corporate Licensing Department

Fax: +81-3-3241-4913 Phone: +81-3-3241-4524

To LICENSEE: Cyrenaic Pharmaceuticals, Inc.

47 Hulfish Street Suite 310

Princeton NJ 08542 United States of America Attn: Jerry Karabelas Fax: 001-609-683-5787 Phone: 001-609-683-3662

With a copy to: Cyrenaic Pharmaceuticals, Inc.

47 Hulfish Street

Suite 310

Princeton NJ 08542 United States of America Attn: Lorenzo Pellegrini Fax: 001-609-683-5787 Phone: 001-609-683-3677

And with a copy to: Index Ventures

2 rue Jargonnant 1207 Genève Switzerland

Attn: Michèle Ollier Fax: 0041-22-737-0099 Phone: 0041-22-737-0026

13.5 <u>Applicable Law</u>. This Agreement shall be governed by and construed in accordance with the laws of New York, the U.S. without regard to the conflicts of law principles

thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Right in question.

13.6 <u>Dispute Resolution</u>.

13.6.1 The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a "Dispute") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) business days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) business days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers are unable to settle the Dispute between themselves within twenty (20) business days, they shall so report to the Parties in writing. The Dispute shall then be referred to mediation as set forth in the Section 13.6.2.

13.6.2 Upon the Parties receiving the Chief Executive Officers' report that the Dispute referred to them pursuant to Section 13.6.1 has not been resolved, a Party shall decide to institute arbitration proceedings, it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be governed by the rules of Conciliation and Arbitration of the International Chamber of Commerce ("ICC") then in force. Each such arbitration shall be conducted by a panel of three arbitrators: one arbitrator shall be appointed by each of LICENSEE and MPC and the third arbitrator, who shall be the Chairman of

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the tribunal, shall be appointed by the two-Party appointed arbitrators. Any such arbitration shall be held in London, England or such other place as may be mutually agreed upon in writing by the Parties. The language of the arbitration shall be English.

- 13.6.3 The tribunal shall issue its award within forty-five (45) days after the date on which the arbitration proceedings have closed. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the ICC.
- 13.7 <u>Competing Product</u>. LICENSEE or its Affiliate to whom it sublicenses its rights under this Agreement, shall not market or sell any Competing Product as long as the Compound is either an active development candidate or the Product is being marketed.
- 13.8 <u>LIMITATION OF LIABILITY</u>. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY EXCEPT TO THE EXTENT OF ANY SUCH DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A CLAIM MADE BY SUCH PARTY FOR WHICH A PARTY IS RESPONSIBLE TO INDEMNIFY THE OTHER PARTY PURSUANT TO SECTION 12.1 OR 12.2.

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- 13.9 <u>Further Assurances</u>. At any time or from time to time on and after the date of this Agreement, each Party shall at the request of the other (i) deliver to the other such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as such Party may reasonably deem necessary or desirable in order for the other Party to obtain the full benefits of this Agreement and the transactions contemplated herein.
- 13.10 <u>Entire Agreement</u>. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.
- 13.11 <u>Headings</u>. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.
- 13.12 <u>Independent Contractors</u>. It is expressly agreed that MPC and LICENSEE shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MPC nor LICENSEE shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.
- 13.13 <u>Waiver</u>. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right

A request for confidential tre been filed separately with th		ect to portions of the following document that are marked with [*]. The redacted portions have				
hereunder or of any other bro	hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.					
	urts. This Agreement may be executed the shall constitute one and the	cuted in two or more counterparts (including by facsimile), each of which shall be deemed an e same instrument.				
		[Signature Page Follows]				
		58				
A request for confidential tre been filed separately with th		ect to portions of the following document that are marked with [*]. The redacted portions have				
IN WITNESS WHI	EREOF, the Parties have executed	d this Agreement as of the Effective Date.				
Cyrenaic Pharmaceuticals, In	nc.					
By: /s/ Argeris N. Karabela	as, Ph.D.					
Name: Argeris (Jerry) N. Ka	rabelas, Ph.D.					
Title: Officer and Director						
Mitsubishi Pharma Corporat	ion					
By: /s/ Takeshi Komine						
Name: Takeshi Komine						
Title: President						
		59				
A request for confidential tre been filed separately with th		ect to portions of the following document that are marked with [*]. The redacted portions have				
Schedule 1.5: Chemical Stru	cture of compound coded as BFI	3-484				
BFB-484:	[*]					
		60				
A request for confidential tre been filed separately with th		ect to portions of the following document that are marked with [*]. The redacted portions have				
Schedule 1.13: Chemical Str	ructure of MT-210 Compound					
MT-210:	[*]					

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Schedule 1.15: Development Plan

Schedule 1.18: Chemical Structure of compounds coded as BFB-687, BFB-512 and BFB-462

BFB-687: [*]

BFB-512: [*]

BFB-462: [*]

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A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

Schedule 1.33: Chemical Structure of Metabolites

BFB-520 (M1) [*]

BFB-999 (M2) [*]

M3 [*]

M4 [*]

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Schedule 1.36: MPC Patents

Patent List on MT-210

Up Date: 21 June, 2007

Novel Cyclic Amide Derivatives

- "Basic patent": Claims include MT-210

Filling Countries	Filling No.	Filling Date	Publication No.	Patent No.	Status	Expiration Date	Assignee
[*]	[*]	[*]	[*]	[*]	[*]	[*]	
[*]	[*]	[*]	[*]		[*]	[*]	
[*]	[*]	[*]	[*]			[*]	
[*]	[*]	[*]				[*]	
[*]	[*]	[*]				[*]	
[*]	[*]	[*]	[*]			[*]	
[*]	[*]	[*]				[*]	MPC
[*]	[*]	[*]	[*]	[*]	[*]	[*]	
[*]	[*]	[*]	[*]	[*]	[*]	[*]	
[*]	[*]	[*]	[*]	[*]	[*]	[*]	
[*]	[*]	[*]	[*]			[*]	
[*]	[*]	[*]		[*]	[*]	[*]	
[*]	[*]	[*]	[*]			[*]	
[*]	[*]	[*]	[*]			[*]	
				65			

A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

Schedule 4.1.1: Services Agreement

Schedule 5.2: Milestone payments

(a) Milestone payments for the Product containing the MT-210 Compound

	TT:	Second	mi . 1 . 1
	First indication	indication	Third indication
Onset of Phase II(a) Study	[*]		
Onset of Phase II(b) Study	[*]		
Onset of Phase II Study	[*]	[*]	[*]
Onset of Phase III Study	[*]	[*]	[*]
Application in the U.S.	[*]	[*]	[*]
Application in the first European Country	[*]	[*]	[*]
Launch in the U.S.	[*]	[*]	[*]
Launch in the first European Country	[*]	[*]	[*]
When cumulative Net Sales first reach [*]		[*]	

(b) Subject to Sections 5.1 and 5.2, additional License Fee and Milestone payments for the Product containing each Alternate Compound

	First indication	Second indication	Third indication
Additional License Fee	[*]		
Onset of Phase II(a) Study	[*]		
Onset of Phase II(b) Study	[*]		
Onset of Phase II Study		[*]	[*]
Onset of Phase III Study	[*]	[*]	[*]
Application in the U.S.	[*]	[*]	[*]
Application in the first European Country	[*]	[*]	[*]
Launch in the U.S.	[*]	[*]	[*]
Launch in the first European Country	[*]	[*]	[*]
When cumulative Net Sales first reach [*]		[*]	

A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

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Schedule 11.2.10: List of all pre-clinical and clinical studies and trials

Mitsubishi Reference	Study Report Title	Facility	Study Number	Report Number	QA	GLP	Status	IND SN#	IB (Ver. 1.0 Reference)	IB (Ver. 2.0 Reference)	IB (Ver. 3.1Reference)
						[*]					
						68					

A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

Schedule 11.3.2: Securities Purchase Agreement

AMENDMENT TO LICENSE AGREEMENT

This Amendment dated as of 16th June, 2011 is entered into between Cyrenaic Pharmaceuticals, Inc., a Delaware corporation, having a place of business located at 47 Hulfish Street, Suite 310 Princeton NJ 08542, U.S.A. ("LICENSEE") and Mitsubishi Tanabe Pharma Corporation, a Japanese corporation, having a place of business located at 6-18, Kitahama 2 Chome, Chuo-ku, Osaka 541-8505, Japan ("MTPC").

WITNESSETH:

WHEREAS, LICENSEE and Mitsubishi Pharma Corporation (a predecessor of MTPC) entered into LICENSE AGREEMENT relating to MT-210 dated as of August 30, 2007 ("LICENSE AGREEMENT"); and

WHEREAS, LICENSEE desires and MTPC agrees to modify the development diligence milestones set forth in Section 4.1.5 of the LICENSE AGREEMENT.

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

- 1. <u>Defined Words and Expressions.</u> Unless the context otherwise requires, all words and expressions defined in the LICENSE AGREEMENT shall have the same meanings in this Amendment.
- Amendment of the Development Diligence Milestone for Phase II (b) Study. Section 4.1.5(b) of the LICENSE AGREEMENT shall be amended to read as follows:
 - "(b) Onset of the first Phase II (b) Study by [*]."
- Increase of the Extension Payment. In consideration of the extension of the development diligence milestone for Phase II (b) Study set forth Section 2 above, the amount of the second Extension Payment shall be increased to [*]. Therefore, the third sentence of the last paragraph of Section 4.1.5 of the LICENSE AGREEMENT shall be amended to read as follows:

"LICENSEE will have the right to make an unlimited number of Extension Payments in conjunction with the development of Product containing the MT-210 or of a Product containing a Back-Up Compound pursuant to Section 4.1.3(b), provided that the payment amount will increase to [*] beginning with the second Extension Payment."

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A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

- Contents of Additional Evaluation. Immediately after the execution of this Amendment, LICENSEE shall provide MTPC with the plan and schedule of which LICENSEE intends to conduct its activities relating to the Compound and Product during the period from the execution date of this Amendment to
- Effective Date of This Amendment. Notwithstanding the actual date of the execution of this Amendment, this Amendment shall become effective as of March 20, 2011.
- Other Provisions. Save as amended by this Amendment, the terms of the LICENSE AGREEMENT shall remain in full forth and effect.

IN WITNESS WHEREOF, the parties have executed this Amendment as of the date first set forth above.

Cyrenaic Pharmaceuticals, Inc.

Mitsubishi Tanabe Pharma Corporation

/s/ A.N. Karabelas /s/ Seiichi Kiso Bv: Name: A.N. Karabelas Name: Seiichi Kiso Title: Chairman Title: General Manager

Executive Officer

Business Development & Licensing Department

SECOND AMENDMENT TO LICENSE AGREEMENT

This Second Amendment ("SECOND AMENDMENT") dated as of 20 January, 2014 ("AMENDMENT DATE") is entered into between Minerva Neurosciences, Inc. (F/K/A Cyrenaic Pharmaceuticals, Inc., a Delaware corporation, having a place of business located at 245 First Street, Suite 1800, Cambridge MA 02142, U.S.A. ("LICENSEE") and Mitsubishi Tanabe Pharma Corporation, a Japanese corporation, having a place of business located at 6-18, Kitahama 2 Chome, Chuo-ku, Osaka 541-8505, Japan ("MTPC").

WITNESSETH:

WHEREAS, LICENSEE and Mitsubishi Pharma Corporation (a predecessor of MTPC) entered into LICENSE AGREEMENT relating to MT-210 dated as of August 30, 2007 ("LICENSE AGREEMENT") and AMENDMENT TO THE LICENSE AGREEMENT dated as of 16th June, 2011; and

WHEREAS, LICENSEE desires to develop the Product containing MT-210 Compound for the therapy of schizophrenia with its priority, and LICENSEE and MTPC agrees to modify the terms and conditions of the LICENSE AGREEMENT in order that LICENSEE conducts the development by itself or together with a third party by way of sub-licensing on LICENSEE's own responsibility.

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

1. Defined Words and Expressions.

Unless the context otherwise requires, all words and expressions defined in the LICENSE AGREEMENT shall have the same meanings in this SECOND AMENDMENT.

2. Termination of First Amendment.

The AMENDMENT TO THE LICENSE AGREEMENT dated as of 16th June, 2011 between LICENSEE and MTPC shall be terminated at the time of execution of this SECOND AMENDMENT and shall no longer be in force and effect.

3. Amendment of Definition of Net Sales.

The definition of "Net Sales" is hereby amended to delete the reference to "sublicensees" such that except as set forth in Section 7 of this SECOND AMENDMENT, no royalties shall

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be paid on any Net Sales made by any Sublicensee (defined below); provided, however, that "Net Sales" of any Sublicensee shall be included for determining whether the Net Sales Milestone in Section 5.2.1(d) has been achieved.

4. Withdrawal of Right of First Negotiation.

MTPC agrees to withdraw its Right of First Negotiation set forth in Section 2.3 of the LICENSE AGREEMENT. Therefore, Section 2.3 of the LICENSE AGREEMENT shall be amended and restated in its entirety to read as follows:

"2.3 Sublicense Rights. LICENSEE and its Affiliate shall have the right to grant sublicenses under all or part of the licenses granted under Sections 2.1 and 2.2. In such case, LICENSEE shall provide MTPC with a copy of the sublicense agreement including the payment conditions entered into between LICENSEE and its sublicensee, promptly following the execution of such agreement."

5. Amendment to Development Diligence.

- (a) Section 4.1.5 of the LICENSE AGREEMENT is hereby amended by deleting subparagraphs (a) through (d) in its entirety and replacing said diligence obligations with the following:
 - "Commencement of the clinical pharmacology study of the Product containing MT-210 Compound by the end of April, 2015;"
- (b) Section 4.1.5 of the LICENSE AGREEMENT shall be further amended to delete any reference to the term "any of the milestones" or any reference to multiple milestones and replace such references to similar language to reflect the fact that there is only a single milestone (i.e., the commencement of the clinical pharmacology study).
- (c) The last paragraph of Section 4.1.5 of the LICENSE AGREEMENT beginning with the sentence "Notwithstanding the foregoing, LICENSEE may extend the time to achieve any of the milestones ..." shall be deleted in its entirety and replaced with the following:

"Notwithstanding the foregoing, LICENSEE may extend the time to achieve the milestone set forth in Section 4.1.5 above for one (1) year, at its sole discretion, by making a payment of [*] to MTPC before the date on which the milestone was to have been originally achieved (the

LICENSEE will have the right to make an unlimited number of Extension Payments in conjunction with the development of Product containing the MT-210 Compound. For the avoidance of doubt, Extension Payments will be in addition to the milestone that is otherwise payable to MTPC as set forth in Section 5 of this Agreement."

6. Amendment to Milestone Payments.

- (a) Section 5.1 of the LICENSE AGREEMENT is hereby amended by deleting such section in its entirety and replacing it as follows:
- "5.1 <u>Initial Licensing Fee</u>. In consideration of the licenses granted by MTPC to LICENSEE, LICENSEE has previously paid MTPC the total amount of [*] as the initial license fee."
- (b) Section 5.2.1 of the LICENSE AGREEMENT is hereby amended by deleting such section in its entirety and replacing it with the foregoing:
- "5.2.1. <u>Milestone Payments</u>. In addition to the initial license fee, in consideration of the licenses granted by MTPC to LICENSEE, LICENSEE shall pay to MTPC the milestone payments as follows:
- (a) Onset of Phase II(a) Study [*]
 (b) Launch in the first European Country [*]
 (c) Launch in the U.S. [*]
 (d) When cumulative Net Sales first reach US\$300,000,000 (the "Net Sales Milestone")

Notwithstanding the foregoing, the milestone payments set forth in paragraphs (b) and (c) above shall be reduced or eliminated, if applicable, by the amount of Sublicense Consideration (as defined below) received by MTPC. For clarification, in the event that the Launch in the United States takes place prior to the Launch in the first European Country and the total amount of Sublicense Consideration paid to MTPC on or before the Launch in the United States is less than [*], LICENSEE shall pay to MTPC the amount of the difference between such [*] and the actual amount of the Sublicense Consideration paid to MTPC, within sixty (60) days after the Launch in the United States, which payment shall be in full satisfaction for the milestone payment due in subparagraph (c) above for Launch in the United States. If the Sublicense

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Consideration is in excess of [*] on or before the Launch in the United States, no milestone payment for the Launch in the United States shall be due and Sublicense Consideration upon such Launch for the portion of such excess shall not be paid.

In the event that the Launch in the first European Country takes place prior to the Launch in the United States and the total amount of Sublicense Consideration paid to MTPC on or before the Launch in the first European Country is less than [*], LICENSEE shall pay to MTPC the amount of the difference between such [*] and the actual amount of the Sublicense Consideration paid to MTPC, within sixty (60) days after the Launch in the first European Country, which payment shall be in full satisfaction for the milestone payment due in subparagraph (b) above for Launch in the first European Country. If the Sublicense Consideration is in excess of [*] on or before the Launch in the first European Country, no milestone payment for the Launch in the first European Country shall be due and Sublicense Consideration upon such Launch for the portion of such excess shall not be paid.

In the event that the total amount of the Sublicense Consideration paid to MTPC on or before the Launch in the United States or the first European Country, which takes place later, is less than [*], LICENSEE shall pay to MTPC the amount of difference between (i) such [*] and (ii) the sum of the total amount paid to MTPC prior to the sublicense as the milestone payments set forth in subparagraphs (b) and (c) above on or before such Launch, if any, and the amount of the Sublicense Consideration paid to MTPC, within sixty (60) days after the Launch in the first European Country or in the United States, which takes place later. Notwithstanding any other provision in this Agreement, if the Sublicense Consideration is in excess of [*] on or before the Launch in the first European Country or in the United States, which takes place later, no milestone payment for the Launch in the first European Country or in the United States, which takes place later, shall be due.

Both Parties acknowledge that LICENSEE has already paid the initial license fee and the Five Hundred Thousand United States Dollars (\$500,000) milestone payment set forth in subparagraph (a) above."

- (c) Schedule 5.2 of the LICENSE AGREEMENT is hereby amended by deleting such section in its entirety. For the avoidance of doubt, except as set forth in Section 5.2.1 of the LICENSE AGREEMENT, no additional milestone payments shall be due under the LICENSE AGREEMENT.
- (d) Section 5.2 of the LICENSE AGREEMENT is amended by renumbering the existing Section 5.2.2 as 5.2.3 and adding a new Section 5.2.2 that shall read in its entirety as follows:
- "5.2.2 <u>Sublicensing Fee in Case of Sublicenses.</u> In the event that LICENSEE sublicenses all or part of its rights under the MPC Intellectual Property to make, have made, use, have used, sell, offer for sale, have sold, import and have imported Product in the Field for purposes of commercialization in the LICENSEE Territory to a third party ("Sublicensee"), in consideration of the licenses granted by MTPC to LICENSEE herein, LICENSEE shall pay to MTPC [*] of all payments, including the upfront payments, milestone payments, and the sale of any Company equity or debt securities, but excluding the royalties, received in connection with any such sublicense from a Sublicensee that are related to the Product ("Sublicense Consideration"), in addition to the milestone payments set forth in Section 5.2.1, but subject to reduction or elimination in connection with the receipt of Sublicense Consideration as provided for in Section 5.2.1 above.

Such payments shall be made within sixty (60) days as and when such payments are received by LICENSEE from such Sublicensee. For purposes of clarification, Sublicense Consideration shall not include any royalties received by LICENSEE from the sale of Product. For the avoidance of doubt, LICENSEE and MTPC acknowledge that if the Sublicense Consideration payable to MTPC is in excess of the aggregate milestones payable to MTPC set forth in Section 5.2.1(b) and (c) above, then MTPC shall be entitled to any Sublicense Consideration payable in excess of such amount."

- (e) The renumbered Section 5.2.3 is hereby amended by deleting such section in its entirety and replacing it with the foregoing:
- "5.2.3 Reports and Payments. The milestone payments set forth in Section 5.2.1 shall be made no more than once with respect to the achievement of each milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such milestones (but payable on the first achievement of such milestone). For clarification, if any milestone set forth in Section 5.2.1 is paid with respect to any

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Product containing the MT-210 Compound, then no further milestone payment shall be made upon the achievement of such milestone with respect to any Product containing an Alternate Compound or an MT-210 Back-Up. LICENSEE shall notify MTPC in writing within sixty (60) days after the achievement of the milestones specified in Section 5.2.1 and each such notice shall be accompanied by the appropriate milestone payment."

7. Amendment to Royalties Payments by LICENSEE. Notwithstanding Section 5.3 in the LICENSE AGREEMENT, in the event that LICENSEE sublicenses its rights under MPC Intellectual Property to a Sublicensee, in consideration of the licenses granted by MTPC to LICENSEE herein, LICENSEE shall pay to MTPC [*] of all royalties received by LICENSEE from Sublicensee related to the sale of Product, and no additional royalties will be due and owing to MTPC as a result of sales of Product by any such Sublicensee. For clarification, in the event that LICENSEE does not sublicense its rights under MPC Intellectual Property to a Sublicensee, LICENSEE shall pay to MTPC a Royalty pursuant to Section 5.3 of the LICENSE AGREEMENT.

8. Other Provisions.

- (a) Governing Law. This SECOND AMENDMENT shall be governed by, and interpreted in accordance with the laws of the State of New York, without reference to conflicts of laws principles thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Rights in question.
- (b) <u>Counterparts</u>. This SECOND AMENDMENT may be executed in several duplicates, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.
- (c) <u>Assumption of the Obligations and Benefits.</u> In the event that LICENSEE sells their shares or their assets relating to the Compound and/or Product, all of the obligations and benefits in the LICENSE AGREEMENT and in this Amendment shall be assigned to the purchaser of such shares or assets.
- (d) No Other Amendments. Save as amended by this SECOND AMENDMENT, the terms of the LICENSE AGREEMENT shall remain in full force and effect.

[Signature Page Follows]

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IN WITNESS WHEREOF, the parties have executed this SECOND AMENDMENT as of the date first set forth above.

Minerva Neurosciences, Inc.

Mitsubishi Tanabe Pharma Corporation

By: /s/ Rogerio Vivaldi Coelho By: /s/ Seiichi Murakami
Name: Rogerio Vivaldi Coelho Name: Seiichi Murakami

Title: President and CEO Title: Managing Executive Officer



LICENSE AGREEMENT

THIS LICENSE AGREEMENT (hereinafter referred to as "<u>Agreement</u>") dated as of September 1, 2008 (hereinafter referred to as "<u>Effective Date</u>"), is entered into between Sonkei Pharmaceuticals, Inc., a Delaware corporation, having a place of business located at 47 Hulfish Street, Suite 310, Princeton, NJ 08542, United States of America (hereinafter referred to as "<u>LICENSEE</u>") and Mitsubishi Tanabe Pharma Corporation, a Japanese corporation, having a place of business located at 2-10, Dosho-machi 3 chome, Chuo-ku, Osaka 541-8505, Japan (hereinafter referred to as "<u>MTPC</u>").

WITNESSETH:

WHEREAS, MTPC is the owner of the patents, patent applications and other intellectual property relating to a certain pharmaceutical compound coded as Wf-516;

WHEREAS, LICENSEE desires to obtain an exclusive license, with a right to grant sublicenses, under the MTPC Intellectual Property (hereinafter defined); and

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

ARTICLE 1 DEFINITIONS

For purposes of this Agreement, the terms defined in this Article 1 shall have the respective meanings set forth below, it being understood that words in the singular include the plural and vice versa:

- 1.1 "Affiliate" shall mean any person, corporation, joint venture or business entity of such party which, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with such party, as the case may be. As used herein, "control" means (a) to possess, the power to direct the management or policies of such company or other business entity, through ownership of voting securities or by contract relating to voting rights or corporate governance, or (b) direct or indirect beneficial ownership of more than fifty percent (50%) of the voting share capital in such company or other business entity.
- 1.2 "Allocable Overhead" shall mean costs incurred by a Party or for its account (and not reimbursed by a Third Party) which are attributable to its supervisory, services, occupancy costs, payroll, information systems, human relations or purchasing functions and which are allocated to company departments involved in and relevant to the subject matter of this Agreement, based on space occupied, headcount, or activity-based method, in all cases as determined by such Party in accordance with GAAP (hereinafter defined). "Allocable Overhead" shall not include any costs attributable to general corporate activities including, by way of example only, executive management, investor relations, business development, legal, finance and government affairs, and shall not include any costs or expenses which are reimbursed by the other Party or any Third Party.

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- 1.3 "Application" shall mean a New Drug Application ("NDA") submitted (and the submission of which has been accepted) with the Food and Drug Administration in the United States ("FDA") or a corresponding application for approval for commercial sales which has been submitted (and the submission of which has been accepted for review) with a regulatory agency in a country of the LICENSEE Territory other than the United States, in each case for the Product in the Field.
- 1.4 "<u>Bulk Drug Substance</u>" shall mean the Compound in bulk form, which if appropriately formulated and finished, would constitute the Product.
- 1.5 "Calendar Quarter" shall mean the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30 and December 31.
 - 1.6 "Calendar Year" shall mean each successive period of twelve (12) months commencing on January 1 and ending on December 31.
 - 1.7 "Clinical Studies" shall mean Phase I Studies, Phase II(a) Studies, Phase II(b) Studies, and Phase III Studies.
- 1.8 "Commercially Reasonable Efforts" shall mean efforts and resources normally used by a Party for a product owned by it or to which it has exclusive rights, which is of similar market potential at a similar stage in its development or product life, taking into account issues of safety and efficacy, product profile, the competitiveness of the marketplace, the proprietary position of the compound or product, the regulatory and reimbursement structure involved, the profitability of the applicable products, and other relevant factors.
- 1.9 "Competing Product" shall mean any prescription pharmaceutical product for the same indication as the Product and having the same mechanism of action as the Product including binding to each of the following receptors and transporters with binding affinity expressed as Ki value of less than sixty (60) nmol/L:. serotonin transporter inhibition, serotonin 1a receptor antagonism, serotonin 2a receptor antagonism, dopamine transporter inhibition, adrenergic alpha 1a receptor, adrenergic alpha 1b receptor and adrenergic alpha 1d receptor.

- 1.10 "Compound" shall mean (i) compound known as Wf-516 with the chemical name [*], having the molecular structure set forth in Schedule 1.10 (hereinafter referred to as the "Wf-516 Compound"), and (ii) other compounds included in the Valid Claims and in certain examples in US patent Registration No. 6720320.; and (iii) any solvate, salt form, enantiomers, racemate, w-crystal anhydride, hydrate, prodrug, polymorph or amorphous of (i) or (ii) and (iv) Main Metabolites.
- 1.11 "Development Work" shall mean all works to be performed by or on behalf of LICENSEE, its Affiliates and/or sublicensees, under appropriate support, if requested by LICENSEE, its Affiliates and/or sublicensees, to be provided by FORENAP, to obtain the data and information necessary or useful for the Registration and future commercial operation of the Product, including all necessary pre-clinical, clinical studies and formulation development and manufacturing of the Compound and/or Product.

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- 1.12 "Development Plan" shall mean LICENSEE's and/or Affiliate's and/or its sublicensee's development plan for the Compound and Product with timeline. The initial Development Plan is set forth on Schedule 1.12.
 - 1.13 "Effective Date" shall have the meaning set forth in the introductory paragraph of this Agreement.
- 1.14 "<u>European Country</u>" shall mean a country which is a member of the European Union as of the Effective Date, or which join the European Union after the Effective Date.
 - 1.15 "<u>Facility</u>" shall mean MTPC's GMP manufacturing facility.
 - 1.16 "Field" shall mean all uses of the Product in humans to treat, manage or prevent diseases other than non-systemic ophthalmic uses.
- 1.17 "FORENAP" shall mean FORENAP PHARMA EURL, having its registered offices at 27 rue du 4ème RSM B.P. 27, 68250 Rouffach, France.
- 1.18 "Fully Burdened Manufacturing Cost" shall mean the cost of production of the Compound or the Product, comprised of the sum of: (a) the manufacturing cost of goods produced as determined in accordance with GAAP as applied by the manufacturer of such Compound or Product including, without limitation, direct labor, material and product testing costs incurred in connection with the manufacture or quality control testing of such product, as well as Allocable Overhead and shipping containers, (b) the manufacturer's allocable intellectual property licensing and acquisition costs paid to Third Parties which are necessary for the manufacture of such Compound or Product and (c) any other costs borne by the manufacturer for the transport, customs clearance and storage of such Compound or Product (if necessary) at the request of LICENSEE or its Affiliates or sublicensees (i.e., freight, duty, insurance, and warehousing).
 - 1.19 "GAAP" shall mean generally accepted accounting principles in the United States.
- 1.20 "Generic Competition" shall mean, with respect to a particular country in the LICENSEE Territory where LICENSEE, its Affiliate or its sublicensee is selling Product, one or more Third Parties, other than a sublicensee of LICENSEE, is/are selling a Generic Drug in such country and the Generic Drug or Generic Drugs together has/have obtained a market share in such country of greater than [*] of the total number of units sold of the Products together with such Generic Drugs in such country for two (2) consecutive Calendar Quarters, despite LICENSEE, its Affiliate and/or its sublicensee using Commercially Reasonable Efforts to market and sell the Product in such country.
- 1.21 "Generic Drug(s)" shall mean any product containing Compound for which Registration is obtained by an abbreviated NDA ("ANDA") or other abridged procedure in the United States or a corresponding application in any country of the LICENSEE Territory, other than a Product introduced in such country by LICENSEE, its Affiliates or its sublicensees.

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- 1.22 "GMP" shall mean current good manufacturing practice and standards as provided for (and as amended from time to time) in the Current Good Manufacturing Practice Regulations of the U.S. Code of Federal Regulations Title 21 (21 C.F.R. § 11, § 210 and § 211) and in European Community Directive 2004/27/EC and 2004/28/EC (Principle and guidelines of good manufacturing practice for medical products) and the equivalent in Japan in relation to the production of pharmaceutical products, as interpreted by the ICH Harmonized Tripartite Guideline, any U.S., Japanese, European, or other applicable laws, regulations or respective guidance documents subsequently established in Japan, the US and Europe, and any arrangements, additions or clarifications agreed from time to time between the parties.
- 1.23 "IND" shall mean an Investigational New Drug filed with FDA or a corresponding application filed with a regulatory agency with respect to development of a Product in the Field.
- 1.24 "Know-How" shall mean any proprietary, non-public information or materials, relating to the research, development, registration, manufacture, marketing, use or sale of the Compound and/or Product which prior to or during the term of this Agreement are developed by or is in a Party's possession or control through license or otherwise (provided that such Party is permitted to make disclosure thereof to the other Party without violating the terms of any Third Party agreement). Know-How may include, without limitation: (i) all biological, chemical, pharmacological, toxicological, pharmaceutical, physical and analytical, clinical, safety and quality control data and information related to the Compound and/or Product; (ii) compositions of matter, assays and biological materials, necessary or useful for development, manufacture, use or sale of the Compound and/or Product; (iii) data and information necessary for manufacturing the Compound and/or Product; and (iv) all applications, registrations licenses, authorizations, approvals and

correspondences submitted to or received from any regulatory authorities with jurisdiction over an investigational drug containing the Compound and/or Product.

- 1.25 "<u>Launch</u>" shall mean, with respect to any Product after Registration, the first sale to a Third Party by LICENSEE, its Affiliate or its sublicensees of that Product in such country. Sales for test marketing, clinical study purposes or compassionate, named patient or similar use shall not constitute a sale.
- 1.26 "LICENSEE Intellectual Property" shall mean all intellectual property and proprietary rights in (i) all LICENSEE Patents and (ii) all LICENSEE Know-How.
- 1.27 "LICENSEE Know-How" shall mean any Know-How owned or controlled by LICENSEE and/or its Affiliates that is developed by LICENSEE or its Affiliates after the Effective Date in connection with its performance of its activities under this Agreement.
- 1.28 "<u>LICENSEE Patents</u>" shall mean any Patent Right owned or controlled by LICENSEE or its Affiliate, to the extent such Patent Right both (a) covers a Compound or Product and (b) the underlying invention of which was conceived and reduced to practice after the Effective Date by LICENSEE in connection with its performance of its activities under this Agreement.

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- 1.29 "<u>LICENSEE Territory</u>" shall mean all countries in the world, excluding the MTPC Territory.
- 1.30 "Main Metabolites" shall mean the main metabolites of Wf-516 Compound described in the pharmacokinetic reports listed in Schedule 11.2.11.
 - 1.31 "Major Countries" shall mean the United States, Canada, the United Kingdom, Germany, France, Italy and Spain.
- 1.32 "MTPC Intellectual Property" shall mean all intellectual property and proprietary rights in (i) all MTPC Patents and (ii) all MTPC Know-How.
 - 1.33 "MTPC Know-How" shall mean Know-How owned or controlled by MTPC.
- 1.34 "MTPC Patents" shall mean any Patent Right owned or controlled by MTPC during the term of this Agreement which relates to Compound or Product, and, absent rights hereunder, would be infringed by the research, development, manufacture, use, importation, sale or offer for sale of the Compound and/or Product, including the Patent Rights listed on Schedule 1.34, and any patents that may issue from, or claim priority to or through, the applications listed on Schedule 1.34.
- 1.35 "MTPC Territory" shall mean Bangladesh, Brunei, India, Indonesia, Japan, Malaysia, Pakistan, People's Republic of China (including Hong Kong), Philippines, Singapore, South Korea, Sri Lanka, Taiwan, Thailand and Vietnam.
- 1.36 "Net Sales" shall mean, with respect to any Product, the aggregate gross amount invoiced by LICENSEE or its Affiliates or sublicensees on all sales of such Product in the LICENSEE Territory to an unaffiliated Third Party, less reasonable and customary deductions from such gross amounts, including:
 - 1.36.1 bad debts actually written off which are attributable to sales of the Product;
- 1.36.2 credits or allowances for damaged goods, returns or rejections or recalls of Product and shelf stock and other retroactive price adjustments;
 - 1.36.3 normal and customary trade, cash, quantity and volume based discounts, allowances and credits;
 - 1.36.4 sales or similar taxes (other than income taxes);
 - 1.36.5 freight, postage, shipping, insurance charges;
- 1.36.6 chargebacks and rebates to managed healthcare organizations or to federal, state and local governments, their agencies, or to trade customers, including without limitation, wholesalers and chain pharmacy buying groups;

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- 1.36.7 inventory management, distribution, warehousing, and related services fees, and
- 1.36.8 any other reduction or specifically identifiable amounts included in the invoice price that should be credited for any reasons substantially equivalent to those listed above.

Each of the deductions set forth above shall be determined on an accrual basis in accordance with GAAP. To the extent that any discounts or other similar deductions that are based on sales to the customer of multiple products are included in determining Net Sales of the Product, such discounts or

deductions shall be allocated to the Product and the other relevant products on a pro rata basis.

- 1.37 "Onset" shall mean the first dosing of the first patient in a Clinical Study.
- 1.38 "Party," shall mean one of MTPC and LICENSEE, as appropriate. Where used in the plural, "Parties" shall mean MTPC and LICENSEE.
- 1.39 "Patent Rights" shall mean (a) all national, regional and international patents and patent applications, including provisional patent applications, (b) all patent applications filed either from such patents, patent applications or provisional applications or from an application claiming priority from either of these, including divisionals, continuations, continuations-in-part, provisionals, converted provisionals, and continued prosecution applications, (c) any and all patents that have issued or in the future issue from the foregoing patent applications ((a) and (b)), including utility models, petty patents and design patents and certificates of invention, (d) any and all extensions or restorations by existing or future extension or restoration mechanisms, including revalidations, reissues, re-examinations and extensions (including any supplementary protection certificates and the like) of the foregoing patents or patent applications ((a), (b) and (c)), and (e) any similar rights, including so-called pipeline protection, or any importation, revalidation, confirmation or introduction patent or registration patent or patent of additions to any such foregoing patent applications and patents.
- 1.40 "Person" shall mean an individual, corporation, partnership, trust, business trust, association, joint stock company, joint venture, pool, syndicate, sole proprietorship, unincorporated organization, governmental authority or any other form of entity not specifically listed herein.
- 1.41 "<u>Phase I Studies</u>" shall mean that portion of the clinical development program which provides for the first introduction into humans of a Product including small scale clinical studies conducted in normal volunteers or patients to get information on Product safety.
- 1.42 "<u>Phase II(a) Studies</u>" shall mean that portion of the clinical development program which provides for the initial trials of a Product on a limited number of patients for the purpose of determining whether the Product affects a surrogate marker or indicator of pharmacological or clinical activity in the proposed disease state/therapeutic indication.
- 1.43 "Phase II(b) Studies" shall mean that portion of the clinical development program carried out either post-Phase II(a) Studies or concurrently with Phase II(a) Studies and which

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provides information for the definitive, well controlled clinical trials of a Product in patients, including clinical studies conducted in patients and designed to indicate clinical efficacy for the Product for one or more indications and its safety, as well as to obtain an indication of the dosage regimen required.

- 1.44 "Phase II Studies" shall mean Phase II(a) Studies and Phase II(b) Studies.
- 1.45 "Phase III Studies" shall mean large scale clinical studies conducted in a sufficient number of patients to establish the Product clinical efficacy in the Field and its safety.
- 1.46 "<u>Proprietary Information</u>" shall mean any and all scientific, clinical, regulatory, marketing, financial and commercial information or data, whether communicated in writing, orally or by any other means, which is owned and/or under the protection of one Party and is being provided by that Party to the other Party in connection with this Agreement.
- 1.47 "Product" shall mean a pharmaceutical preparation containing Compound which has been manufactured into an oral dosage form (including sustained release formulation), injectable formulation or any other formulation, packaged and labeled for administration in the Field. Combination product may be included in this defined term of "Product", provided, however, that calculation method of Net Sales of the combination product shall be separately agreed upon between the Parties.
- 1.48 "Royalty Period" shall mean the period, on a country-by-country and Product-by-Product basis, until the later of: (a) the expiration of the last-to-expire Valid Claim covering such Product in such country; or (b) ten (10) years from the Launch of such Product in such country of the LICENSEE Territory.
- 1.49 "Royalty Year" shall mean (i) for the year in which the Launch occurs (the "First Royalty Year"), the period commencing with the first day of the Calendar Quarter in which the Launch occurs and expiring on the last day of the Calendar Year in which the Launch occurs and (ii) for each subsequent year, each successive Calendar Year.
- 1.50 "Registration(s)" shall mean, in relation to any Product, such authorizations of the regulatory authorities in a given country (including marketing, marking and pricing approvals) as may be legally required before such Product may be commercialized or sold in such country.
- 1.51 "Regulatory Requirements" shall mean (i) compliance with all applicable laws, rules, guidelines, regulations and standards of governmental authorities, including GMP, and (ii) obtaining and maintaining all licenses and other authorizations required by regulatory authorities, that in each case are applicable to the manufacturing, processing, and supply activities hereunder, the Facility, or any other facilities at which any of the manufacturing or process activities hereunder may be performed or are applicable in Europe, the US and Japan.
 - 1.52 "Specifications" shall mean the specifications of the Wf-516 Bulk (defined in Section 1.56 below), which are set out in Schedule 1.52.
- 1.53 "<u>Steering Committee</u>" shall mean a committee established by the Parties subject to Section 4.3.1 to coordinate, review and assess the development of Product, to harmonize

worldwide objectives for Product and, after MTPC decides to initiate clinical development in the MTPC Territory, to facilitate the transfer of data and regulatory communications, including the handling and reporting of adverse events, between the Parties.

- 1.54 "Territory" shall mean the LICENSEE Territory or the MTPC Territory, as applicable.
- 1.55 "Third Party" shall mean any person or entity other than MTPC, LICENSEE, or an Affiliate of either Party.
- 1.56 "<u>Valid Claim</u>" shall mean a claim within the MTPC Patents (a) in an unexpired and issued patent that has not been revoked, held invalid, declared unpatentable or unenforceable by a body of competent jurisdiction and (b) that has not been rendered unenforceable through disclaimer or otherwise.
 - 1.57 "Wf-516 Bulk" shall mean the Bulk Drug Substance of the Wf-516 Compound.

ARTICLE 2 GRANT OF LICENSE

- 2.1 <u>License Grant to LICENSEE</u>. MTPC hereby grants to LICENSEE and its Affiliate an exclusive license (even as to MTPC) under the MTPC Intellectual Property to research, develop, have developed, register, have registered, make, have made, use, have used, sell, offer for sale, have sold, import and have imported Product in the Field for purposes of commercialization in the LICENSEE Territory.
- 2.2 <u>Compound Manufacturing Right</u>. Subject to the provisions of Section 4.5, MTPC hereby grants to LICENSEE and its Affiliate under the MTPC Intellectual Property (a) a semi-exclusive license, with the right to sublicense, to make and have made Compound in the LICENSEE Territory solely for purposes of manufacturing the Product in the LICENSEE Territory; it being understood that such semi-exclusive license will allow MTPC the right to make and have made Compound in the LICENSEE Territory solely for purposes of researching, developing and/or commercializing Product in the MTPC Territory; and (b) a non-exclusive license, with the right to sublicense, to make and have made the Compound in the MTPC Territory solely for the purposes of researching, developing and/or commercializing Product in the LICENSEE Territory.
- 2.3 <u>Sublicense Rights.</u> LICENSEE and its Affiliate shall have the right to grant sublicenses under all or part of the licenses granted under Sections 2.1 and 2.2; provided, however, prior to sublicensing such rights, LICENSEE shall provide MTPC with the opportunity to negotiate terms under which MTPC would collaborate in or obtain a license for research, development and/or commercialization of the Compound and/or Product in the LICENSEE Territory (a "Right of First Negotiation"). A Right of First Negotiation shall operate as follows:
- 2.3.1 LICENSEE shall promptly notify MTPC in writing (the "<u>Right of First Negotiation Notification</u>") of its intention to enter into a sublicensing arrangement for the research, development and/or commercialization of the relevant Compound and/or Product and shall provide to MTPC a reasonably detailed written description of such proposed sublicense,

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together with any data, results materials or information related to such Compound and/or Product which LICENSEE reasonably believes is necessary and useful for evaluation of an interest in participating in such proposed sublicense by MTPC and has not previously been provided to MTPC.

- 2.3.2 Within ten (10) business days of its receipt of the Right of First Negotiation Notification (the "Response Period"), MTPC shall notify LICENSEE of its interest, if any, in initiating discussions regarding such proposed sublicense.
- 2.3.3 In the event that MTPC notifies LICENSEE prior to the expiration of the Response Period that it has an interest in participating in such proposed sublicense (an "Expression of Interest"), then the Parties shall negotiate in good faith in an effort to reach a definitive agreement regarding such sublicense for a period of up to sixty (60) days from the date of LICENSEE's receipt of the Expression of Interest; provided that, at MTPC's option, the negotiation period may be extended one time for an additional sixty (60) days.
- 2.3.4 In the event that (a) MTPC fails to notify LICENSEE prior to the termination of the Response Period that it has an interest in participating in such proposed sublicense, or (b) MTPC notifies the LICENSEE prior to the termination of the Response Period that it has no interest in such sublicense, or (c) MTPC timely provides LICENSEE with an Expression of Interest but MTPC decides and notifies LICENSEE not to continue negotiation regarding such sublicense within the period specified in Section 2.3.3 or (d) the Parties are unable to reach agreement despite good faith negotiations in accordance with Section 2.3.3 above, then LICENSEE shall be free to enter into a sublicense with a Third Party with respect to such Compound and/or Product and the terms of any such sublicense agreement shall not be inconsistent with terms and conditions set forth in this Agreement; provided, however, that LICENSEE shall use its Commercially Reasonable Efforts to impose on such Third Party sub-licensee the same obligations as LICENSEE undertakes under this Agreement.
- 2.3.5 For the duration of the Response Period, and if MTPC timely delivers the Expression of Interest, the sixty (60) day period specified in Section 2.3.3, and additional sixty (60) days period specified in Section 2.3.3 if the Parties continue the negotiation regarding such sublicense, LICENSEE shall not negotiate such sublicense arrangement with a Third Party, nor enter into any agreements with such Third Party or propose terms to such Third Party.
- 2.4 <u>License Grant to MTPC</u>. LICENSEE or its Affiliate shall grant to MTPC and its Affiliate a non-exclusive and royalty-free license, with the right to grant sublicenses, under LICENSEE Intellectual Property for the purpose of developing and commercializing the Compound and/or the Product in the MTPC Territory. Subject to the provisions of Section 3.3 below, LICENSEE or its Affiliate shall use its Commercially Reasonable Efforts to cause its sublicensees to grant to MTPC and its Affiliate a non-exclusive and royalty-free license, with the right to grant sublicenses, under such sublicensee's intellectual property for the purpose of developing or commercializing the Compound and/or the Product in the MTPC Territory.

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conditions of the Compound and/or Product for an exclusive discussion period of sixty (60) days from the date of the receipt by LICENSEE of MTPC's offer. MTPC shall provide to LICENSEE a reasonably detailed written description of such proposed license.

During such sixty (60) days period the Parties will negotiate in good faith in order to reach a definitive agreement regarding such license. After the expiration of such 60-day discussion period if the Parties have failed to reach agreement or LICENSEE has notified MTPC that it does not wish to enter into a license, MTPC shall be free to enter into any discussion or license with a Third Party with respect to the Compound and/or Product for the MTPC Territory provided that MTPC will use its Commercially Reasonable Efforts to ensure that any such Third Party complies with the terms of this Agreement.

ARTICLE 3 DISCLOSURE

- 3.1 <u>Disclosure by MTPC</u>. Within thirty (30) days after the Effective Date, and throughout the term of this Agreement as new MTPC Intellectual Property is developed, MTPC shall disclose to LICENSEE any and all then-available MTPC Intellectual Property, including without limitation, any regulatory filings or information related thereto, which has not already been disclosed and made available to LICENSEE or its Affiliate, on an "as-is" basis.
- 3.2 Technical Assistance by MTPC. Upon specific request from LICENSEE, MTPC shall cooperate with LICENSEE and provide LICENSEE with technical assistance, to the extent such technical assistance is reasonably available to MTPC, with respect to the MTPC Know-How in order to enable LICENSEE to use such MTPC Know-How to manufacture and produce the Compound or Product. If LICENSEE requests and MTPC accepts in its sole discretion that MTPC's technical personnel shall be dispatched to the facilities of LICENSEE or its Affiliate or Third Party contractor for the purposes of providing such technical assistance, LICENSEE shall pay to MTPC a reasonable per diem or hourly rate fee for such assistance in an amount to be negotiated in good faith by the Parties and shall reimburse MTPC for the actual out-of-pocket costs incurred in providing such technical assistance.
- 3.3 <u>Disclosure by LICENSEE</u>. During the term of this Agreement, LICENSEE shall disclose to MTPC any and all then available LICENSEE Intellectual Property, including without limitation relevant information contained in any IND and NDA. LICENSEE or its Affiliate shall use its Commercially Reasonable Efforts to cause its sublicensees to disclose to MTPC all sublicensee intellectual property and relevant information for the purposes of developing or commercializing the Compound and/or the Product in the MTPC Territory, provided, however, that those sublicensee's data and information which are (i) reasonably necessary for the regulatory application in the MTPC Territory and/or (ii) required to submit by the regulatory agencies in the MTPC Territory, shall be disclosed to and made available to MTPC free of charge. If MTPC requests and LICENSEE accepts in its sole discretion to conduct certain study or experiment to obtain certain additional data and information relating to LICENSEE Intellectual Property solely for the purpose of development and/or Application of the Product in MTPC Territory specifically but such additional data and information will not be useful for the purpose of development and/or Application of the Product in LICENSEE Territory, MTPC shall pay to LICENSEE a reasonable per diem or hourly rate fee for obtaining such additional data and

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information in an amount to be negotiated in good faith by the Parties and shall reimburse LICENSEE for the actual out-of-pocket costs incurred in providing such additional data and information.

- 3.4 <u>Technical Assistance by LICENSEE</u>. Upon specific request from MTPC, LICENSEE shall reasonably cooperate with MTPC and provide MTPC with technical assistance with respect to the LICENSEE Know-How in order to enable MTPC to use such LICENSEE Know-How to manufacture and produce the Compound or Product. If MTPC requests and LICENSEE accepts in its sole discretion that LICENSEE's technical personnel shall be dispatched to the facilities of MTPC, its Affiliate, its licensee or Third Party contractor for the purposes of providing such technical assistance, MTPC shall pay to LICENSEE a reasonable per diem or hourly rate fee for such assistance in an amount to be negotiated in good faith by the Parties and shall reimburse LICENSEE for the actual out-of-pocket costs incurred in providing such technical assistance.
- 3.5 Transfer of Data and Information. Within sixty (60) days of the Effective Date, MTPC shall provide to LICENSEE copies in English of all substantive or material information (in electronic format where available), relating to the following: (1) pre-clinical and clinical data and other Know-How compiled as of the Effective Date with respect to the Compounds, including any and all data which MTPC reasonably considers necessary for LICENSEE to file an IND with the FDA, and (2) all prior correspondence with the FDA or other regulatory equivalent for countries in the LICENSEE Territory other than the United States and in the MTPC Territory related to the Compound. Notwithstanding anything to the contrary contained herein, if FDA or equivalent regulatory agency outside the US makes a specific request for information, MTPC, as soon as practical but in no event later than fifteen (15) days after such request, must provide to LICENSEE such information, to the extent that it is or was in MTPC's possession or control at any time, and to the extent such information has not already been transferred to LICENSEE.

ARTICLE 4
DEVELOPMENT; REGULATORY MATTERS;
POST REGISTRATION ACTIVITIES

4.1.1 <u>Development Work.</u> In accordance with the Development Plan, LICENSEE, its Affiliates and its sublicensees shall, at their own expense, use Commercially Reasonable Efforts to conduct the Development Work and shall pursue Registrations for the Product in the Field in the LICENSEE Territory, including the preparation and filing of regulatory submissions. In conducting the Development Work, LICENSEE and/or its Affiliates or sublicensees may utilize FORENAP for support in conducting the Development Work which shall include the services set forth in the Services Agreement dated September 1, 2008 between LICENSEE and FORENAP, a copy of which is attached as Schedule 4.1.1 (hereinafter referred to as "Services Agreement"). Further, LICENSEE may subcontract portions of the Development Work to any other Third Party having enough knowledge, experience and capability for pre-clinical and/or Clinical Studies; provided, however, that such subcontracted Third Party shall be subject to an agreement with LICENSEE consistent with the confidentiality obligations in

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accordance with Article 8 below. LICENSEE shall be responsible for the Development Work to be performed by FORENAP and any other subcontracted Third Party.

- 4.1.2 <u>Development Plan.</u> For each Compound and Product, LICENSEE shall prepare a Development Plan that describes the significant development activities to be undertaken by LICENSEE, its Affiliates and/or its sublicensees with respect to the Compound and Product in the Field in the LICENSEE Territory. As part of the Services Agreement, LICENSEE, and/or its Affiliates shall prepare the initial Development Plan for the Compound in consultation with FORENAP. The initial Development Plan for the Compound shall take into consideration the following strategies for development in order to avoid the occurrence of expected adverse effects including phospholipidosis;
- (a) To use reasonable, appropriate and available biomarkers for monitoring of phospholipidosis in the liver, kidney, lung, spleen and lymph nodes; and
 - (b) To avoid exposure to patients with excessive plasma level of the Compound and its metabolites for a long time.

The Development Plan may be modified from time to time as LICENSEE, its Affiliates and/or sublicensees deem necessary, and with respect to the Compound, within the scope of the development strategy set forth in this Section 4.1.2; provided, however, LICENSEE shall to extent it is aware of such revisions promptly inform MTPC of any material revision of such Development Plan and will use good faith efforts to inform MTPC of any other revision of such Development Plan, If the Development Plan for the Compound is modified by LICENSEE, and/or its Affiliates beyond the development strategy considerations set forth in Section 4.1.2(a) — (b), LICENSEE shall promptly inform MTPC of such revision of such Development Plan and MTPC may provide any comments it may have on such modifications within eight (8) business days and LICENSEE shall consider in good faith any such comments. LICENSEE shall be responsible for preparing and implementing any modifications or amendments to the Development Plan.

- 4.1.3 <u>Clinical Studies Protocol</u>. Before commencement of any Clinical Studies conducted by Party in relation to this Compound and/or a Product the Party so conducting the Clinical Trial shall provide to the other the final draft of the protocol for such Clinical Study. The other Party may comment within fifteen (15) business days on such protocol and the Party conducting the Clinical Trial shall consider in good faith any such comments; provided, however, the final decision with respect to any such protocol shall be taken by the Party conducting the Clinical Trial at its sole discretion.
- 4.1.4 <u>Development Diligence.</u> Without prejudice to any other remedies available at law or otherwise provided for in this Agreement, MTPC shall have the right to terminate this Agreement in the event that LICENSEE, its Affiliate or its sublicensee fails to meet any of the following milestones for the Product:
 - (a) Filing of the first IND in one of the Major Countries within [*] months after the Effective Date;

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- (b) Onset of the first Phase II(b) Study within [*] months after the first IND filing;
- (c) Onset of the first Phase III Study within [*] months after completion of the last Phase II(b) Study; and
- (d) Filing of the first NDA within [*] years after the first IND filing;

Provided, however, that MTPC shall not have the right to terminate this Agreement if the failure of LICENSEE, its Affiliate or its sublicensee to meet any of the milestones set forth above is due to or caused by any of the following:

Reason(s) beyond the reasonable control of LICENSEE, its Affiliate or its sublicensee. For the avoidance of doubt and without prejudice to other reasons, the following reasons will be deemed beyond the reasonable control of LICENSEE, its Affiliate or its sublicensee: a requirement by the FDA or other applicable regulatory agency that LICENSEE, its Affiliate or its sublicensee (i) perform additional studies or trials, (ii) reformulate or alter the manufacturing process of any Product, (iii) cease any clinical trial or redesign any clinical trial, or (iv) perform any other action or cease to perform any action that otherwise delays the clinical development of any Product. LICENSEE, its Affiliate or its sublicensee will present to MTPC evidence of such FDA or other applicable regulatory agency action.

(2) Activities performed in the best interest of the Product as reasonably determined by LICENSEE, its Affiliate or its sublicensee, subject to MTPC's approval, not to be unreasonably withheld. For the avoidance of doubt and without prejudice to other activities, the following activities will be deemed in the best interest of the Product: (i) an expanded clinical program scope; (ii) additional safety studies, including drug-

drug interaction studies and special population studies; (iii) reformulation efforts; or (iv) business development efforts following initiation of a Phase II(b) Study. A plan of such activities will be communicated to MTPC by LICENSEE, its Affiliate or its sublicensee.

(3) LICENSEE's decision to discontinue development of the Product containing the Compound, pursuant to Section 10.3.

The Steering Committee will review the overall progress of the Development Plan and will agree on reasonable time extensions or milestone adjustments to accommodate delays due to clause (1) or (2) set forth above based on information presented by LICENSEE, its Affiliate or its sublicensee.

Notwithstanding the foregoing, LICENSEE may extend the time to achieve any of the milestones set forth in Section 4.1.4(a) through (d) set forth above for one (1) year, at its sole discretion, by making a payment of [*] to MTPC before the date on which such milestone was to have been originally achieved (the "Extension Payment"). If such Extension Payment is made, all following milestones will be concomitantly extended by one (1) year. LICENSEE will have the right to make an unlimited number of Extension Payments in conjunction with the development of Product, provided that the payment amount will increase to [*] beginning with the third Extension Payment. For the avoidance of doubt, Extension Payments will be in

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addition to any milestone that is otherwise payable to MTPC as set forth in Section 5 of this Agreement.

- 4.1.5 <u>Progress Reports.</u> Every six (6) months until the Registration is obtained in any country in the LICENSEE Territory, LICENSEE shall prepare and deliver to MTPC a written report summarizing LICENSEE's, its Affiliates' and/or sublicensees' significant activities of the Development Work, including all pre-clinical tests and Clinical Studies, with respect to the Compound and Product in the Field in the LICENSEE Territory performed by LICENSEE, its Affiliates and/or sublicensees. MTPC may comment on the progress of the Development Work when reviewing such process reports and LICENSEE or its Affiliates, shall, in its or their sole discretion, consider in good faith any such comments; provided, however, the final decision as to the Development Work shall be taken by the LICENSEE or its Affiliates or sublicensees at its or their sole discretion.
- 4.1.6 <u>Regulatory Matters</u>. LICENSEE and/or its Affiliates or sublicensees shall own, control and retain primary legal responsibility for, and shall be responsible for funding and the preparation, filing and prosecution of all filings and regulatory applications required to obtain Registration of Product in the LICENSEE Territory in the Field.
- 4.1.7 Reporting of Adverse Events and Adverse Drug Reactions. LICENSEE and its Affiliates and sublicensees and MTPC and its Affiliates and licensees shall cooperate with respect to the exchange of adverse event and safety information associated with the Product. Details of the cooperation in the handling of adverse event and safety information related to the Product shall be included in a separate agreement to be negotiated in good faith between the Parties at the time MTPC, its Affiliates, its licensee or its sublicensee initiates development of the Product in the MTPC Territory. Such agreement shall set forth a standard operating procedure governing the collection, investigation, reporting, and exchange of information concerning adverse drug reactions/experiences sufficient to permit each Party to comply with its legal obligations in its respective Territory. Each Party will designate a regulatory affairs or pharmacovigilance liaison to be responsible for communicating with the other Party regarding the reporting of adverse event and safety information associated with the Compound and Product.
- 4.2 <u>Launch and Marketing Efforts</u>. LICENSEE, its Affiliates or its sublicensees shall use Commercially Reasonable Efforts to launch and market the Product in the LICENSEE Territory.
 - 4.3 <u>Coordination of Development Efforts.</u>
- 4.3.1 <u>Steering Committee</u>. MTPC, LICENSEE and their respective Affiliates, agree to establish a Steering Committee on the Effective Date to facilitate the disclosure described in Article 3. The specific composition, role and responsibility of the Steering Committee, and details relating to meetings and decision-making, shall be negotiated in good faith in a separate agreement to be entered into between the Parties within thirty (30) days after the Effective Date.

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- 4.3.2 <u>Development in the MTPC Territory.</u> MTPC shall own, control and retain primary legal responsibility for, and shall be responsible for funding, the preparation, filing and prosecution of all filings and regulatory applications required to obtain Registration of Product in the MTPC Territory; provided that MTPC agrees that it will not do or omit to do anything in relation to the Compound and/or the Product which would have a detrimental effect on the LICENSEE's rights under this Agreement and in particular its development and commercialization of the Product in the LICENSEE Territory. LICENSEE will be allowed to comment on the development program for development of the Product in MTPC Territory in the Steering Committee.
- 4.3.3 <u>Supply of the Bulk Drug Substance and Product for Development in the MTPC Territory.</u> Upon the reasonable request from MTPC, LICENSEE shall discuss in good faith with MTPC terms and conditions under which LICENSEE would be willing to supply the Bulk Drug Substance and/or the Product to MTPC, its Affiliates or its licensee for development in the MTPC Territory. The price of such Bulk Drug Substance and/or the Product shall be equal to the amount of the Fully Burdened Manufacturing Cost plus two percent (2%). The detailed terms and conditions of such supply shall be discussed in good faith and agreed upon between the Parties.
- 4.4 <u>Supply of the Bulk Drug Substance and Product for Commercialization in the MTPC Territory.</u> Upon the reasonable request from MTPC, LICENSEE shall discuss in good faith with MTPC terms and conditions under which LICENSEE would be willing to supply the Bulk Drug Substance and/or

the Product to MTPC, its Affiliate or its licensee for commercialization in the MTPC Territory. The detailed terms and conditions of such supply (including supply price) shall be discussed in good faith and agreed upon between the Parties.

- 4.5 <u>Supply of the Bulk Drug Substance for Development to LICENSEE</u>.
- 4.5.1 <u>Supply to LICENSEE</u>. MTPC shall supply LICENSEE with not more than seventy kilograms (70 kg) of the WF-516 Bulk solely for the purpose of the Development Work in response to LICENSEE's firm order of sixty (60) days prior to the shipment. Such orders shall be made within two (2) years from the Effective Date and no more than once a year. The exact supply amount will be determined by MTPC and LICENSEE in good faith.
- 4.5.2 <u>Supply Terms.</u> MTPC shall deliver the Wf-516 Bulk, EXW (Incoterms 2000) at MTPC's facility for collection by a carrier designated by LICENSEE. Risk of loss of the Wf-516 Bulk will be transferred to LICENSEE upon delivery to the carrier.
- 4.5.3 <u>Shipping</u>. The Wf-516 Bulk shall be shipped packaged in containers in order to protect it during transportation in accordance with the applicable Specifications or as otherwise agreed by the Parties in writing. Each such container will be individually labeled in accordance with any Regulatory Requirements which may include a description of its contents, including the manufacturer lot number, quantity of the Wf-516 Compound, and expiration date and/or retest date and marked for shipment to LICENSEE's specified receiving point.
- 4.5.4 <u>Price and Costs.</u> The price for the Wf-516 Bulk shall be discussed in good faith and agreed upon between the Parties separately; provided that in part consideration of

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the initial license fee payable pursuant to Section 5.1 below, MTPC will provide six kilograms (6kg) of Wf-516 Bulk to LICENSEE within thirty (30) days of the Effective Date. In addition, LICENSEE shall pay MTPC [*] per analysis for analytical cost relating to the Wf-516 Bulk. MTPC shall submit an invoice to LICENSEE upon shipment of the Wf-516 Bulk. All invoices will be sent to LICENSEE's address set out in Section 13.4 and each invoice will state the aggregate and unit price for the Wf-516 Bulk in a given shipment, plus any taxes, or other costs incident to the purchase or shipment to be borne by LICENSEE under this Agreement. All payments under this Section 4.5.4 shall be made by wire transfer in [US dollar] within thirty (30) days of LICENSEE's receipt of the Wf-516 Bulk.

- 4.5.5 <u>Quality</u>. All Wf-516 Bulk supplied by MTPC shall meet the current Specifications and shall be manufactured, packaged, tested and stored in accordance with the Specifications, all applicable regulatory approvals and Regulatory Requirements, including GMP manufacturing and record keeping procedures.
- 4.5.6 Quality Control. Prior to each shipment of the Wf-516 Bulk, MTPC and/or a LICENSEE approved third party shall perform quality control testing procedures and inspections to verify that the Wf-516 Bulk to be shipped conforms fully to the Specifications, as set forth in the Specifications. Each shipment of the Wf-516 Bulk shall be accompanied by a Certificate of Analysis issued by MTPC in a form agreed upon with LICENSEE, describing all current requirements of the Specifications, results of test performed certifying that the Wf-516 Bulk supplied has been manufactured, controlled and released in accordance with the Specifications, all regulatory approvals and applicable Regulatory Requirements. In the event of a dispute between the Parties over a GMP issue(s), LICENSEE and MTPC agree to submit the issue to a mutually agreed upon independent consultant, and the consultant's opinion shall be binding upon the both Parties in regards to that GMP issue(s). The expenses of obtaining the independent consultant's binding opinion shall be borne by the losing party.
- 4.5.7 Acceptance by LICENSEE. Acceptance by LICENSEE of the Wf-516 Bulk delivered by MTPC shall be subject to inspection and applicable testing, as set forth in the Specifications, by LICENSEE or its designee as set forth in the Specifications. If (a) on such inspection of testing, LICENSEE or its designee discovers that any Wf-516 Bulk fails to conform with the Specifications, any GMP requirements, any Regulatory Requirements, or otherwise fails to conform to the warranties in Sections 11.2.12 to 11.2.16 below, or (b) if LICENSEE becomes aware of any defect in any Wf-516 Bulk that is not discoverable upon a reasonable inspection or quality control testing as set forth in the Specifications within seventy (70) days after the delivery, LICENSEE or such designee may reject such Wf-516 Bulk, which rejection will be accomplished by giving written notice to MTPC that specifies the manner in which the Wf-516 Bulk fails to meet the foregoing requirements. Upon request from MTPC, LICENSEE shall return the rejected Wf-516 Bulk in accordance with MTPC's reasonable instructions at MTPC's expense, provided that such instructions comply with all applicable laws, regulations and Regulatory Requirements.
- 4.5.8 <u>Disputes</u>. In the event of a dispute between the Parties over the validity of a rejection, LICENSEE and MTPC agree to submit a sample of the rejected Wf-516 Bulk to an independent test facility to be agreed by both Parties, and to accept the results of the testing

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performed by that facility as binding with regard to that lot of the Wf-516 Bulk. The expense of such testing shall be borne by the losing party.

4.5.9 <u>Consequence of rejection</u>. MTPC shall use Commercially Reasonable Efforts to replace rejected Wf-516 Bulk within the shortest possible time after MTPC's receipt of notice thereof provided materials are available, and in any event within sixty (60) days if, subsequent to investigation, Wf-516 Bulk deemed by LICENSEE to be rejected is found to meet the Specifications, then LICENSEE will not only pay for the originally shipped Wf-516 Bulk but also any replacement Wf-516 Bulk made, or in process, while the investigation was being conducted. The warranties given by MTPC in Section 11.2.12 to 11.2.16 below shall survive any failure to reject by LICENSEE under this Section 4.5.9.

ARTICLE 5 PAYMENTS AND ROYALTIES

5.1 <u>Initial License Fee.</u> In consideration of the licenses granted by MTPC to LICENSEE, LICENSEE shall pay to MTPC the total amount of half a million United States Dollars (US\$500,000) as the initial license fee within thirty (30) days after the Effective Date. For the avoidance of doubt, the initial license fee set forth in this Section 5.1 shall not be creditable against future milestone payments or royalties.

5.2 <u>Milestone Payments</u>.

- 5.2.1 <u>Milestone Payments</u>. In addition to the initial license fee, in consideration of the licenses granted by MTPC to LICENSEE, LICENSEE shall pay to MTPC the milestone payments set forth in <u>Schedule 5.2</u> for the Product.
- 5.2.2 Reports and Payments. The milestone payments shall be made no more than once with respect to the achievement of each milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such milestones (but payable on the first achievement of such milestone). LICENSEE shall notify MTPC in writing within thirty (30) days after the achievement of the milestones specified on Schedule 5.2 and each such notice shall be accompanied by the appropriate milestone payment. For the avoidance of doubt, the milestone payments pursuant to this Section 5.2 shall not be creditable against future milestone payments or royalties.

5.3 Royalties Payable by LICENSEE.

5.3.1 In addition, in consideration of the licenses granted by MTPC to LICENSEE herein, LICENSEE shall pay to MTPC a royalty on Net Sales in each Royalty Year in the LICENSEE Territory, on a Product-by-Product, as follows:

Annual Net Sales in the LICENSEE Territory	Royalty Rate
[*]	[*]
[*]	[*]
[*]	[*]
("M" means "million".)	
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As an example, for Net Sales of [*] in the LICENSEE Territory, the royalties payable by LICENSEE to MTPC will represent [*].

- 5.3.2 Royalties set forth in this Section 5.3 shall accrue from the date of Launch of Product in each country and shall continue and accrue on Net Sales until the end of the Royalty Period in such country.
- 5.3.3 One Royalty. No more than one royalty payment shall be due with respect to a sale of a particular Product. No multiple royalties shall be payable because any Product, or its manufacture, sale or use is covered by more than one Valid Claim. No royalty shall be payable under this Section 5.3 with respect to sales of the Products among LICENSEE and its Affiliates or sublicensees for resale, nor shall a royalty be payable under this Section 5.3 with respect to the Products distributed for use in research and/or development, in clinical trials, as donations to nonprofit institutions or government agencies or as promotional free samples.
- 5.3.4 <u>Generic Competition</u>. At any time after Generic Competition exists in a country of the LICENSEE Territory, in each Calendar Quarter during the Royalty Period, Net Sales from such country shall be reduced by [*] before including same into Net Sales in all countries in the LICENSEE Territory for the purpose of calculating the applicable royalty rates set forth in Section 5.3.1.
- 5.4 Third Party's New Formulation Technology. LICENSEE may, at its discretion, introduce any third party formulation technology for the development and commercialization of the Product. LICENSEE shall bear the costs and expenses for the development of such third party new formulation technology. If MTPC becomes interested in the Product using such third party's new formulation technology, LICENSEE, to the extent it has the right and ability to do so, shall provide MTPC with any and data and information with regard to such third party's new formulation technology (hereinafter referred to as "Third Party Technology") as a part of the LICENSEE Intellectual Property. Further, if MTPC decides to develop and commercialize the Product in MTPC Territory using such Third Party Technology, LICENSEE, to the extent it has the right and ability to do so, shall grant or have such third party grant to MTPC the right to make, have made, use, sell, offer for sale, have sold and import the Product in MTPC Territory using .such Third Party Technology as a part of the LICENSEE Intellectual Property. In such case, in consideration of the license granted to MTPC herein, MTPC shall pay to such third party royalties for commercialization of the Product using such Third Party Technology in the MTPC Territory which rate is equivalent to the royalties for such license granted to LICENSEE.

ARTICLE 6 ROYALTY REPORTS AND ACCOUNTING

Reports. During the Royalty Period, LICENSEE shall furnish to MTPC a written report for the Calendar Quarter showing, on a country by country and Product by Product basis, (a) the gross sales of all Products sold by LICENSEE and its Affiliates and sublicensees during such Calendar Quarter, (b) the Net Sales, (c) the royalties, payable in United States Dollars, which shall have accrued hereunder based upon Net Sales of Products, (d) the withholding taxes, if any, required by law to be deducted in respect of such royalties, (e) the date of the Launch of each Product in each country in the LICENSEE Territory and (f) the exchange rates used in

determining the amount of United States Dollars, as more specifically provided in Section 7.2. Reports shall be due sixty (60) days following the close of each Calendar Quarter. LICENSEE shall keep complete and accurate records in sufficient detail to properly reflect all gross sales and Net Sales and to enable the royalties payable hereunder to be determined in accordance with Section 6.2.

6.2 Audit.

- 6.2.1 Audit Rights. Upon the reasonable written request of MTPC and not more than once in each Calendar Year, LICENSEE shall permit MTPC and/or an independent certified public accounting firm of nationally recognized standing, selected by MTPC and reasonably acceptable to LICENSEE, at MTPC's expense, to have access during normal business hours on at least ten (10) days' prior written notice, to such of the records of LICENSEE and its Affiliates as may be reasonably necessary to verify the accuracy of the royalty reports hereunder for any Calendar Year ending not more than thirty-six (36) months prior to the date of such request; provided that MTPC shall not be entitled to audit the same period of time more than once.
- 6.2.2 Audit Results. If such accounting firm concludes that additional royalties were owed during such period, LICENSEE shall remit to MTPC within thirty (30) days of the date MTPC delivers to LICENSEE such accounting firm's written report so concluding: (a) the amount of such additional royalties; and (b) interest on the amounts overdue of such underpayment which shall be calculated pursuant to Section 7.4. In the event such accounting firm concludes that amounts were overpaid by LICENSEE during such period, LICENSEE shall have a credit against future royalties payable to MTPC in the amount of such overpayment; provided, however, that LICENSEE may have an independent certified public accounting firm of nationally recognized standing, selected by LICENSEE and reasonably acceptable to MTPC, at LICENSEE's expense, confirm the results of the audit conducted by MTPC's accounting firm. The fees charged by MTPC's accounting firm shall be paid by MTPC; provided, however, if an error in favor of MTPC of more than five percent (5%) of the royalties due hereunder for the period being reviewed is discovered, then LICENSEE shall pay the reasonable fees and expenses charged by such accounting firm.
- 6.2.3 <u>Confidential Financial Information</u>. MTPC shall treat all financial information subject to review under this Article 6 as confidential, and shall cause its accounting firm to retain all such financial information in confidence.

ARTICLE 7 PAYMENTS

- 7.1 <u>Payments Terms</u>. Royalties shown to have accrued by each royalty report provided for under Section 6.1 shall be due and payable on the date such royalty report is due.
- 7.2 <u>Payment Method</u>. All payments by LICENSEE to MTPC under this Agreement shall be paid in United States Dollars. If any currency conversion shall be required in connection with the payment of any royalties hereunder, such conversion shall be made by using the average of the exchange rates for the purchase and sale of United States Dollars reported by the Bank of

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Tokyo Mitsubishi UFJ on the last business day of the Calendar Quarter to which such royalty payments relate.

- 7.3 <u>Exchange Control</u>. If at any time legal restrictions prevent the prompt remittance of part or all of the royalties with respect to any country in the LICENSEE Territory where the Product is sold, LICENSEE shall have the right, at its option, to make such payments by depositing the amount thereof in local currency to MTPC's account in a bank or other depository designated by MTPC in such country.
- 7.4 Overdue Payments. In the event the initial payment, any milestone payment or any royalty payment is not made when due, such outstanding payment shall accrue interest (from the date such payments is due through and including the date upon which full payment is made) at the annual rate of [*].
- 7.5 Withholding Taxes. LICENSEE shall be entitled to deduct from any payment due MTPC under this Agreement the amount of any withholding taxes payable by LICENSEE or its Affiliates, or any taxes required to be withheld by LICENSEE or its Affiliates, to the extent LICENSEE or its Affiliates pay to the appropriate governmental authority on behalf of MTPC such taxes, levies or charges. LICENSEE shall use reasonable efforts to minimize any such taxes, levies or charges required to be withheld on behalf of MTPC by LICENSEE or its Affiliates. LICENSEE promptly shall deliver to MTPC proof of payment of all such taxes, levies and other charges, together with copies of all communications from or with such governmental authority with respect thereto. Upon reasonable request from MTPC, LICENSEE shall cooperate with MTPC to supply forms or documentation required by any applicable taxation laws, treaties or agreements to such withholding or as necessary to claim a benefit.

ARTICLE 8 CONFIDENTIALITY

- 8.1 <u>Nondisclosure Obligations</u>. Except as otherwise provided in this Article 8, during the term of this Agreement and for a period of five (5) years thereafter, both Parties shall maintain in confidence and use only for purposes of this Agreement the Proprietary Information supplied by the other Party.
- 8.2 <u>Permitted Disclosures</u>. To the extent it is reasonably necessary or appropriate to fulfill its obligations or exercise its rights under this Agreement, a Party (including its Affiliates and sublicensees) may disclose Proprietary Information of the other Party which it is otherwise obligated under this Article 8 not to disclose (a) to its Affiliates, its sublicensees and potential sublicensees, its consultants, investors and potential investors, outside contractors and clinical investigators, on a need-to-know basis on condition that such Persons agree to keep the Proprietary Information confidential for the same time periods and to the same extent as such Party is required to keep the Proprietary Information confidential; and (b) to government or other regulatory authorities to the extent that such disclosure is required by applicable law (including without limitation all applicable securities laws), regulation, agency or

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disclosure or to request confidential treatment thereof. The obligation not to disclose or use Proprietary Information received from the other Party shall not apply to any part of such Proprietary Information that (i) is or becomes patented, published or otherwise part of the public domain other than by acts of the Party obligated not to disclose such Proprietary Information in contravention of this Agreement; (ii) is disclosed to the receiving Party by a Third Party, provided such Proprietary Information was not obtained by such Third Party directly or indirectly from the other Party on a confidential basis; (iii) prior to disclosure under this Agreement, was already in the possession of the receiving Party, provided such Proprietary Information was not obtained directly or indirectly from the other Party; (iv) is subsequently and independently developed by the receiving Party without the knowledge of the Proprietary Information or (v) is disclosed in a press release agreed to by both Parties, which agreement shall not be unreasonably withheld.

8.3 <u>SEC Filings</u>. The Parties will consult with each other on the provisions of this Agreement to be redacted in filings, if any, made by the Parties with the Securities and Exchange Commission or as otherwise required by law. The Parties agree that either Party may make such disclosures pursuant to Form 8-K or otherwise as it determines, based on advice of counsel, are reasonably necessary to comply with laws or regulations or for appropriate market disclosure, with the prior written consent by the other Party. The Parties shall consult with one another before any such filing, and shall seek protection for any Proprietary Information (including any terms and conditions of this Agreement).

8.4 <u>Press Release and Publication</u>.

- 8.4.1 <u>Press Release</u>. In the event that either Party desires to issue a press release relating to this Agreement, the Parties shall discuss in good faith and agree upon the contents and timing of such press release.
- 8.4.2 Scientific Publication. In the event that either Party, its Affiliate or its sublicensee(s) or licensee(s) is willing, required or obliged to make any publication in a scientific journal or at a conference in any academic society on the information obtained from its Development Work on the Compound and/or the Product, such Party, to the extent it has a right to review any such publication or presentation, shall endeavor in good faith to submit to the other Party the full text of such publication, at least thirty (30) days before the date of such publication and to consult with the other Party and to solicit comments with respect to such publication or presentation; provided, however, that such other Party shall not prevent the first Party from complying with regulatory requirements.

ARTICLE 9 INTELLECTUAL PROPERTY

9.1 <u>Ownership of Improvements</u>. Each Party shall solely own, and such Party alone shall have the right to apply for, any patents within and outside its Territory for any improvements regarding the Compound and/or the Products made solely by such Party's employees in the course of the performance of any work under this Agreement. Improvements made jointly by employees of MTPC and LICENSEE, its Affiliates or its sublicensees shall be

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owned jointly by MTPC and LICENSEE, its Affiliates or its sublicensees and shall be included in the licenses described in Article 2 hereof.

9.2 <u>Patents Prosecution and Maintenance</u>.

- 9.2.1 MTPC Patents. MTPC shall have the initial right to control the filing, prosecution and maintenance of the MTPC Patents in the LICENSEE Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the MTPC Patents in the LICENSEE Territory. MTPC shall be responsible for the payment of all such patent prosecution and maintenance costs of the MTPC Patents in the Major Countries and LICENSEE shall be responsible for the payment of all such patent prosecution and maintenance costs of the MTPC Patents in the remaining countries in the LICENSEE Territory if LICENSEE desires to prosecute and maintain the MTPC Patents in such remaining countries. MTPC shall solicit LICENSEE's review of the nature and text of any such patent applications in the LICENSEE Territory and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and MTPC takes into account LICENSEE's reasonable comments related thereto. MTPC, taking such LICENSEE's request into consideration but at its sole discretion, shall file patent claims related to the Compound or Product proposed by LICENSEE in any MTPC Patent or a continuation or divisional of the foregoing. MTPC shall inform LICENSEE of any significant developments in the prosecution of pending patent applications included in the MTPC Patents in the LICENSEE Territory, including the issuance of any final office actions, allowance of claims, or upcoming grant of any domestic or foreign patent based thereon. If MTPC decides not to file, prosecute or maintain a MTPC Patent in any country in the LICENSEE Territory, and LICENSEE shall have the right but not the obligation, at its sole expense, to file, prosecute or maintain such MTPC Patent in such country, and MTPC Patent shall no longer be deemed MTPC Patent.
- 9.2.2 <u>LICENSEE Patents</u>. LICENSEE shall have the right to control the filing, prosecution, and maintenance of the LICENSEE Patents in the respective Territory, and to select all patent counsel or other professionals to advise, represent or act for it in all matters relating to the LICENSEE Patents. LICENSEE shall be responsible for the payment of all such patent prosecution and maintenance costs. LICENSEE shall solicit MTPC's review of the nature and text of any such patent applications in the MTPC Territory and important prosecution matters related thereto in reasonably sufficient time prior to filing thereof, and LICENSEE shall take into account MTPC's reasonable comments related thereto. LICENSEE shall inform MTPC of any significant developments in the prosecution of pending patent applications included in the LICENSEE Patents in the MTPC Territory, including the issuance

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title and interest in and to such LICENSEE Patent in such country and such LICENSEE Patent shall no longer be deemed LICENSEE Patent.

9.3 <u>Cooperation</u>. Each Party shall make available as far as possible to the other Party or to the other Party's authorized attorneys, agents, representatives, employees or consultants any documents necessary or appropriate to enable the other Party to file, prosecute and maintain patent applications and resulting patents, as set forth in Section 9.2, for a period of time sufficient for the other Party to obtain the assistance it needs from the first Party. Where appropriate, each Party shall sign or cause to have signed all documents relating to said patent applications or patents at no charge to the other Party.

9.4 <u>Enforcement of Patents</u>.

- 9.4.1 Excluding Action. Each of the Parties shall notify the other of any activity or product which it reasonably believes constitutes an infringement or misappropriation of the MTPC Patents or MTPC Know-How in the LICENSEE Territory or of any claim of invalidity or other challenge or opposition in respect of a MTPC Patent. LICENSEE shall have the right, in the first instance, to enforce the MTPC Patents against such infringing technology or to defend any such claim of invalidity or other challenge or opposition within the LICENSEE Territory. In the event LICENSEE declines to prosecute such infringing technology or to defend such claim within ninety (90) days (or twenty-one (21) days from the receipt of paragraph IV certificate or aware of the ANDA application) of becoming aware thereof, MTPC shall have the right to so enforce or defend. The Parties agree that the costs of such prosecution or defense of validity, in connection with an infringement in the LICENSEE Territory shall be borne by the Party who prosecutes or defends the action.
- 9.4.2 <u>Settlements, Allocation of Monetary Award</u>. The Party controlling the action may not settle the action or otherwise consent to an adverse judgment in such action that diminishes the rights or interests of the non-controlling Party without the express written consent of the non-controlling Party, which consent shall not be unreasonably withheld. Notwithstanding the foregoing, MTPC and LICENSEE shall cooperate with each other in the planning and execution of any action to enforce the MTPC Patents. Any recovery and proceeds of any awards, judgments or settlements obtained by LICENSEE or MTPC shall be shared as follows, whether the recovery is by settlement or otherwise:
- (a) the enforcing or defending Party shall first be entitled to recoup all of its out-of-pocket costs and expenses (including reasonable attorneys' fees) incurred in connection with the action;
- (b) the other Party, if joined or cooperating in the action, shall then be entitled to recover its out-of-pocket costs and expenses (including reasonable attorneys' fees) incurred in connection with the action, not already reimbursed by the enforcing or defending Party;
- (c) any recovery remaining shall be allocated between the Parties on a pro rata basis based upon the respective lost profits of the Parties as a result of the infringing activities, which allocation ratio shall be separately agreed upon in writing by the Parties.

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- 9.4.3 Each Party agrees to furnish the other with such cooperation, including consenting to act as a Party to litigation if required, and exchange of information as the other Party may reasonably request in connection with the prosecution of any such action and the Party prosecuting an infringement or defending a claim of invalidity shall consult periodically with the other Party in connection with any such action. Neither Party shall take any action which would admit the invalidity of a MTPC Patent without the consent of the other Party, which consent shall not be unreasonably withheld.
- 9.5 <u>Patent Term Restoration</u>. The Parties, their Affiliates or their sublicensees shall cooperate with each other, execute all documents and take all actions that may be necessary to pursue patent term extensions, supplemental protection certificates or their future equivalents applicable to the LICENSEE Patents or the MTPC Patents, under appropriate laws and/or regulations in the LICENSEE Territory and/or MTPC Territory. MTPC and LICENSEE shall discuss and determine which patents shall be extended in the respective Territory. All filings for such patent term extension or supplemental protection certificates shall be made by the Party who owns the patent at its sole cost and expense.
- 9.6 Infringement of Third Party Rights. Each Party or its Affiliate shall promptly notify the other Party in writing of any allegation by a Third Party that the manufacture, development, importation, use, offer for sale or sale of a Compound or Product covered by the MTPC Intellectual Property, infringes or may infringe the intellectual property rights of such Third Party in any country of the LICENSEE Territory or the MTPC Territory. LICENSEE or its Affiliate or sublicensee shall have the first right to control the defense of any claim alleging that the manufacture, development, importation, use, offer for sale or sale of such Compound or Product in the LICENSEE Territory infringes any such Third Party rights or may settle on terms that it deems advisable in its sole discretion, provided that any final disposition of the litigation that will restrict the claims in or admit any invalidity of any MTPC Patent shall not be made without full consultation with and approval by MTPC, not to be unreasonably withheld. If LICENSEE or its Affiliate or sublicensee fails to proceed in a timely manner with respect to such defense, MTPC shall have the right to control the defense of such claim. The Parties shall consult and cooperate fully to determine a course of action. If, finally, LICENSEE or its Affiliate or sublicensee is required by order or judgment of any court in any jurisdiction, or LICENSEE or its Affiliate or sublicensee in its sole discretion after having obtained an outside legal opinion, believes it necessary to obtain a license, obtains a license under such intellectual property right from such Third Party, and makes payments to such Third Party to avoid alleged infringement, then [*] of the royalty or other payments required to be paid by LICENSEE or its Affiliate or sublicensee to such Third Party as the result of a judgment or settlement under this Section 9.6 ("Third Party Payment") shall be creditable against the royalty payments pursuant to Section 5.3 due MTPC with respect to the sale of such

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settle on terms that it deems advisable in its sole discretion, provided that MTPC and any MTPC Affiliate or licensee will not take any step in relation to such proceedings which might have a detrimental effect on LICENSEE's rights under this Agreement and in particular the prosecution, maintenance and defence of the MTPC Patents in the LICENSEE Territory.

ARTICLE 10 TERM AND TERMINATION

10.1 <u>Expiration</u>. This Agreement shall come into effect on the Effective Date and, unless earlier terminated, shall continue in effect until the expiration of LICENSEE's obligations to pay royalties. After the expiration of this Agreement, on a country-by-country basis, in such country in the Territory, LICENSEE will have a fully paid-up, non-exclusive, perpetual, irrevocable license, with the right to grant and authorize sublicenses, with respect to the MTPC Patents and MTPC Know-How in such country in the LICENSEE Territory or in the case of the manufacture of Compound, anywhere in the world for the purpose of manufacturing the Product to be sold in the LICENSEE Territory.

10.2 <u>Termination for Cause</u>.

- 10.2.1 Either Party may terminate this Agreement upon or after the breach of any material provision of this Agreement by the other Party, if the breaching Party has not cured such breach within sixty (60) days after notice thereof from the non-breaching Party. This Agreement shall terminate, at the option of the non-breaching Party, at the expiration of such sixty (60) day cure period; provided, however, that if the breach is not capable of being cured within sixty (60) days of such written notice, this Agreement may not be terminated so long as the breaching Party commences and is taking commercially reasonable actions to cure such breach as promptly as practicable.
- 10.2.2 Either Party may terminate this Agreement upon giving notice to the other Party, which termination notice shall have immediate effect, in the case of any adjudication of bankruptcy or insolvency, appointment of a receiver by a court of competent jurisdiction, assignment for the benefit of creditors, or institution of liquidation proceedings by or against the other Party.
- 10.2.3 Notwithstanding anything to the contrary contained in Section 10.2.1, 10.2.2 or 13.2, in the event that MTPC is entitled to terminate this Agreement pursuant to Section 10.2.1 or 10.2.2, prior to exercising such termination right, MTPC shall offer LICENSEE's sublicensees the ability to assume LICENSEE's rights and obligations under this Agreement and to continue this Agreement in full force and effect between MTPC and such sublicensee.
- 10.3 Other LICENSEE Termination. In the event that LICENSEE believes that (1) certain data and information with regard to any safety or efficacy or scientific or regulatory issue in relation to the Compound or Product obtained through the Development Work does not justify continued development of the Product by LICENSEE, its Affiliate and/or sublicensee or (2) LICENSEE believes that commercial considerations or other factors for marketing of the Product do not justify continued development, commercialization or marketing of the Product by

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LICENSEE, its Affiliate and/or its sublicensees, LICENSEE may terminate this Agreement in its sole discretion at any time during the term hereof in its entirety, or on a country-by-country, Compound-by-Compound or Product-by-Product basis (a) on not less than ninety (90) days prior written notice to MTPC if such termination occurs prior to Launch of such Product in such country, or (b) on not less than one hundred eighty (180) days prior written notice to MTPC if such termination occurs after the Launch of such Product in such country, informing MTPC of and discussing with MTPC the reasonable reason for which it is terminating all or part of this Agreement; provided however that if LICENSEE desires to terminate this Agreement in the cases safety problems caused by the Compound or Product, LICENSEE shall explain MTPC the reasonable reasons why such safety problems could not be avoided despite LICENSEE's clinical development plan to decrease the risk of such safety problems. In which case LICENSEE's obligation to perform any further work under this Agreement shall cease in such country or for such Compound or for such Product as of the date of the end of the period set forth in Section 10.3. (a) or 10.3.(b).

10.4 Effect of Expiration and Termination. Expiration or termination of this Agreement shall not relieve the Parties of any obligation accruing on or prior to such expiration or termination. LICENSEE and its Affiliates and sublicensees shall have the right to sell or otherwise dispose of the stock of any Product subject to this Agreement then on hand or in process of manufacture, subject to Articles 5, 6 and 7. In addition to any other provisions of this Agreement which shall by their terms continue after the expiration of this Agreement, the provisions of Article 8 shall survive the expiration or termination of this Agreement and shall continue in effect during the term set forth in Section 8.1. In addition, any other provision required to interpret and enforce the Parties' rights and obligations under this Agreement shall also survive, but only to the extent required for the full observation and performance of this Agreement. Except as expressly set forth herein, the rights to terminate as set forth herein shall be in addition to all other rights and remedies available under this Agreement, at law, or in equity, or otherwise.

Effect of Termination Without MTPC's Cause. In the event that this Agreement shall be terminated by MTPC pursuant to Section 4.1.4, 10.2 or by LICENSEE pursuant to Section 10.3, LICENSEE or its Affiliate shall return to MTPC all written MTPC Know-How and all copies thereof and furnish MTPC with all of LICENSEE, its Affiliates or its sublicensee Know-How not already provided to MTPC with a royalty-free worldwide right to use all LICENSEE Patents and LICENSEE Know-How. LICENSEE or its Affiliate shall further transfer free of charge to MTPC or its nominee any IND, Application or other documents filed with any government agency in LICENSEE Territory and any Registration obtained in LICENSEE Territory LICENSEE shall, at the request of MTPC, cooperate with MTPC or its nominee for the smooth transfer of them.

ARTICLE 11 REPRESENTATIONS AND WARRANTIES

- 11.1 <u>Mutual Representations</u>. The Parties hereby represent and warrant as follows:
- 11.1.1 <u>Corporate Existence and Power</u>. Such Party (a) is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction in which it is

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incorporated, and (b) has the corporate power and authority and the legal right to own and operate its property and assets, to lease the property and assets it operates under lease, and to carry on its business as it is now being conducted;

- 11.1.2 <u>Authorization and Enforcement of Obligations</u>. Such Party (a) has the corporate power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (b) has taken all necessary corporate action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations hereunder. This Agreement has been duly executed and delivered on behalf of such Party, and constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;
- 11.1.3 <u>Consents.</u> All necessary consents, approvals and authorizations of all governmental authorities and other Persons required to be obtained by such Party in connection with this Agreement have been obtained; and
- 11.1.4 <u>No Conflict</u>. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (a) do not conflict with or violate any requirement of applicable laws or regulations and (b) do not conflict with, or constitute a default under, any contractual obligation of such Party.
 - 11.2 Representations and Warranties of MTPC. MTPC additionally represents and warrants to LICENSEE as of the Effective Date that:
- the MTPC Intellectual Property is owned or controlled by MTPC free and clear of any liens, charges and encumbrances, and no other person, corporate or other private entity, or governmental or university entity or subdivision thereof, has any valid claim of ownership with respect to the MTPC Intellectual Property, whatsoever;
- 11.2.2 MTPC has not previously granted, and will not grant during the term of this Agreement, any right, license or interest in and to the MTPC Intellectual Property, or any portion thereof, inconsistent with the licenses granted to LICENSEE herein;
- 11.2.3 MTPC does not have any knowledge of the existence of any references or conduct that would bring into question the validity or enforceability of the MTPC Intellectual Property in the Field;
- 11.2.4 there are no pending or, to the knowledge of MTPC, threatened actions, suits, investigations, claims or proceedings in any way relating to the MTPC Intellectual Property;
- 11.2.5 MTPC has disclosed to FORENAP or LICENSEE all material scientific and technical information known to MTPC or its Affiliates relating to the safety and efficacy of the Wf-516 Compound and Product containing the Wf-516 Compound;
- 11.2.6 MTPC has disclosed to FORENAP or LICENSEE all information which MTPC reasonably considers necessary for LICENSEE to file an IND with the FDA;

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- 11.2.7 <u>Schedule 1.34</u> contains a complete and accurate list of all Patents Rights relating to the Compound or the Product containing the Compound owned or controlled by MTPC in the LICENSEE Territory and such Patents Rights have been diligently prosecuted and all fees payable in relation to such Patent Rights have been paid on or before their due date.
- to the knowledge of MTPC, the patents encompassed within the MTPC Patents, are, or, upon issuance, will be, valid and enforceable patents.
- 11.2.9 to the knowledge of MTPC, the manufacture, use, sale, offer for sale, supply or importation by LICENSEE (or its Affiliates or sublicensees) of the Wf-516 Compound or Product containing the Wf-516 Compound does not and will not infringe any issued patent of any Third Party or, if and when issued, any claim within any published patent application of any Third Party;

- 11.2.10 MTPC has heretofore disclosed to LICENSEE or FORENAP, all material filings, notices, reports and other correspondence and contact information between MTPC and the FDA or any other regulatory authority regarding the Wf-516 Compound or the Product containing the Wf-516 Compound;
- 11.2.11 Schedule 11.2.11 sets forth a complete and accurate listing of all pre-clinical and clinical studies and trials, together with the dates and titles of such studies and trials, previously or currently undertaken or sponsored by MTPC or its Affiliates with respect to the Compounds and Products. True, complete and accurate copies of all data and reports with respect to the studies and trials listed on Schedule 11.2.11 have been provided for review to LICENSEE or FORENAP, and MTPC has otherwise provided for review to LICENSEE or FORENAP all material preclinical and clinical studies and trials of all Compounds and Products;
- 11.2.12 Wf-516 Compound and Product containing the Wf-516 Compound are being developed, manufactured, stored, labeled, distributed and tested by MTPC or its Affiliates or any Third Party acting on behalf of MTPC in compliance in all applicable laws, rules and regulations at that time;
- 11.2.13 All Wf-516 Bulk supplied hereunder shall comply with the Specifications and shall conform with the information shown on the Certificate of Analysis provided for the particular shipment pursuant to Section 4.5.6 above;
- 11.2.14 The Facility, the manufacturing and supply activities contemplated herein and all Wf-516 Bulk supplied hereunder shall comply with the Regulatory Requirements and the Specifications, and all raw materials used in the manufacture of Wf-516 Bulk hereunder shall comply with the applicable specifications, and the Regulatory Requirements;
 - 11.2.15 None of the Wf-516 Bulk supplied to LICENSEE under this Agreement shall be adulterated or misbranded; and
- 11.2.16 Title to all Wf-516 Bulk supplied under this Agreement shall pass as provided in this Agreement, free and clear of any security interest, lien, or other encumbrance.

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- 11.3 Representations of LICENSEE. LICENSEE additionally represents and warrants to MTPC that:
 - 11.3.1 LICENSEE is a corporation duly organized and validly existing and in good standing under the laws of the State of Delaware,

U.S.A.;

- 11.3.2 upon request by LICENSEE, LICENSEE will be funded in accordance with the terms and conditions of a Securities Purchase Agreement by and among Care Capital, LLC Index Ventures (or other respective Affiliates) and the LICENSEE, a copy of which is attached as Schedule 11.3.2; and
- 11.3.3 LICENSEE has an ability to conduct the Development Work and to prepare the Development Plan in consultation with FORENAP.
- 11.4 Disclaimer of Representations. EXCEPT AS OTHERWISE EXPRESSLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATION OR EXTENDS ANY WARRANTIES OF ANY KIND EITHER EXPRESS OR IMPLIED, INCLUDING BUT NOT LIMITED TO WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, NONINFRINGEMENT, OR VALIDITY OF ANY PATENTS ISSUED OR PENDING.

ARTICLE 12 INDEMNIFICATION

- 12.1 <u>LICENSEE's Obligation</u>. LICENSEE shall defend, indemnify, and hold harmless MTPC, its Affiliates and their respective directors, officers, shareholders, employees and agents ("<u>MTPC Indemnitees</u>"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, but not limited to reasonable attorney's fees (collectively "<u>MTPC Damages</u>") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against an MTPC Indemnitee that is due to or based upon:
 - 12.1.1 any breach of a representation, warranty, covenant or agreement of LICENSEE under this Agreement,
 - 12.1.2 any negligent act of LICENSEE, its Affiliates or its sublicensees under this Agreement, or
- 12.1.3 development, manufacture, use, sale or labeling of Compound, Bulk Drug Substance or Product by LICENSEE, its Affiliates or its sublicensees.

However, LICENSEE shall not indemnify or hold harmless MTPC Indemnitees from MTPC Damages to the extent that such MTPC Damages are finally determined to have resulted from an item for which MTPC is obligated to indemnify LICENSEE pursuant to Section 12.2. LICENSEE's obligations under this Section shall survive the expiration or termination of this Agreement for any reason.

12.2 <u>MTPC's Obligation</u>. MTPC shall defend, indemnify, and hold harmless LICENSEE, its Affiliates and their respective directors, officers, shareholders, employees and

agents ("<u>LICENSEE Indemnitees</u>"), from and against any and all liabilities, damages, losses, penalties, fines, costs, interest, and expenses, including, but not limited to reasonable attorney's fees (collectively "<u>LICENSEE Damages</u>") arising from or occurring as a result of a Third Party's claim, action, suit, judgment or settlement against an LICENSEE Indemnitee that is due to or based upon:

- 12.2.1 any breach of a representation, warranty, covenant or agreement of MTPC under this Agreement,
- 12.2.2 any negligent act of MTPC, its Affiliates or its sublicensees under this Agreement; or
- 12.2.3 development, manufacture, use, sale or labeling of Compound, Bulk Drug Substance or Product by MTPC, its Affiliates or its sublicensees.

However, MTPC shall not indemnify or hold harmless LICENSEE Indemnitees from LICENSEE Damages to the extent that such LICENSEE Damages are finally determined to have resulted from an item for which LICENSEE is obligated to indemnify MTPC pursuant to Section 12.1. MTPC's obligations under this Section shall survive the expiration or termination of this Agreement for any reason.

12.3 <u>Insurance</u>. LICENSEE, its Affiliates and/or its sublicensees shall maintain and keep in force for the term of this Agreement comprehensive general liability insurance including Products/Completed Operations, Contractual and Broad Form Property Damage covering its indemnification obligations hereunder combined single limit for Bodily Injury and Property Damage. It is understood that such insurance shall not be construed to limit LICENSEE's liability with respect to such indemnification obligations.

ARTICLE 13 MISCELLANEOUS

- 13.1 <u>Force Majeure</u>. Neither Party shall be held liable or responsible to the other Party nor be deemed to have defaulted under or breached this Agreement for failure or delay in fulfilling or performing any term of this Agreement to the extent, and for so long as, such failure or delay is caused by or results from causes beyond the reasonable control of the affected Party including but not limited to fire, floods, embargoes, power shortage or failure, war, acts of war (whether war be declared or not), insurrections, riots, civil commotions, strikes, lockouts or other labor disturbances, acts of God or acts, omissions or delays in acting by any governmental authority or the other Party.
- Assignment. This Agreement may not be assigned or otherwise transferred, nor, except as expressly provided hereunder, may any right or obligations hereunder be assigned or transferred by either Party without the prior written consent of the other Party (which consent shall not be unreasonably withheld); provided, however, that either MTPC or LICENSEE may, without the other Party's consent, assign this Agreement and its rights and obligations hereunder to an Affiliate or in connection with the transfer or sale of all or substantially all of its business to which this Agreement relates, or in the event of its merger or consolidation or change in control

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

- 13.3 Severability. Each Party hereby acknowledges that it does not intend to violate any public policy, statutory or common laws, rules, regulations, treaty or decision of any government agency or executive body thereof of any country or community or association of countries. Should one or more provisions of this Agreement be or become invalid, the Parties shall substitute, by mutual consent, valid provisions for such invalid provisions which valid provisions in their economic effect are sufficiently similar to the invalid provisions that it can be reasonably assumed that the Parties would have entered into this Agreement with such provisions. In case such provisions cannot be agreed upon, the invalidity of one or several provisions of the Agreement shall not affect the validity of this Agreement as a whole, unless the invalid provisions are of such essential importance to this Agreement that it is to be reasonably assumed that the Parties would not have entered into this Agreement without such invalid provisions.
- Notices. Any consent, notice or report required or permitted to be given or made under this Agreement by one of the Parties to the other shall be in writing, delivered personally or by facsimile (and promptly confirmed by personal delivery, first class mail or courier), first class mail or courier, postage prepaid (where applicable), addressed to such other Party at its address indicated in the Section 13.4, or to such other address as the addressee shall have last furnished in writing to the addressor and (except as otherwise provided in this Agreement) shall be effective upon receipt by the addressee.

To MTPC: Mitsubishi Tanabe Pharma Corporation

3-2-10, Dosho-machi, Chuo-ku, Osaka 541-8505, Japan Attn: Head of Business Development & Licensing Department

Fax: +81-6-6205-5289 Phone: +81-6-6205-5508

To LICENSEE: Sonkei Pharmaceuticals, Inc.

47 Hulfish Street, Suite 310, Princeton, NJ 08542, U.S.A.

Attn: Jerry Karabelas Fax: +1-609-683-5787 Phone: +1-609-683-3662

With a copy to: Sonkei Pharmaceuticals, Inc.

47 Huffish Street, Suite 310, Princeton, NJ 08542, U.S.A.

Attn: Lorenzo Pellegrini

Fax: +1-609-683-5787 Phone: +1-609-683-3677

And with a copy to:

Index Ventures 2 rue Jargonnant 1207 Genève Switzerland Attn: Michèle Ollier

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Fax: +41-22-737-0099 Phone: +41-22-737-0026

13.5 <u>Applicable Law.</u> This Agreement shall be governed by and construed in accordance with the laws of the State of New York, the U.S. without regard to the conflicts of law principles thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Right in question.

13.6 <u>Dispute Resolution</u>.

- 13.6.1 The Parties agree to attempt initially to solve all claims, disputes, or controversies arising under, out of, or in connection with this Agreement (a "<u>Dispute</u>") by conducting good faith negotiations. Any Disputes which cannot be resolved by good faith negotiation within twenty (20) business days, shall be referred, by written notice from either Party to the other, to the Chief Executive Officer of each Party. Such Chief Executive Officers shall negotiate in good faith to achieve a resolution of the Dispute referred to them within twenty (20) business days after such notice is received by the Party to whom the notice was sent. If the Chief Executive Officers are unable to settle the Dispute between themselves within twenty (20) business days, they shall so report to the Parties in writing. The Dispute shall then be referred to mediation as set forth in the Section 13.6.2.
- 13.6.2 Upon the Parties receiving the Chief Executive Officers' report that the Dispute referred to them pursuant to Section 13.6.1 has not been resolved, a Party may decide to institute arbitration proceedings, in which case it shall give written notice to that effect to the other Party. The Parties shall refrain from instituting the arbitration proceedings for a period of sixty (60) days following such notice. During such period, the Parties shall continue to make good faith efforts to amicably resolve the dispute without arbitration. If the Parties have not reached a settlement during that period the arbitration proceedings shall go forward and be governed by the rules of Conciliation and Arbitration of the International Chamber of Commerce ("ICC") then in force. Each such arbitration shall be conducted by a panel of three arbitrators: one arbitrator shall be appointed by each of LICENSEE and MTPC and the third arbitrator, who shall be the Chairman of the tribunal, shall be appointed by the two-Party appointed arbitrators. Any such arbitration shall be held in London, England or such other place as may be mutually agreed upon in writing by the Parties. The language of the arbitration shall be English.
- 13.6.3 The tribunal shall issue its award within forty-five (45) days after the date on which the arbitration proceedings have closed. The arbitrators shall have the authority to grant specific performance. Judgment upon the award so rendered may be entered in any court having jurisdiction or application may be made to such court for judicial acceptance of any award and an order of enforcement, as the case may be. In no event shall a demand for arbitration be made after the date when institution of a legal or equitable proceeding based on such claim, dispute or other matter in question would be barred by the applicable statute of limitations. Each Party shall bear its own costs and expenses incurred in connection with any arbitration proceeding and the Parties shall equally share the cost of the mediation and arbitration levied by the ICC.

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- 13.7 <u>Competing Product</u>. LICENSEE or its Affiliate to whom it sublicenses its rights under this Agreement, shall not market or sell any Competing Product as long as the Compound is either an active development candidate or the Product is being marketed.
- 13.8 <u>LIMITATION OF LIABILITY</u>. NEITHER PARTY SHALL BE LIABLE TO THE OTHER FOR ANY SPECIAL, CONSEQUENTIAL, INCIDENTAL OR INDIRECT DAMAGES ARISING OUT OF THIS AGREEMENT, HOWEVER CAUSED, UNDER ANY THEORY OF LIABILITY EXCEPT TO THE EXTENT OF ANY SUCH DAMAGES PAID TO A THIRD PARTY IN CONNECTION WITH A CLAIM MADE BY SUCH PARTY FOR WHICH A PARTY IS RESPONSIBLE TO INDEMNIFY THE OTHER PARTY PURSUANT TO SECTION 12.1 OR 12.2.
- 13.9 <u>Further Assurances</u>. At any time or from time to time on and after the date of this Agreement, each Party shall at the request of the other (i) deliver to the other such records, data or other documents consistent with the provisions of this Agreement, (ii) execute, and deliver or cause to be delivered, all such consents, documents or further instruments of transfer or license, and (iii) take or cause to be taken all such actions, as such Party may reasonably deem necessary or desirable in order for the other Party to obtain the full benefits of this Agreement and the transactions contemplated herein.
- 13.10 <u>Entire Agreement</u>. This Agreement contains the entire understanding of the Parties with respect to the subject matter hereof. All express or implied agreements and understandings, either oral or written, heretofore made are expressly superseded by this Agreement. This Agreement may be amended, or any term hereof modified, only by a written instrument duly executed by both Parties.
- 13.11 <u>Headings</u>. The captions to the several Articles and Sections hereof are not a part of this Agreement, but are merely guides or labels to assist in locating and reading the several Articles and Sections hereof.

- 13.12 <u>Independent Contractors</u>. It is expressly agreed that MTPC and LICENSEE shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency. Neither MTPC nor LICENSEE shall have the authority to make any statements, representations or commitments of any kind, or to take any action, which shall be binding on the other Party, without the prior written consent of the other Party to do so.
- 13.13 <u>Waiver</u>. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by said other Party whether of a similar nature or otherwise.
- 13.14 <u>Counterparts</u>. This Agreement may be executed in two or more counterparts (including by facsimile), each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

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

Sonkei Pharmaceuticals, Inc.

By: /s/ Michele Ollier

Name: Michele Ollier

Title: Partner, Director and Chairman

Mitsubishi Tanabe Pharma Corporation

By: /s/ Natsuki Hayama

Name: Natsuki Hayama

Title: President & Representative Director

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Schedule 1.10. Chemical Structure of the Wf-516 Compound

[*]

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Schedule 1.12. Development Plan

[*]

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Schedule 1.34. The List of MTPC Patents

Patent List of Wf-516

Revised on August 26, 2008

No.	Summary of patent	State	Application number	Date of filling	Publication number	Patent number	Grant date	Others
1	[*]	[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	[*]	[*]	[*]	

		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	_			[*]
		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	[*]			[*]
		[*]	[*]	[*]	[*]	[*]	[*]	
		[*]	[*]	[*]	_	[*]	[*]	
		[*]	[*]	[*]	_	[*]	[*]	[*]
2	[*]	[*]	[*]	[*]	[*]			

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Schedule 1.52. Specifications

Specifications for WE-516 Drug Substance

Test Item	Specific	ation	Analytical Method
Description	[*]	[*]	
Identification			
(1) [*]	[*]	[*]	
(2) [*]	[*]	[*]	
Purity			
(1) [*]	[*]	[*]	
(2) [*]	[*]	[*]	
(3) [*]	[*]	[*]	
[*]	[*]	[*]	
[*]	[*]s	[*]	
[*] [*]	[*]		
[*]	[*]		
[*]	[*]		
[*]	[*]		
[*]	ĹĴ		
[*]			
(4) [*]		[*]	
[*]	[*]	l J	
[*]	[*]		
(5) [*]	[*]	[*]	
(6) [*]	l J	[*]	
(v) []		LJ	
[*] [*]	[*]		
[*]	[*]		
[*]	[*]		
[*]	[*]		
[*]	[*]		
[.]	[*]		
[*]	[*]	[*]	
[*] [*]	[*]	[*]	
[*]	[*]	[] [*]	
[*]	[*]	[*] [*]	
[*]	LJ	[*]	
/1) []			
(1)[]			
(2)[]			
(4)[1]			
[*] (C)*			
(3) []			
	38		
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Schedule 4.1.1. Services Agreement

Schedule 5.2. Milestone Payments

Event	MDD*	All other indications other than MDD**
Onset of Phase II(a) Study	[*]	
Onset of Phase II(b) Study	[*]	
Onset of Phase III Study	[*]	[*]
Application in the US	[*]	[*]
Application in the first European Country	[*]	[*]
Launch in the US	[*]	[*]
Launch in the first European Country	[*]	[*]
When the Net Sales in the US exceed [*] in a Calendar Year		[*]

[&]quot;MDD" shall mean major depression disorder defined in ICD 10.

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Schedule 11.2.11. List of all pre-clinical and clinical studies and trials

Reference Number in Mitsubishi IB, Reference version 1	Study Repo		Investigator	Version or Amendment Number	Date of report/amendment	Language of original report	Status (Note)	Target completion date	Target final report date	PDF files	Status of Database
[*] [*]	[*] [*	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]

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Schedule 11.3.2. Securities Purchase Agreement

^{**} All other mood disorders (other than MDD) shall be treated as a single "indication".

AMENDMENT TO LICENSE AGREEMENT

This Amendment ("AMENDMENT") dated as of 20 January, 2014 ("AMENDMENT DATE") is entered into between Minerva Neurosciences, Inc. (Formerly known as Sonkei Pharmaceuticals, Inc.), a Delaware corporation, having a place of business located at 245 First Street, Suite 1800, Cambridge MA 02142, U.S.A. ("LICENSEE") and Mitsubishi Tanabe Pharma Corporation, a Japanese corporation, having a place of business located at 6-18, Kitahama 2 Chome, Chuo-ku, Osaka 541-8505, Japan ("MTPC").

WITNESSETH:

WHEREAS, LICENSEE and Mitsubishi Pharma Corporation (a predecessor of MTPC) entered into LICENSE AGREEMENT relating to Wf-516 dated as of September 1, 2008 ("LICENSE AGREEMENT"); and

WHEREAS, LICENSEE desires to develop the Product containing Wf-516 Compound for the therapy of major depressive disorder with its priority, and LICENSEE and MTPC agrees to modify the terms and conditions of the LICENSE AGREEMENT in order that LICENSEE conducts the development by itself or together with a third party by way of sub-licensing on LICENSEE's own responsibility.

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

1. Defined Words and Expressions.

Unless the context otherwise requires, all words and expressions defined in the LICENSE AGREEMENT shall have the same meanings in this AMENDMENT.

2. Amendment of Definition of Net Sales.

The definition of "Net Sales" is hereby amended to delete the reference to "sublicensees" such that except as set forth in Section 6 of this AMENDMENT, no royalties shall be paid on any Net Sales made by any Sublicensee (defined below); provided, however, that "Net Sales" of any Sublicensee shall be included for determining whether the Net Sales Milestone in Section 5.2.1(c) has been achieved.

1

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3. Withdrawal of Right of First Negotiation.

MTPC agrees to withdraw its Right of First Negotiation set forth in Section 2.3 of the LICENSE AGREEMENT. Therefore, Section 2.3 of the LICENSE AGREEMENT shall be amended and restated in its entirety to read as follows:

"2.3 Sublicense Rights. LICENSEE and its Affiliate shall have the right to grant sublicenses under all or part of the licenses granted under Sections 2.1 and 2.2. In such case, LICENSEE shall provide MTPC with a copy of the sublicense agreement including the payment conditions entered into between LICENSEE and its sublicensee, promptly following the execution of such agreement."

4. Amendment to Development Diligence.

- (a) Section 4.1.4 of the LICENSE AGREEMENT is hereby amended by deleting subparagraphs (a) through (d) in its entirety and replacing said diligence obligations with the following:
- "First patient enrolled in either a Phase II(a) Study or Phase II(b) Study in major depressive disorder with the Product containing Wf-516 Compound by the end of April 2015;"
- (b) Section 4.1.4 of the LICENSE AGREEMENT shall be further amended to delete any reference to the term "any of the milestones" or any reference to multiple milestones and replace such references to similar language to reflect the fact that there is only a single milestone (i.e., the first patient enrollment in either a Phase II(a) Study or Phase II(b) Study in major depressive disorder).
- (c) The last paragraph of Section 4.1.4 of the LICENSE AGREEMENT beginning with the sentence "Notwithstanding the foregoing, LICENSEE may extend the time to achieve any of the milestones ..." shall be deleted in its entirety and replaced with the following:
 - "Notwithstanding the foregoing, LICENSEE may extend the time to achieve the milestone set forth in Section 4.1.4 above for one (1) year, at its sole discretion, by making a payment of [*] to MTPC before the date on which the milestone was to have been originally achieved (the "Extension Payment"). If such Extension Payment is made, the milestone will be concomitantly extended by one (1) year. LICENSEE will have the right to make an unlimited number of Extension Payments in conjunction with the development of Product containing the Wf-516 Compound. For the avoidance of doubt, Extension Payments will be in addition

to the milestone that is otherwise payable to MTPC as set forth in Section 5 of this Agreement."

5. Amendment to Milestone Payments.

- (a) Section 5.1 of the LICENSE AGREEMENT is hereby amended by deleting such section in its entirety and replacing it as follows:
- "5.1 <u>Initial Licensing Fee</u>. In consideration of the licenses granted by MTPC to LICENSEE, LICENSEE has previously paid MTPC the total amount of Five Hundred Thousand United States Dollars (US\$500,000) as the initial license fee."
- (b) Section 5.2.1 of the LICENSE AGREEMENT is hereby amended by deleting such section in its entirety and replacing it with the foregoing:
- "5.2.1. <u>Milestone Payments</u>. In addition to the initial license fee, in consideration of the licenses granted by MTPC to LICENSEE, LICENSEE shall pay to MTPC the milestone payments as follows:

(a)	Launch in the first European Country	[*]
(b)	Launch in the U.S.	[*]
(c)	When cumulative Net Sales first reach US\$500,000,000 (the "Net Sales Milestone")	[*]

Notwithstanding the foregoing, the milestone payments set forth in paragraphs (a) and (b) above shall be reduced or eliminated, if applicable, by the amount of Sublicense Consideration (as defined below) received by MTPC. For clarification, in the event that the Launch in the United States takes place prior to the Launch in the first European Country and the total amount of Sublicense Consideration paid to MTPC on or before the Launch in the United States is less than [*], LICENSEE shall pay to MTPC the amount of the difference between such [*] and the actual amount of the Sublicense Consideration paid to MTPC, within sixty (60) days after the Launch in the United States, which payment shall be in full satisfaction for the milestone payment due in subparagraph (b) above for Launch in the United States. If the Sublicense Consideration is in excess of [*] on or before the Launch in the United States, no milestone payment for the Launch in the United States shall be due and Sublicense Consideration upon such Launch for the portion of such excess shall not be paid.

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In the event that the Launch in the first European Country takes place prior to the Launch in the United States and the total amount of Sublicense Consideration paid to MTPC on or before the Launch in the first European Country is less than [*], LICENSEE shall pay to MTPC the amount of the difference between such [*] and the actual amount of the Sublicense Consideration paid to MTPC, within sixty (60) days after the Launch in the first European Country, which payment shall be in full satisfaction for the milestone payment due in subparagraph (a) above for Launch in the first European Country. If the Sublicense Consideration is in excess of [*] on or before the Launch in the first European Country, no milestone payment for the Launch in the first European Country shall be due and Sublicense Consideration upon such Launch for the portion of such excess shall not be paid.

In the event that the total amount of the Sublicense Consideration paid to MTPC on or before the Launch in the United States or the first European Country, which takes place later, is less than [*], LICENSEE shall pay to MTPC the amount of difference between (i) such [*] and (ii) the sum of the total amount paid to MTPC prior to the sublicense as the milestone payments set forth in subparagraphs (a) and (b) above on or before such Launch, if any, and the amount of the Sublicense Consideration paid to MTPC, within sixty (60) days after the Launch in the first European Country or in the United States, which takes place later. Notwithstanding any other provision in this Agreement, if the Sublicense Consideration is in excess of [*] on or before the Launch in the first European Country or in the United States, which takes place later, no milestone payment for the Launch in the first European Country or in the United States, which takes place later, shall be due.

Both Parties acknowledge that LICENSEE has already paid the initial license fee."

- (c) Schedule 5.2 of the LICENSE AGREEMENT is hereby amended by deleting such section in its entirety. For the avoidance of doubt, except as set forth in Section 5.2.1 of the LICENSE AGREEMENT, no additional milestone payments shall be due under the LICENSE AGREEMENT.
- (d) Section 5.2 of the LICENSE AGREEMENT is amended by renumbering the existing Section 5.2.2 as 5.2.3 and adding a new Section 5.2.2 that shall read in its entirety as follows:
- "5.2.2 <u>Sublicensing Fee in Case of Sublicense.</u> In the event that LICENSEE sublicenses all or part of its rights under the MPC Intellectual Property to make, have made, use, have used, sell, offer for sale, have sold, import and have imported Product

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A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

in the Field for purposes of commercialization in the LICENSEE Territory to a third party ("Sublicensee"), in consideration of the licenses granted by MTPC to LICENSEE herein, LICENSEE shall pay to MTPC [*] of all payments, including the upfront payments, milestone payments, and the sale of any Company equity or debt securities, but excluding the royalties, received in connection with any such sublicense from a Sublicensee that are related

to the Product ("Sublicense Consideration"), in addition to the milestone payments set forth in Section 5.2.1, but subject to reduction or elimination in connection with the receipt of Sublicense Consideration as provided for in Section 5.2.1 above.

Such payments shall be made within sixty (60) days as and when such payments are received by LICENSEE from such Sublicensee. For purposes of clarification, Sublicense Consideration shall not include any royalties received by LICENSEE from the sale of Product. For the avoidance of doubt, LICENSEE and MTPC acknowledge that if the Sublicense Consideration payable to MTPC is in excess of the aggregate milestones payable to MTPC set forth in Section 5.2.1(a) and (b) above, then MTPC shall be entitled to any Sublicense Consideration payable in excess of such amount."

- (e) The renumbered Section 5.2.3 is hereby amended by deleting such section in its entirety and replacing it with the foregoing:
- "5.2.3 Reports and Payments. The milestone payments set forth in Section 5.2.1 shall be made no more than once with respect to the achievement of each milestone and no amounts shall be due hereunder for any subsequent or repeated achievement of such milestones (but payable on the first achievement of such milestone). For clarification, if any milestone set forth in Section 5.2.1 is paid with respect to any Product containing the Wf-516 Compound, then no further milestone payment shall be made upon the achievement of such milestone with respect to any other Product containing a Compound or Main Metabolite. LICENSEE shall notify MTPC in writing within sixty (60) days after the achievement of the milestones specified in Section 5.2.1 and each such notice shall be accompanied by the appropriate milestone payment."
- 6. Amendment to Royalties Payments by LICENSEE. Notwithstanding Section 5.3 in the LICENSE AGREEMENT, in the event that LICENSEE sublicenses its rights under MPC Intellectual Property to a Sublicensee, in consideration of the licenses granted by MTPC to LICENSEE herein, LICENSEE shall pay to MTPC [*] of all royalties received by LICENSEE from Sublicensee related to the sale of Product, and no additional royalties will be due and owing to MTPC as a result of sales of Product by any such Sublicensee. For clarification, in the event that LICENSEE does not sublicense its rights under MPC

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Intellectual Property to a Sublicensee, LICENSEE shall pay to MTPC a Royalty pursuant to Section 5.3 of the LICENSE AGREEMENT.

7. Other Provisions.

- (a) Governing Law. This AMENDMENT shall be governed by, and interpreted in accordance with the laws of the State of New York, without reference to conflicts of laws principles thereof except matters of patent law, which shall be determined in accordance with the national intellectual property laws relevant to the Patent Rights in question.
- (b) <u>Counterparts</u>. This AMENDMENT may be executed in several duplicates, each of which shall be deemed to be an original, but all of which together shall constitute one and the same instrument.
- (c) <u>Assumption of the Obligations and Benefits.</u> In the event that LICENSEE sells their shares or their assets relating to the Compound and/or Product, all of the obligations and benefits in the LICENSE AGREEMENT and in this Amendment shall be assigned to the purchaser of such shares or assets.
- (d) No Other Amendments. Save as amended by this AMENDMENT, the terms of the LICENSE AGREEMENT shall remain in full force and effect.

[Signature Page Follows]

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IN WITNESS WHEREOF, the parties have executed this AMENDMENT as of the date first set forth above.

Minerva Neurosciences, Inc.

Mitsubishi Tanabe Pharma Corporation

By: /s/ Rogerio Vivaldi Coelho Name: Rogerio Vivaldi Coelho

Title: President and CEO

By: /s/ Seiichi Murakami

Name: Seiichi Murakami

Title: Managing Executive Officer

CO-DEVELOPMENT AND LICENSE AGREEMENT

BY AND BETWEEN

JANSSEN PHARMACEUTICA, N.V.

AND

MINERVA NEUROSCIENCES, INC.

DATED

FEBRUARY 13, 2014

A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

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CO-DEVELOPMENT AND LICENSE AGREEMENT

THIS CO-DEVELOPMENT AND LICENSE AGREEMENT (the "**Agreement**"), executed as of February 13, 2014 (the "**Execution Date**"), is made by and between Janssen Pharmaceutica, N.V., a corporation organized and existing under the laws of Belgium, having its principal place of business is at Turnhoutseweg 30, 2340 Beerse, Belgium (hereinafter "**Janssen**"), and Minerva Neurosciences, Inc., a corporation organized under the laws of the State of Delaware, having its principal place of business at 245 First Street, Cambridge, Massachusetts (hereinafter "**Minerva**"). Janssen and Minerva are sometimes referred to herein individually as a "**Party**" and collectively as the "**Parties**."

RECITALS

WHEREAS, Janssen is a pharmaceutical company that is in the business of discovering, developing and marketing pharmaceutical products. Janssen has substantial experience and expertise in discovering and developing useful drugs in many fields;

WHEREAS, as part of its drug discovery effort, Janssen has discovered certain antagonist compounds with specificity for the Orexin-2 variant of the Orexin Receptor;

WHEREAS, Minerva desires to license from Janssen rights with respect to certain Orexin-2 Receptor antagonist compounds; and

WHEREAS, the Parties are interested in co-developing and commercializing in their respective territories such Orexin-2 Receptor antagonist compounds in accordance with the terms and conditions of this Agreement.

NOW, THEREFORE, in consideration of the above premises, and the various promises and mutual covenants and agreements set forth herein, and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the Parties hereby agree as follows.

ARTICLE 1

DEFINITIONS

As used in this Agreement, the following words and phrases shall have the following meanings or, if not listed below, the meaning designated where first used in this Agreement:

1.1. "**AB Rated Product**" means a pharmaceutical product that (a) is "therapeutically equivalent" to a Licensed Product, applying the definition of "therapeutically equivalent" set forth in the Preface to the current edition of the FDA publication "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "**Orange Book**"), as such requirements may be amended in the future, and (b) has been approved by a Regulatory Authority based upon an application that contains scientific evidence establishing, through *in vitro* and/or *in vivo* studies, the bioequivalence of such product to a Licensed Product developed under this Agreement and which product contains the same active pharmaceutical ingredient as such Licensed Product,

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such that such pharmaceutical product would be substitutable by a pharmacist for such Licensed Product when filling a prescription written for such Licensed Product without having to seek authorization to do so from the physician writing such prescription.

- **1.2.** "Adaptive Phase IIa/IIb Trial" means a Phase II Trial comprising a Phase IIa Trial and a Phase IIb Trial under which the performance of such Phase IIb Trial is contingent upon the results of such Phase IIa Trial.
- **1.3.** "Adverse Event" means any unwanted or harmful medical occurrence in a patient or subject who is administered a Licensed Product, whether or not considered related to such Licensed Product, including any undesirable sign (including abnormal laboratory findings of clinical concern), symptom or disease temporally associated with the use of such Licensed Product.
- **1.4.** "Affiliate" means, with respect to Janssen or Minerva, a particular corporation, partnership, or other entity that controls, is controlled by or is under common control with such Party. For the purposes of this definition, 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 or cause the direction of the management and policies of such entity, whether by the ownership of at least fifty percent (50%) of the voting stock of such entity, or by contract or otherwise.
 - **1.5.** "**API**" means active pharmaceutical ingredient.
- **1.6.** "Applicable Laws" means any national, international, federal, state or local laws, treaties, statutes, ordinances, rules and regulations, including any rules, regulations, guidance, guidelines or requirements of (a) any government authority (including any Regulatory Authority) having the force or effect of law or (b) any national securities exchange or securities listing organization, in each case as in effect from time to time during the Term.
 - **1.7.** "Asian Country" means each of Japan, China, Taiwan, Korea, Australia and India.
- **1.8.** "Business Day" means a day other than Saturday or Sunday on which banking institutions in New York, New York and Beerse, Belgium are open for business.
 - **1.9.** "Calendar Quarter" means a calendar quarter based on the Calendar Year.
- **1.10.** "Calendar Year" means a calendar year based on the Johnson & Johnson Universal Calendar for that year. A copy of the Johnson & Johnson Universal Calendar for 2014 is attached as <u>EXHIBIT A</u>, which exhibit shall be updated by Janssen for each Calendar Year of the Term consistent with the Johnson & Johnson Universal Calendar used for Janssen's internal business purposes.
- **1.11.** "Change of Control" means the occurrence of any of the following: (a) any consolidation or merger of a Party with or into any Third Party, or any other corporate reorganization involving a Third Party, in which those persons or entities that are stockholders of such Party immediately prior to such consolidation, merger or reorganization own less than fifty

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percent (50%) of the surviving entity's voting power immediately after such consolidation, merger or reorganization; (b) a change in the legal or beneficial ownership of fifty percent (50%) or more of the voting securities of any Party (whether in a single transaction or series of related transactions) where, immediately after giving effect to such change, the legal or beneficial owner of more than fifty percent (50%) of the voting securities of such Party is a Third Party; or (c) the sale, transfer, lease, license or other disposition of all or substantially all of a Party's assets related to this Agreement in one or a series of related transactions to a Third Party.

- **1.12.** "Clinical Trial Material" means a Licensed Product or placebo, as applicable, that is in a finished pharmaceutical dosage form that is (a) suitable for administration and dosing to humans in clinical trials, but (b) not intended for commercial sale (for example, in a form that does not include external packaging and package inserts).
- **1.13.** "Combination Product" means a Licensed Product containing both (a) a Compound as an API and (b) one or more other APIs, which Licensed Product is sold as a unit at a single price either as a fixed dosage form or as separate dosage forms.
 - **1.14.** "Commercial Territory" means, in the case of Minerva, the Minerva Territory and, in the case of Janssen, the Janssen Territory.
- **1.15.** "Commercialization" means all activities that relate to the marketing and sale of a Licensed Product for human use, including advertising, education, planning, marketing, promotion, distribution, market and product support studies, product-related public relations, governmental affairs activities

for reimbursement and formulary acceptance, sales force training, and trademark selection, filing, prosecution and enforcement. The terms "Commercialize" and "Commercializing" shall have a corresponding meaning.

1.16. "Commercially Reasonable Efforts" means, with respect to any efforts relating to the Development or Commercialization of a Licensed Product by a Party, generally or with respect to a territory, those efforts normally used by such Party, in the relevant territory, with respect to a product Controlled by such Party or to which such Party has similar rights, in each case which product is of similar market potential in the relevant territory, and is at a similar stage in its Development or product life cycle, as such Licensed Product, and in each case taking into account all Relevant Factors in effect at the time such efforts are to be expended. "Relevant Factors" means all relevant factors that may affect the Development, Manufacture or Commercialization of such Licensed Product, including, as applicable: actual or potential issues of safety, efficacy or stability relative to competitive products in the marketplace or in development by others; product profile (including product modality, category and mechanism of action); stage of Development or life cycle status; actual or projected Development, Regulatory Approval and Commercialization costs; any issues regarding the ability to Manufacture or have Manufactured such Licensed Product; the likelihood of obtaining Regulatory Approvals; the timing of such Regulatory Approvals; the current guidance and requirements for Regulatory Approval for such Licensed Product and similar products and the current and projected regulatory status; labeling or anticipated labeling; the thencurrent competitive environment and the likely competitive environment at the time of projected entry into the market; the nature and extent of market exclusivity (i.e., proprietary position, including strength and duration of patent coverage and regulatory exclusivity); past performance of such Licensed Product or similar

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products; present and future market potential; existing or projected pricing, sales, reimbursement and profitability; pricing or reimbursement changes in relevant countries; and other relevant scientific, technical, operational and commercial factors. Commercially Reasonable Efforts shall be determined on a market-by-market and indication-by-indication basis for a Licensed Product and it is anticipated that the level of efforts will be different for different markets, and will change over time, reflecting changes in the status of such Licensed Product and the market(s) involved.

- 1.17. "Committee" means, individually, the JSC, JMC, JMktgC and any other Subcommittee established pursuant to Section 3.2.
- **1.18.** "Competing Product" means any orally bioavailable compound or Product, other than a Compound or Licensed Product, that binds with and is an antagonist of the Orexin-2 Receptor such that the compound is more potent than [*].
- **1.19.** "Compound" means a compound that binds with and is a selective antagonist of the Orexin-2 Receptor, of which the composition is Covered by a Janssen Patent at any time during its pendency or as issued, including the compound designated [*], or any isomer, tautomer, enantiomer, diastereomer, prodrug, ester, salt, hydrate, solvate, racemate, metabolite, polymorph, or isotopic substitution thereof.
- **1.20.** "Contract Manufacturer" means any Third Party contract manufacturer or analytical laboratory with which a Party or its Affiliate(s) or Sublicensee(s) contracts for the Manufacture of any Compound (including any intermediate compounds) or Licensed Product.
- **1.21.** "Control" means, with respect to any intellectual property or right therein, that a Party or an Affiliate thereof owns or has a license to such intellectual property and has the ability to grant a license or sublicense in or to such intellectual property or right as set forth herein without violating Applicable Laws or the terms of any agreement or other arrangement with any Third Party.
- **1.22.** "Cover" means, with respect to any Patent, in reference to specified subject matter (such as a composition of matter or method of use), that a Valid Claim of such Patent reads on or literally encompasses such subject matter, whether generically or specifically.
- 1.23. "Currency Hedge Rate" means a weighted average hedge rate of the outstanding external foreign currency forward hedge contract(s) of Johnson & Johnson's Global Treasury Services Center ("GTSC") with Third Party banks. Such hedge contracts are entered into to protect the transactional foreign exchange risk exposures of Janssen by reducing the impact of foreign currency volatility through a systematic buildup of yearly Currency Hedge Rates.
- **1.24.** "Data" means any and all research data, results, pharmacology data, medicinal chemistry data, preclinical data, clinical data (including investigator reports (both preliminary and final), statistical analyses, expert opinions and reports, and safety and other electronic databases), in any and all forms, including files, reports, raw data, source data (including patient medical records and original patient report forms, but excluding patient-specific data to the extent required by Applicable Laws) and the like, in each case directed to, or used in the

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Development, Manufacture or Commercialization of, any Compound or Licensed Product hereunder.

1.25. "Development" means all activities relating to conducting preclinical studies, Phase I Trials, Phase II Trials and Phase III Trials upon a Licensed Product, obtaining the Regulatory Approval of a Licensed Product, and developing the ability to Manufacture Clinical Trial Material or Finished Product. This includes, but is not limited to, activities relating to chemical synthesis, toxicology, pharmacology, test method development and stability testing, formulation, delivery system development, quality assurance and quality control development, statistical analysis, pharmacovigilance, clinical studies, regulatory affairs, Manufacturing process development for bulk and final forms of a Compound, Clinical Trial Material or Finished Product, validation documentation, and documentation generated in connection with the Manufacturing, processing and quality assurance with respect to Clinical Trial Material or Finished Product, to the extent each of the foregoing occur prior to the First Commercial Sale of the relevant Licensed Product for human use and are not undertaken or intended for sale, promotional purposes, or other post-Regulatory Approval purposes. The term "Develop" shall have a corresponding meaning.

- **1.26.** "**Development Budget**" means the two (2) year rolling budget for conducting Development pursuant to the Development Plan during a given Calendar Year and the succeeding Calendar Year, as developed and approved by the JSC in accordance with Section 3.10(d), which budget shall be updated and amended concurrently with the Development Plan in accordance with Section 3.10(c).
- 1.27. "Development Costs" means the following costs incurred by the Parties following the Effective Date in Developing Licensed Products in the Field, in each case to the extent incurred in accordance with this Agreement and the Development Plan: (a) all Third Party invoiced costs and expenses incurred for activities specified in the Development Plan; (b) the costs and expenses of scientific, medical, technical or managerial personnel directly engaged in such efforts, which costs shall be determined based on the applicable Development FTE Rate based on time actually spent performing the applicable activities, unless another basis is otherwise agreed by the Parties in writing; (c) the costs and expenses of Clinical Trial Material and the cost of clinical trial insurance, each as set forth in the Development Plan; (d) the costs and expenses incurred in connection with seeking and attempting to obtain Regulatory Approvals, including related Regulatory Filings (allocated, in the case of costs and expenses of preparing and filing an MAA, as provided for in Section 3.11, and excluding any costs and expenses for validating any manufacturing facility or equipment); (e) the costs and expenses incurred in connection with:

 (i) Manufacturing process, formulation and delivery system development and validation (provided that such costs, to the extent associated with or used for products in addition to the Licensed Product(s) shall be fairly and equitably allocated to the Licensed Product(s) and other product(s) such that the Licensed Product(s) do not bear a disproportionate portion of such costs); (iii) Manufacturing scale-up (excluding, however, any capital costs, costs associated with physical plant improvements or similar costs); (iii) stability testing; (iv) quality assurance/quality control development; and (v) internal and Third Party costs and expenses incurred in connection with qualification and validation of Contract Manufacturers; and (f) any other related or incidental costs and expenses incurred that are expli

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costs and expenses associated with pre- and post-approval commitments mandated by Regulatory Authorities (which costs and expenses shall be borne solely by the Party in whose Commercial Territory the commitment is required).

- **1.28.** "Development FTE Rate" means [*] per FTE, which amount shall be adjusted in proportion to the United States Consumer Price Index All Urban Consumer, as published by the U.S. Department of Labor, Bureau of Labor Statistics, upon each anniversary of the Effective Date during the Term, for scientific, medical, technical, research, clinical, regulatory, Manufacturing and managerial personnel engaged in activities under the Development Plan.
- **1.29.** "Development Plan" means a comprehensive written plan and budget, as it may be amended from time to time pursuant to Section 3.10(c), for the Development of the Licensed Products in the Field in the Territory, designed to (a) generate the preclinical, clinical and regulatory information required to obtain Regulatory Approvals within the Territory and (b) describe the Manufacturing development activities to be performed to enable the Development and Commercialization of the Licensed Products hereunder. The initial Development Plan in provisional form is attached hereto as EXHIBIT B.
- **1.30.** "**DMF**" means a Drug Master File maintained with the FDA or an equivalent Regulatory Filing, such as an active substance master file, maintained with a Regulatory Authority in any other country.
 - **1.31.** "EMA" means the European Medicines Agency or any successor agency thereof.
- **1.32.** "European Union" or "EU" means the supra national community which consists of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Hungary, Germany, Greece, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and the United Kingdom.
 - **1.33. "FDA"** means the United States Food and Drug Administration, or a successor federal agency thereto in the United States.
 - **1.34.** "**Field**" means all therapeutic, prophylactic and diagnostic uses for humans.
- **1.35.** "**Finished Product**" means a Licensed Product in a finished pharmaceutical dosage form that is suitable for commercial sale following Regulatory Approval thereof, including external packaging and package inserts.
- **1.36.** "First Commercial Sale" means, with respect to any country, the first commercial sale for monetary value of a Licensed Product by a Party or its Affiliate or Sublicensee for use, consumption or resale of such Licensed Product in such country where Regulatory Approval of such Licensed Product has been obtained by such Party, its Affiliate, or a Sublicensee. Sale of a Licensed Product by and between a Party and its Affiliate or Sublicensee, or between the Parties (or their respective Affiliates or Sublicensees), shall not constitute a First Commercial Sale, unless such Party, Affiliate or Sublicensee is the end user of the Licensed Product.

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- **1.37.** "FTE" means a full-time equivalent person year consisting of a total of [*] hours of work per Calendar Year directed to scientific, medical, technical, research, clinical, regulatory, Manufacturing and managerial activities under the Development Plan.
 - **1.38.** "GAAP" means United States generally accepted accounting principles applied on a consistent basis.
- **1.39.** "Good Clinical Practice" or "GCP" means the then current standards for clinical trials for pharmaceuticals, as set forth in the ICH guidelines and applicable regulations promulgated thereunder, as amended from time to time, and such standards of good clinical practice as are promulgated

by the FDA, EMA and other Regulatory Authorities in countries in which a Licensed Product is intended to be sold to the extent such standards are not less stringent than the ICH guidelines.

- **1.40.** "Good Manufacturing Practice" or "GMP" means (a) the regulatory requirements for current good manufacturing practices promulgated by the FDA under the U.S. Food, Drug and Cosmetic Act (as set forth at 21 C.F.R. §§ 210-211) and under the Public Health Service Act, Biological Products (as set forth at 21 C.F.R. §§ 600-610), as the same may be amended from time to time; and (b) such standards of good manufacturing practice as are promulgated by the EMA and other Regulatory Authorities in countries in which a Licensed Product is intended to be Manufactured or sold, to the extent such standards are not less stringent than the FDA regulatory requirements stated above.
- **1.41.** "ICH" means the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use.
- **1.42.** "**IND**" means an Investigational New Drug Application filed with the FDA as more fully defined in 21 C.F.R. §312.3 necessary to commence human clinical trials of a drug in conformance with Applicable Laws or any foreign equivalent thereof.
- **1.43.** "Information" means information, results and data of any type whatsoever, in any tangible, written, documentary, electronic, or digital form, including instructions, processes, compositions, materials, expert opinions, databases, inventions, practices, methods, techniques, specifications, formulations, formulae, knowledge, know-how, skill, experience, test data, including pharmacological, biological, chemical, biochemical, toxicological and clinical test data, analytical and quality control data, stability data, studies and procedures, and patent and other legal information or descriptions.
 - **1.44.** "**Initial Formulations**" means any oral dosage form of a Product.
 - **1.45.** "**Initial Indications**" means any disease, disorder or condition of the central nervous system for which a Product is indicated.
- **1.46.** "Janssen Know-How" means any Know-How Controlled by Janssen on the Effective Date that is necessary or useful to the Development or Commercialization of a Compound or Licensed Product, and any Know-How which comes under the Control of Janssen following the Effective Date that is necessary or useful to the Development or Commercialization of a Compound or Licensed Product.

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- **1.47.** "Janssen Manufacturing IP" means the Patents and Know-How Controlled by Janssen during the Term that are necessary or reasonably useful for the Manufacture of the applicable Licensed Product in the Field, in its then current formulation as of the time (if any) that control and responsibility with respect to the Manufacture of such Licensed Product is transferred to Minerva pursuant to Section 4.3.
- **1.48.** "Janssen Patent" means those Patents Controlled by Janssen and set forth on <u>EXHIBIT C</u> and any Patents Controlled by Janssen claiming priority thereto.
- **1.49.** "**Janssen Territory**" means any country or territory in the world excluding the Minerva Territory, and is subject to modification in accordance with Section 3.10(g)(iii)(A).
- **1.50. "Know-How"** means any non-public, proprietary Information. For clarification, Know-How does not include any Information in published Patents.
 - **1.51.** "Latin American Country" means each of Brazil, Argentina, Peru, Ecuador and Venezuela.
 - **1.52.** "Licensed Product" means any Product containing or comprised of a Compound, alone or in combination with one or more other APIs.
- **1.53.** "MAA" means a marketing authorization application for a country or region, requesting approval from the applicable Regulatory Authority for commercial sale of a Licensed Product in such country or region (excluding pricing and reimbursement approvals), such as an NDA filed with the FDA, together with all subsequent submissions, supplements, and amendments thereto.
 - **1.54.** "Major EU Country" means each of France, Germany, Italy, Spain and the United Kingdom.
- 1.55. "Manufacture" or "Manufacturing" means all activities directed to the manufacture, receipt, incoming inspections, storage and handling of raw materials and intermediates and the manufacture, processing, formulation, packaging, labeling, warehousing, quality control testing (including inprocess release and stability testing), supplying, shipping and release of any Compound, intermediates or Licensed Product, including manufacturing process development, scale-up and validation.
- 1.56. "Manufacturing Cost" means, with respect to a Compound or Licensed Product (including both Clinical Trial Material and Finished Product), the supplying Party's reasonable and necessary internal and Third Party costs incurred in Manufacturing or acquisition of such Compound or Licensed Product, determined in accordance with the supplying Party's standard cost accounting policies that are in accordance with GAAP and consistently applied across the supplying Party's manufacturing network to other products that the supplying Party manufactures, including any depreciation costs with respect to capital investments in plant and property and capital improvements (provided such costs are fairly and equitably allocated to the Licensed Product(s) and other products such that the Licensed Product(s) do not bear a disproportionate portion of such costs).

- **1.57.** "Minerva Know-How" means any Know-How Controlled by Minerva on the Effective Date that is necessary or useful to the Development, Manufacture or Commercialization of a Compound or Licensed Product, and any Know-How which comes under the Control of Minerva following the Effective Date in connection with it or its Affiliates Developing, Manufacturing or Commercializing a Compound or Licensed Product and that is necessary or useful to the Development, Manufacture or Commercialization of a Compound or Licensed Product.
- **1.58.** "Minerva Patent" means those Patents Controlled by Minerva on the Effective Date Covering any Compound as a composition of matter, such as [*] or any isomer, tautomer, enantiomer, diastereomer, prodrug, ester, salt, hydrate, solvate, racemate, metabolite, polymorph, or isotopic substitution thereof, which Patents are set forth in <u>EXHIBIT E</u> and any Patents Controlled by Minerva claiming priority thereto.
- **1.59.** "Minerva Territory" means, collectively, the European Union, Switzerland, Liechtenstein, Iceland and Norway, and is subject to modification in accordance with Section 3.10(g)(iii)(A).
- **1.60.** "**NDA**" means a New Drug Application submitted and filed with the FDA as more fully defined in 21 C.F.R. § 314.5 *et seq.* or any equivalent application filed with any equivalent Regulatory Authority in a country other than the United States.
 - **1.61.** "New Formulation" means any formulation (including dosage form or dosage amount) of a Product other than an Initial Formulation.
 - **1.62.** "New Indication" means any disease, disorder or condition for which a Product is indicated other than an Initial Indication.
- 1.63. "Net Sales" means, with respect to a given period, the gross amounts invoiced on sales of a Licensed Product by a Party or its Affiliates or Sublicensees hereunder to a Third Party purchaser in an arms-length transaction, less the following customary deductions, determined in accordance with GAAP and standard internal policies and procedures and accounting standards consistently applied throughout such Party's organization, to the extent specifically and solely allocated to such Licensed Product and actually taken, paid, accrued, allowed, included or allocated: [*]. Sales between a Party and its Affiliates or Sublicensees shall be excluded from the computation of Net Sales and no payments will be payable on such sales except where such Affiliates or Sublicensees are end users, but Net Sales shall include the subsequent final sales to Third Parties by such Affiliates or Sublicensees.

All aforementioned deductions shall only be allowable to the extent they are commercially reasonable and shall be determined, on a country-by-country basis, as incurred in the ordinary course of business in type and amount consistent with the Party's, the Affiliate's, or Sublicensee's (as the case may be) business practices consistently applied across its product lines and accounting standards and verifiable based on its sales reporting system. All such discounts, allowances, credits, rebates, and other deductions shall be fairly and equitably allocated to such Licensed Product and other products of the Party and its Affiliates and Sublicensees such that such Licensed Product does not bear a disproportionate portion of such deductions.

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Notwithstanding the foregoing, Net Sales of a Combination Product, for the purposes of determining royalty payments, shall be determined by multiplying the Net Sales of the Combination Product by the fraction A/A+B, where A is the average sale price of the Licensed Product containing solely a Compound (and not any other API which itself could form the basis of a separate product) when sold separately in finished form (without the other separately-saleable API(s) included within the Combination Product) in a particular country during the applicable period and B is the average sale price of products incorporating the other API(s) sold separately in finished form in such country during such period. In the event that such average sale price cannot be determined for both the Licensed Product containing solely such Compound (and not any other API which itself could form the basis of a separate product) and such other product(s) in combination in the relevant country during the applicable period, Net Sales for the purposes of determining royalty payments with respect to such Combination Product shall be commercially reasonable and determined by good faith negotiation between Payor and Payee consistent with the ratio referenced above.

In the case of discounts on "bundles" of separate products or services which include Licensed Products, Payor may with notice to Payee discount the bona fide list price of a Licensed Product in a particular country by a commercially reasonable amount, provided that the price of such Licensed Product for purposes of calculating Net Sales in such country shall be deemed to be the undiscounted list price of such Licensed Product in such country or, if such Licensed Product is not sold other than in such a "bundle" in such country, such imputed undiscounted list price as the Parties may negotiate in good faith for such Licensed Product with respect to such country based on the unbundled, undiscounted list price of such Licensed Product in similar markets.

Notwithstanding anything the contrary in this Agreement, the transfer of a Licensed Product to an Affiliate, Sublicensee, or other Third Party (i) in connection with the research, development or testing of a Licensed Product, (ii) for purposes of distribution as promotional samples, or (iii) for indigent or similar public support or compassionate use programs shall not, in any case, be considered a sale of a Licensed Product under this Agreement.

- **1.64.** "North American Country" means each of Canada, Mexico and the United States.
- **1.65.** "**Orexin Receptor**" means a G-protein-coupled receptor that binds the neuropeptide hormone orexin, there being two variants, the "**Orexin-1 Receptor**" and the "**Orexin-2 Receptor**," each encoded by a different gene, HCRTR1 (Genbank Accession Number NM_001526) and HCRTR2 (Genbank Accession Number NP_001517), respectively.
- 1.66. "Patent" means any (a) patent, including any United States and foreign patent (including utility patents and certificates of invention), together with any and all substitutions, extensions and term restorations (including supplementary protection certificates or pediatric data exclusivity extensions), registrations, confirmations, re-examinations, reissues, renewals, and foreign counterparts thereof, and (b) pending application for a patent (including any United States and foreign patent application), including provisionals, divisionals, continuations, and continuations-in-part of any of the foregoing, domestic and foreign counterparts of any of the foregoing and patents issuing therefrom.

- **1.67.** "Payee" means a Party entitled to receive payment pursuant to the terms of this Agreement.
- **1.68.** "Payor" means a Party responsible for paying any payment obligations required under this Agreement.
- **1.69. "Phase I Trial"** means a human clinical trial of a Licensed Product in any country that would satisfy the requirements of 21 C.F.R. § 312.21(a), or its successor regulation.
 - **1.70. "Phase Ib Trial"** means a Phase I Trial in a patient population with the indication under investigation.
- **1.71. "Phase II Trial**" means a human clinical trial of a Licensed Product in any country that would satisfy the requirements of 21 C.F.R. §312.21(b), or its successor regulation.
 - **1.72. "Phase IIa Trial"** means a Phase II Trial in a pilot form.
- **1.73. "Phase IIb Trial"** means a Phase II Trial designed to confirm the optimal manner of use of the applicable Licensed Product (dose and dose regimen) prior to the initiation of a Phase III Trial.
- **1.74.** "Phase III Trial" means a human clinical trial of a Licensed Product in an extended human patient population designed to obtain data determining efficacy and safety of such Licensed Product to support Regulatory Approvals in the proposed therapeutic indication, as more fully defined in 21 C.F.R. 312.21(c), or its successor regulation, or the equivalent in any other country.
 - **1.75. "Product**" means a pharmaceutical product in any dosage form for the Field.
- 1.76. "Product-Related Materials" means all advertising and promotional materials (including flyers, brochures, pamphlets and electronic media), labeling and packaging materials, and any materials or items similar to the foregoing, that, in each case, pertain exclusively to the Licensed Products and are in the possession or control of a Party, and all copyright and similar rights to the contents thereof, provided that the foregoing rights shall not include any rights to any trademark, logos, or the like of a Party other than Product Trademarks.
- 1.77. "Product Trademarks" means the trademarks, trade dress, or logos identified and selected by the JSC (as set forth in Section 5.7) and used specifically for, or for which registration is applied for or issued specifically with respect to, any Licensed Product at any time in connection with the use, development, promotion, marketing, distribution, offer for sale, or sale of such Licensed Product, including any and all rights to the foregoing existing solely under common law, statute, or similar bases not requiring explicit government notice or registration.
- **1.78.** "**Program Invention**" means any invention, discovery, or improvement, whether or not patentable, relating to any Compounds or Licensed Products (such as their manufacture, formulation, administration or use) invented by or on behalf of one or both of the Parties (such as through one or more employees or agents of one Party, solely or jointly with one or more

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employees or agents of the other Party) in the Parties' Development of any Compounds or Licensed Products under the Development Plan.

- **1.79.** "**Program Patent**" means any Patent disclosing (in the specification) and claiming (by at least one claim), generally or specifically, a Program Invention.
- **1.80.** "**Prosecuting**" means, with regard to specified Patents, preparing, filing, prosecuting, maintaining, and defending such Patents, including with respect to any reexamination, reissue, interference, derivation, inter parties review, post grant review, or opposition proceedings. For the avoidance of doubt, "Prosecuting" excludes any infringement suits or other legal proceedings to enforce the specified Patents, regardless of whether or not such proceedings involve the defense of the Patents in suit.
- **1.81.** "Regulatory Approval" means any and all approvals (including supplements and amendments), licenses, registrations or authorizations of any national, supra-national (e.g., the European Commission or the Council of the European Union), regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the Manufacture, distribution, use, sale, or marketing of a Licensed Product in the Field in a regulatory jurisdiction, including, if required for the sale or marketing of a Licensed Product, approvals for pricing and reimbursement.
- **1.82.** "**Regulatory Authority**" means any regulatory agency, ministry, department, or other governmental body having authority in any country, region, or supra-national territory to approve pharmaceutical products for marketing or sale, such as the FDA and EMA.
- **1.83.** "Regulatory Documentation" means, with respect to a Licensed Product, all material regulatory filings and supporting documents created or submitted to the FDA or any Regulatory Authority outside of the United States, and all data contained therein including the contents of any IND, MAA, DMF, Regulatory Dossier, correspondence to and from the applicable Regulatory Authority, minutes from meetings (whether in person or by teleconference or videoconference) with the applicable Regulatory Authority, registrations and licenses, regulatory drug lists, advertising and promotion documents shared with the applicable Regulatory Authority, adverse event files, complaint files and Manufacturing records.
- **1.84.** "**Regulatory Dossier**" means the dossier maintained by a Regulatory Authority for, and including submissions related to, the investigative use and/or Regulatory Approval of a Licensed Product in the Field, including any IND or MAA filed with a Regulatory Authority in any country with which a Licensed Product must be registered or approved for the Manufacture, marketing, use, distribution or sale of such Licensed Product in the Field.

pediatric drug exclusivity designation by the FDA or any other Regulatory Authority; or (b) data protection in such jurisdiction for regulatory data submitted by the Party Commercializing such Licensed Product hereunder (or its Affiliates or Sublicensees) relating to such Licensed Product, including protection against unfair commercial use or public release consistent with, or no less stringent than, TRIPS Article 39.3.

- **1.86.** "Regulatory Filing" means an IND, MAA, and any other filings required by Regulatory Authorities relating to the Development, Manufacture, or Commercialization of any Licensed Product.
 - **1.87. "Territory**" means, collectively, the Janssen Territory and the Minerva Territory.
- **1.88.** "Third Party" means any individual, corporation, partnership, limited liability company or other entity other than (a) Janssen, (b) Minerva, or (c) their respective Affiliates.
 - **1.89.** "United States" means the United States of America and its territories and possessions
- 1.90. "Valid Claim" means (a) a claim of any pending patent application for which no more than [*] have elapsed from the First Commercial Sale, on a country-by-country basis, of a Licensed Product covered by such claim in such pending patent application or (b) a claim of any issued, unexpired (including by virtue of any patent term extension and/or patent term restoration) United States or foreign patent that has not been dedicated to the public, disclaimed, abandoned or held invalid or unenforceable by a court or other body of competent jurisdiction from which no further appeal can be taken, and that has not been explicitly disclaimed, or admitted in writing, by (in either case) the owner or licensee thereof to be invalid or unenforceable or of a scope not covering Licensed Products through reissue, disclaimer or otherwise.
- **1.91. Additional Defined Terms**. Each of the following terms shall have the respective meaning set forth in the Section of this Agreement indicated below:

Defined Term	Section
Abandoning Party	8.2(d)
Agreement	Preamble
Alleged Infringement	8.3(a)
Alliance Manager	3.7
Audited Site	3.11(e)
Bankruptcy	11.4
Claim	12.1(a)
Clinical Studies	3.10(b)
Co-Chair	3.3(a)
Commercial Supply Agreement	4.1
Committee Deadlock	3.3(c)
Confidential Information	9.1
CPR Mediation Procedure	13.3(a)
CPR Rules	13.4(a)
1	3

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Data Package	2.7(b)
Decision Point 1	3.10(g)(i)(A)
Decision Point 2	3.10(g)(i)(B)
Decision Point 3	3.10(g)(i)(C)
Decision Point 4	3.10(g)(i)(D)
Development Reconciliation Procedures	3.10(f)(ii)
Development Supply Agreement	3.10(i)
Dispute	13.1
Effective Date	11.1
Enforcing Party	8.3(b)
Execution Date	Preamble
GTSC	1.23
Indemnitee(s)	12.1(a)
Indemnitor	12.1(a)
Initial Stage	3.10(f)(iv)(A))
Initial Stage Cap	3.10(f)(iv)(A)

Involved Party	14.2
IPO Closing	11.1
Janssen	Preamble
Janssen Royalty Term	6.3(a)
JMC	3.2(a)
JMktgC	3.2(b)
JSC	3.1(a)
Losses	12.1(a)
Marketing Party	8.3(b)
Minerva	Preamble
Minerva Royalty Term	6.2(a)
Noninvolved Party	14.2
Orange Book	1.1
Outside Date	11.1
Party(ies)	Preamble
Party Name Marks	5.7(a)
Permitted Cost Overrun	3.10(f)(iii)(A)
Pharmacovigilance Agreement	5.4(a)
Policy	9.6
Prior Agreements	9.6
Protocol	13.4(h)
Publication Strategy	9.5(a)
Recovery	8.3(d)
Relevant Factors	1.16
ROFN	2.7(b)
ROFN Notice	2.7(b)
ROFN Party	2.7(a)
Second Stage	3.10(f)(iv)(B)
Second Stage Cap	3.10(f)(iv)(B)
Subcommittee	3.2
Sublicense	2.7(a)
Sublicensee	2.7(a)
Sublicensing Party	2.7(a)
14	4

Sublicensing Territory	2.7(a)
Term	11.2
Upfront Payment	6.1

ARTICLE 2

LICENSES AND RIGHTS OF FIRST NEGOTIATION

- **2.1. Development License to Minerva.** As of the Effective Date and subject to the terms and conditions herein, including Janssen's retained rights, Janssen hereby grants to Minerva: (a) a co-exclusive license (with Janssen and its Affiliates), together with the right to sublicense in accordance with Section 2.7, under the Janssen Patents, to use and Develop Licensed Products in the Minerva Territory in the Field, and (b) a non-exclusive license, together with the right to sublicense in accordance with Section 2.7, under the Janssen Patents, to use and Develop Licensed Products outside the Minerva Territory in the Field; provided, however, that any Development of Licensed Products by Minerva or its Affiliates outside of the Minerva Territory shall be: (i) conducted solely as set forth in the Development Plan; and (ii) solely for purposes of seeking Regulatory Approval of Licensed Products in the Minerva Territory in the Field.
- **2.2. Commercialization License to Minerva.** As of the Effective Date and subject to the terms and conditions herein, including Janssen's retained rights, Janssen hereby grants to Minerva an exclusive (even as to Janssen and its Affiliates) license, together with the right to sublicense in accordance with Section 2.7, under the Janssen Patents, to sell, offer for sale, have sold, import and Commercialize Licensed Products in the Minerva Territory in the Field.
- **2.3. Know-How License to Minerva.** As of the Effective Date and subject to the terms and conditions herein, including Janssen's retained rights, Janssen hereby grants to Minerva a non-exclusive license, together with the right to sublicense in accordance with Section 2.7, under the Janssen Know-How, (a) to use, Develop, sell, offer for sale, import and Commercialize Licensed Products in the Minerva Territory in the Field, and (b) to use and Develop Licensed Products outside the Minerva Territory in the Field; provided, however, that any Development of Licensed Products by Minerva or its Affiliates outside of the Minerva Territory shall be: (i) conducted solely as set forth in the Development Plan; and (ii) solely for purposes of seeking Regulatory Approval of Licensed Products in the Minerva Territory in the Field.
- **2.4. Manufacturing Rights.** As of the Effective Date and subject to the terms and conditions herein, including Janssen's retained rights, Janssen hereby grants to Minerva a worldwide, non-exclusive license, together with the right to sublicense in accordance with Section 2.7, under the Janssen Manufacturing IP, to make and have made (including to Manufacture and have Manufactured) Licensed Products in the Field for sale in the Minerva Territory, except that Minerva shall not practice such license (or permit any Affiliate, Sublicensee or Third Party to practice such license) unless and until control and responsibility with respect to the Manufacture of Licensed Products is transferred to Minerva pursuant to Section 4.3.

- **2.5. Development and Manufacturing Licenses to Janssen.** As of the Effective Date and subject to the terms and conditions herein, Minerva hereby grants to Janssen a worldwide, (a) co-exclusive (with Minerva and its Affiliates) license, together with the right to sublicense in accordance with Section 2.7, under the Minerva Patents and Minerva Know-How, to use and Develop Licensed Products in the Field and (b) co-exclusive license (subject to Section 4.3), together with the right to sublicense in accordance with Section 2.7, under the Minerva Patents and Minerva Know-How, to make and have made (including to Manufacture and have Manufactured) Licensed Products in the Field.
- **2.6. Commercialization License to Janssen.** As of the Effective Date and subject to the terms and conditions herein, Minerva hereby grants to Janssen an exclusive license (even as to Minerva and its Affiliates), together with the right to sublicense in accordance with Section 2.7, under the Minerva Patents and Minerva Know-How to use, sell, offer for sale, have sold, import and Commercialize Licensed Products in the Janssen Territory in the Field.

2.7. Right to Sublicense.

- (a) The licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4 and the licenses granted to Janssen pursuant to Sections 2.5 and 2.6 shall not include the right to grant sublicenses except as provided in this Section 2.7. Minerva may grant a sublicense of the rights to Commercialize Licensed Products granted to Minerva pursuant to Sections 2.2 and 2.3 to one or more Third Parties in one or more countries of the Minerva Territory subject to the terms and conditions set forth in this Section 2.7. In addition, at any time during the Term, Janssen may grant rights to Commercialize Licensed Products in the Field (including the grant of a sublicense of the rights granted to Janssen pursuant to Section 2.6) to one or more Third Parties in one or more countries of the Janssen Territory subject to the terms and conditions set forth in this Section 2.7. For purposes of this Section 2.7, (i) the grant of any such rights to a Third Party is referred to herein as a "Sublicense," (ii) the Party granting a Sublicense is referred to herein as the "Sublicensing Party," (iii) the other Party is referred to herein as the "ROFN Party," (iv) such Third Party is referred to herein as a "Sublicensee" and (v) the Commercial Territory of the Sublicensing Party is referred to herein as the "Sublicensing Territory."
- (b) The ROFN Party shall have a right of first negotiation with respect to any proposed Sublicense with respect to one or more countries of the Sublicensing Territory as set forth in this Section 2.7(b) (a "ROFN"). In the event the Sublicensing Party desires to grant such a Sublicense, the Sublicensing Party shall provide the ROFN Party with written notice (a "ROFN Notice") and a detailed Data package with respect to the Licensed Products in such country(ies) of the Sublicensing Territory (to the extent such Data was not previously in the possession of or accessible by the ROFN Party) (a "Data Package"). Upon receipt of the ROFN Notice, the ROFN Party will have the right, to be exercised within [*] days of the ROFN Party's receipt of such ROFN Notice and Data Package, to enter into exclusive negotiations with the Sublicensing Party to enter into an agreement pursuant to which the Sublicensing Party would grant the ROFN Party a right to Commercialize the Licensed Products in the Field in such country(ies) of the Sublicensing Territory. In the event that the ROFN Party elects to exercise its ROFN, the ROFN Party shall so notify the Sublicensing Party in writing within such [*] day period. If the ROFN Party fails to notify the Sublicensing Party in writing that the ROFN Party's

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rights under this Section 2.7(b) shall cease. Upon receipt of the ROFN Party's notification, the Parties will negotiate in good faith with respect to an agreement pursuant to which the Sublicensing Party would grant the ROFN Party a right to Commercialize the Licensed Products in the Field in the applicable country(ies) of the Sublicensing Territory. If the ROFN Party and the Sublicensing Party do not reach an agreement on the terms of such an agreement within [*] days of the ROFN Party's receipt of the ROFN Notice and Data Package, then the Sublicensing Party will be free to enter into a definitive agreement granting a Sublicense in the applicable country(ies) of the Sublicensing Territory to a Third Party in accordance with Section 2.7(c).

- (i) Notwithstanding anything to the contrary in this Agreement, (A) the ROFN provided to Minerva pursuant to this Section 2.7(b) shall only apply in the event that Janssen desires to grant a Sublicense with respect to the United States, any Asian Country(ies) or any Latin American Country(ies), and (B) once Minerva has received a ROFN Notice with respect to the United States, any Asian Country(ies) (alone or in combination) or any Latin American Country(ies) (alone or in combination), as the case may be, and the Parties have complied with the procedural aspects of Section 2.7(b) with respect to such ROFN Notice, Minerva thereafter shall not have any further ROFN with respect to the United States, any Asian Country or any Latin American Country, as the case may be.
- (ii) Notwithstanding anything to the contrary in this Agreement, (A) the ROFN provided to Janssen pursuant to this Section 2.7(b) shall only apply in the event that Minerva desires to grant a Sublicense with respect to any Major EU Country(ies), and (B) once Janssen has received a ROFN Notice with respect to any Major EU Country(ies) (alone or in combination), and the Parties have complied with the procedural aspects of Section 2.7(b) with respect to such ROFN Notice, Janssen thereafter shall not have any further ROFN with respect to any Major EU Country.
 - (c) Without limiting the ROFN Party's rights under Section 2.7(b) above, the Sublicensing Party will provide [*] days advance written notice to the ROFN Party of any proposed Sublicense and the identity of the proposed Sublicensee. Any such Sublicensee will be required to agree in writing to meet all of the quality and ethical standards applicable to the Sublicensing Party under this Agreement and to represent in such agreement that it has not been found to have committed a material violation of any rule or regulation of the FDA or other Regulatory Authority in the portion of the Sublicensing Territory to which the Sublicense applies. All Sublicenses granted by the Sublicensing Party under this Section 2.7 shall be consistent with the terms and conditions of this Agreement, and the Sublicensing Party shall be responsible for ensuring the compliance of its Sublicensees with all obligations owed to the ROFN Party under this Agreement. In addition, following execution of any such agreement granting a Sublicense hereunder, the Sublicensing Party shall promptly provide a copy thereof to the ROFN Party, redacted with respect to information not pertinent to compliance with this Agreement. A Sublicensee of the Sublicensing Party shall have the right to have representatives on, or participate in the activities of, any Committee with the prior written consent of the ROFN Party, which consent shall not be unreasonably conditioned, delayed or withheld.

- (d) The Sublicensing Party shall be entitled to grant sublicenses under the licenses granted to the Sublicensing Party in this Article 2 to any of its Affiliates without the ROFN Party's prior written approval; provided, however, that such sublicenses shall be consistent with the terms and conditions of this Agreement, and the Sublicensing Party shall be responsible for ensuring the compliance of its Affiliates with all obligations owed to the ROFN Party under this Agreement. In addition, the Sublicensing Party shall be entitled to grant non-exclusive sublicenses under the licenses granted to the Sublicensing Party in this Article 2 to any of its permitted Third Party contractors performing Development activities in accordance with Section 3.10(j), without the ROFN Party's prior written approval, solely to the extent necessary for such Third Party contractors to perform such Development activities; provided, however, that such sublicenses shall be consistent with the terms and conditions of this Agreement, and the Sublicensing Party shall be responsible for ensuring the compliance of its Third Party contractors with all obligations owed to the ROFN Party under this Agreement.
- (e) The efforts of a Party's Affiliates or Sublicensees to Develop or Commercialize Licensed Products shall be deemed the efforts of such Party for purposes of satisfying such Party's obligations to Develop or Commercialize Licensed Products under this Agreement, including any obligations to exercise Commercially Reasonable Efforts with respect thereto.
- **2.8. No Implied Licenses.** Each Party acknowledges that the licenses granted under this Article 2 are limited to the scope expressly granted, and all other rights to Patents and Know-How licensed hereunder are expressly reserved to the Party granting the license to such Patents or Know-How. Without limiting the foregoing, it is understood that where an exclusive license under Patents or Know-How is granted to a Party under this Article 2 for a particular purpose, the Party granting such license retains all of its rights to such Patents and/or Know-How for all purposes not expressly licensed.
- **2.9. Retained Rights.** Any rights of Janssen not expressly granted to Minerva under this Agreement will be retained by Janssen, including all rights: (a) to Develop and Commercialize the Licensed Products outside of the Field; (b) subject to Section 2.7, to Commercialize the Licensed Products in the Janssen Territory in the Field; and (c) subject to Section 4.3, to Manufacture the Licensed Products. Further, no rights are granted to Minerva under any other intellectual property Controlled by Janssen other than the Janssen Patents and Janssen Know-How, including any rights to any programs relating to Orexin Receptor subtypes other than Orexin-2, such as Janssen's Orexin-1 Receptor program. Any rights of Minerva not expressly granted to Janssen under this Agreement will be retained by Minerva. In addition, notwithstanding anything to the contrary in this Agreement, the Parties agree and acknowledge that the Development and Commercialization of New Indications and New Formulations shall not be within the scope of the licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4 except as provided in 3.10(h).

2.10. Non-Exclusive Unblocking Licenses.

(a) **Unblocking License to Minerva.** As of the Effective Date and subject to the terms and conditions herein, including Janssen's retained rights, Janssen hereby grants to Minerva a non-exclusive license, together with the right to sublicense in accordance with Section 2.7, under any Patents that (i) are not included in the Janssen Patents or Program

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Patents, (ii) are Controlled by Janssen as of the Effective Date or come under the Control of Janssen following the Effective Date and (iii) but for the license granted under this Section 2.10(a) would be infringed by the exercise of any of the licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4, but only to the extent necessary for Minerva to practice the licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4. Notwithstanding the foregoing, the Patents subject to the license granted under this Section 2.10(a) shall not include (A) in the event of a Change of Control of Janssen, any Patent that was Controlled prior to such Change of Control by the entity acquiring Janssen in such Change of Control or such entity's Affiliates that were not Affiliates of Janssen prior to such Change of Control, and (B) a claim of such Patent Controlled prior to such Change of Control solely to the extent such claim is directed to a pharmaceutical formulation (and not a method of use or composition of matter that comprises the pharmaceutical formulation).

(b) **Unblocking License to Janssen.** As of the Effective Date and subject to the terms and conditions herein, including Minerva's retained rights, Minerva hereby grants to Janssen a non-exclusive license, together with the right to sublicense in accordance with Section 2.7, under any Patents that (i) are not included in the Minerva Patents or Program Patents, (ii) are Controlled by Minerva as of the Effective Date or come under the Control of Minerva following the Effective Date and (iii) but for the license granted under this Section 2.10(b) would be infringed by the exercise of any of the licenses granted to Janssen pursuant to Sections 2.5 and 2.6, but only to the extent necessary for Janssen to practice the licenses granted to Janssen pursuant to Sections 2.5 and 2.6. Notwithstanding the foregoing, the Patents subject to the license granted under this Section 2.10(b) shall not include (A) in the event of a Change of Control of Minerva, any Patent that was Controlled prior to such Change of Control by the entity acquiring Minerva in such Change of Control or such entity's Affiliates that were not Affiliates of Minerva prior to such Change of Control, and (B) a claim of such Patent Controlled prior to such Change of Control solely to the extent such claim is directed to a pharmaceutical formulation (and not a method of use or composition of matter that comprises the pharmaceutical formulation).

ARTICLE 3

GOVERNANCE; DEVELOPMENT AND REGULATORY ACTIVITIES

3.1. Joint Steering Committee.

(a) **Establishment of JSC**. Within [*] days of the Effective Date, the Parties shall establish a Joint Steering Committee (the "JSC") consisting of three (3) representatives (or such other number as may be agreed upon by the Parties) designated by each Party. The initial members of the JSC will be nominated by the Parties promptly following the Effective Date. Such representatives shall be individuals suitable in seniority and experience and having delegated authority to make decisions of the JSC with respect to matters within the scope of the JSC's responsibilities; provided that it is understood that such individuals may need to seek appropriate authority from the relevant Party with respect to certain matters. Unless and until the JSC subsequently

accounting, cost allocation, budgeting and financial reporting). A Party may change one or more of its representatives serving on the JSC at any time upon written notice to the other Party. The JSC shall operate in accordance with the provisions of this Article 3, and, at its meetings, the JSC shall discuss the matters described below and such other matters as are reasonably requested by either Party's Alliance Manager.

- (b) **Responsibilities of JSC**. The JSC shall, directly or through its Subcommittees, perform the following functions:
- (i) develop and approve the overall strategy for, and monitor and oversee, the Development, Manufacture and Commercialization of the Licensed Products in the Field;
 - (ii) prepare and approve revisions and modifications to the Development Plan, including the Development Budget;
- (iii) oversee the Development of the Licensed Products in the Field and monitor whether activities under the Development Plan are performed in accordance with the timelines set forth therein;
- (iv) facilitate communication between the Parties and ensure that each Party keeps the JSC fully informed regarding all material activities performed by such Party regarding the Development, Manufacture and Commercialization of the Licensed Products in the Field;
- (v) oversee and supervise any Subcommittees established pursuant to Section 3.2, and resolve Committee Deadlocks in accordance with Section 3.3(c);
 - (vi) coordinate and conduct the accounting, reporting, reconciliation and other related activities set forth in this Agreement;
 - (vii) perform and review calculations for the reconciliation of payments;
- (viii) coordinate audits pursuant to Section 7.5 by Third Party independent accountants, and review and attempt to resolve discrepancies or issues arising from such audits; and
- (ix) perform such other functions as are specifically designated for the JSC in this Agreement or as the Parties otherwise agree in writing are appropriate to further Development, Manufacture and Commercialization of the Licensed Products in the Field under this Agreement.
- **3.2. Subcommittees.** From time to time, the JSC may establish subcommittees of the JSC to oversee particular projects or activities under this Agreement, and such subcommittees shall be constituted and have such responsibility as the JSC approves (each, a "**Subcommittee**"). The Subcommittees shall operate in accordance with the provisions of this Article 3.
- (a) **Joint Manufacturing Committee.** Promptly, and in any event within thirty (30) days, following Janssen's notice that it shall transfer to Minerva control and responsibility with respect to the Manufacture of the Licensed Products pursuant to Section 4.3, the JSC shall

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establish a Joint Manufacturing Committee (the "**JMC**") as a Subcommittee of the JSC to oversee, review and coordinate the Manufacture of the Licensed Products under this Agreement. The JMC shall include individuals from each Party with reasonable expertise in the areas of Manufacturing and supply chain management. The JMC will be responsible for:

- (i) overseeing and reviewing the Manufacture, supply and distribution for purposes of Development and Commercialization of the Licensed Products;
 - (ii) overseeing and reviewing the Manufacturing strategy for Clinical Trial Material and Finished Product;
- (iii) overseeing and reviewing processes, standard operating procedures and chemistry, manufacturing and controls (CMC) for the Manufacture of the Licensed Products, with the goal to establish and maintain global harmonization of such processes, standard operating procedures and chemistry, manufacturing and controls (CMC);
 - (iv) managing supply shortages;
 - (v) overseeing and reviewing Licensed Product specification changes; and
- (vi) performing such other functions as are specifically designated to the JMC in this Agreement, the Development Supply Agreement or the Commercial Supply Agreement, or as the Parties otherwise agree are appropriate to further the Manufacture of the Licensed Products under this Agreement.

(b) **Joint Marketing Committee.** Promptly, and in any event within [*] days, following submission of the first MAA for a Licensed Product in the Field to the applicable Regulatory Authority in the Territory, the JSC shall establish a Joint Marketing Committee (the "**JMktgC**") as a Subcommittee of the JSC to oversee, review and coordinate the marketing of the Licensed Products in the Field under this Agreement. The JMktgC shall include individuals from each Party with reasonable expertise in the area of Commercialization. The JMktgC will be responsible for reviewing global marketing and promotion strategy and performing such other functions as are specifically designated to the JMktgC in this Agreement, or as the Parties otherwise agree are appropriate to further the marketing of the Licensed Products under this Agreement, and in compliance with Applicable Laws (excluding for the avoidance of doubt pricing).

3.3. Membership, Meetings and Decision Making.

(a) **Membership.** Except as otherwise stated herein, each Committee shall be comprised of [*] representatives (or such other equal number of representatives as the Parties may agree) from each of Janssen and Minerva. Either Party may replace its respective Committee representatives at any time with prior written notice to the other Party, provided that such replacement is of comparable authority and scope of functional responsibility within that Party's organization as the person he or she is replacing. Each Parties' representatives to each Committee shall be individuals suitable in seniority and experience and amongst such representatives shall be at least one representative from each Party with relevant decision-making authority to make decisions within the scope of the applicable Committee's

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responsibilities; provided that it is understood that such individual may need to seek appropriate authority from the relevant Party with respect to certain matters. For each Committee, each Party shall designate one of its representatives on such Committee to co-chair the meetings for such Committee (each, a "Co-Chair"). The Co-Chairs shall, with and through the assistance of the Alliance Managers, coordinate and prepare the agenda for, and ensure the orderly conduct of, the meetings of such Committee. The Co-Chairs shall, with and through the assistance of the Alliance Managers, solicit agenda items from Committee members and provide an agenda, along with appropriate information for such agenda, reasonably in advance of any meeting. Such agenda shall include all items requested by either Co-Chair for inclusion therein. In the event the Co-Chair or another Committee member from either Party is unable to attend or participate in a meeting of such Committee, the Party whose Co-Chair or member is unable to attend may designate a substitute co-chair or other representative for the meeting. For the avoidance of doubt, while the Alliance Managers shall attend meetings of all Committees, the Alliance Managers shall not: (i) serve as a voting member of any such Committee; nor (ii) be counted towards either Party's representation on any such Committee. The Alliance Managers shall be responsible for preparing and circulating minutes of such meeting as provided in Section 3.5.

- (b) **Meetings.** The JSC shall meet at least quarterly, or at a frequency determined by the JSC, for so long as a Licensed Product is in Development or is being Commercialized in the Field pursuant to this Agreement, and JSC meetings may be called at other times to resolve Committee Deadlocks in accordance with Section 3.3(c). The JMC, the JMktgC and other Subcommittees, if any, shall each meet quarterly after the Subcommittee is formed, or as more or less often as otherwise agreed by such Subcommittee. Committee meetings may be conducted by telephone, videoconference or in person. Any in-person Committee meetings shall be held on an alternating basis between Janssen's and Minerva's facilities, unless otherwise agreed by the Parties. Each Party shall be responsible for its own expenses in attending such meetings. As appropriate, the Committee may invite a reasonable number of non-voting employees, consultants and scientific advisors to attend its meetings as nonvoting observers, provided that such invitees are bound by appropriate confidentiality obligations. Each Party may also call for special meetings of a Committee to discuss particular matters requested by such Party. The Alliance Managers shall provide the members of each Committee with no less than [*] Business Days notice of each regularly scheduled meeting and, to the extent reasonably practicable under the circumstances, no less than [*] Business Days notice of any special meetings called by either Party.
- (c) **Decision-Making.** Decisions of each Committee shall be made by unanimous vote, with each Party having one vote. To the extent a Party has voted in favor of a particular action, after commencement of the implementation of such action it shall not be permitted to reverse such vote absent changed facts and circumstances that were not present at the time of the initial vote. In order to make any decision, any Committee must have present (in person or via telephone or videoconference) and voting at least one representative of each Party. Unless otherwise specified by the JSC, in the event that the JMC, the JMktgC or any other Subcommittee cannot or does not reach consensus with respect to a particular matter within the authority of such Subcommittee (a "Committee Deadlock") after endeavoring for [*] days to do so, such matter shall be referred to the JSC for discussion and attempted resolution. In the event that the JSC, after endeavoring for [*] days to do so, does not reach a decision with

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respect to a Committee Deadlock, or with respect to any other matter within the purview of the JSC as set forth in this Agreement, then such matter shall be decided as follows:

- (i) If the disputed matter relates to the [*], then [*] shall have final decision making authority, subject to [*];
- (ii) If the disputed matter relates to the [*], then [*] shall have final decision making authority;
- (iii) If the disputed matter relates to the [*], then [*] shall have final decision making authority; and
- (iv) If the disputed matter relates to [*], then [*].

For the avoidance of doubt, the vesting of final decision authority in a particular Party pursuant to this Section 3.3(c) shall not give such Party any authority to (A) alter or amend the terms and conditions of this Agreement, (B) waive either Party's compliance with the terms and conditions of this Agreement or (C) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

- **3.4. Day-to-Day Decision Making Authority.** Each Party shall have decision making authority with respect to the day-to-day activities of such Party (and such Party's employees, agents and contractors) in connection with the Development, Manufacture and Commercialization of the Licensed Products in the Field in accordance with this Agreement, provided that such decisions are not inconsistent with the Development Plan, the terms and conditions of this Agreement, or the decisions of the appropriate Committee, as applicable.
- **3.5. Meeting Minutes.** Minutes will be kept of all Committee meetings by one of the Alliance Managers (or his or her designees) on a rotating basis and sent to all members of the Committee by facsimile or e-mail for review and approval within [*] days after each meeting. The Committee shall formally accept the minutes of the previous meeting at or before the next Committee meeting. Minutes will be deemed approved unless any member of the Committee objects to the accuracy of such minutes by providing written notice to the other members of the Committee prior to the next meeting of such Committee. Minutes shall list action items and shall designate any issues that need to be resolved by the JSC or applicable resolution process. In the event of any such objection to the minutes that is not resolved by mutual agreement of the Parties, such minutes will be amended to reflect such unresolved dispute.
- **3.6. Limitation of Powers.** Each Committee will have only the powers as are specifically delegated to it under this Agreement. The JSC is not a substitute for the rights of the Parties under this Agreement and is intended to coordinate and facilitate the activities of the Parties during the Term. The JSC will not be involved with the day-to-day management of activities to be performed by a Party under this Agreement. In addition, each Committee shall have no authority to (a) alter or amend the terms and conditions of this Agreement, (b) waive either Party's compliance with the terms and conditions of this Agreement or (c) determine any issue in a manner that would conflict with the express terms and conditions of this Agreement.

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- 3.7. 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 coordinate the Parties' activities under this Agreement (each, an "Alliance Manager"). The Alliance Managers shall provide regular reports to the JSC as well as attend meetings (or designate an appropriate representative to attend meetings on the Alliance Manager's behalf) between the Parties, including Committee meetings; provided, however, that the Alliance Managers shall not be counted as members of any Committee (and shall not vote on matters discussed at any Committee meeting). Each Party may change its designated Alliance Manager from time to time upon written notice to the other Party. For the avoidance of doubt, a Party's Alliance Manager may also be a member of the JSC or any Subcommittee.
- **3.8. Minerva Scientific Advisory Board.** Janssen shall have the right to appoint one member of Minerva's scientific advisory board acceptable to Minerva, who would be permitted to attend all scientific advisory board meetings and receive the same notices and information as the other members. Janssen shall consider in good faith any requests by Minerva to change its representative to its scientific advisory board.
- **3.9. Costs of Governance.** The Parties agree that the costs incurred by each Party in connection with its participation at any Committee meetings under this Article 3 (including Minerva's scientific advisory board meetings) shall be borne by such Party.

3.10. Development.

- (a) **General.** The Parties shall conduct a Development program directed toward the Development of Licensed Products, on the terms and conditions set forth in this Agreement and the Development Plan. Such Development shall be conducted under the supervision of the JSC and in accordance with the then current Development Plan approved by the JSC.
- (b) **Development Plan.** The initial Development Plan and Development Budget are attached hereto as <u>EXHIBIT B</u> in provisional form (the "**Provisional Plan and Budget**"). The Development Plan is intended to include a comprehensive overall plan, including all clinical studies of the Licensed Products ("**Clinical Studies**") for the Initial Indications and Initial Formulations in the Field necessary to satisfy applicable regulatory requirements, for the global Development of the Licensed Products in the Field for the Initial Indications and Initial Formulations. The Development Plan shall allocate responsibility for each Development activity set forth therein to a Party, and the Parties agree to conduct all Development activities relating to the Licensed Products in accordance with the Development Plan.

(c) Updating and Amending the Development Plan.

(i) The JSC shall review the Development Plan not less frequently than annually and shall propose detailed and specific Development Plan updates, which shall include the Development Budget for subsequent Calendar Years, until completion of the Development activities hereunder. The JSC shall provide preliminary approval of all such proposed updates no later than September 1 of each Calendar Year. Upon the JSC's preliminary approval, such updates shall be submitted to each Party for its internal budgeting review and shall be subject to

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final approval by the JSC no later than [*] of each Calendar Year, at which time any updates shall be appended to the Development Plan. In addition, the JSC shall meet, by telephone, videoconference or in person, within [*] days of the Effective Date to finalize and approve the initial Development Plan and Development Budget based upon the Provisional Plan and Budget. The JSC may also develop and approve from time to time other amendments to the Development Plan in its discretion and, upon such approval by the JSC, the Development Plan shall be amended accordingly. Amendments and updates to the Development Plan, including the Development Budget, shall not be effective without the approval of the JSC.

(ii) The Development Plan shall be designed to harmonize Development of Licensed Products in the Janssen Territory and the Minerva Territory to the extent practicable. However, in the event that, based upon written guidance from the applicable Regulatory Authority, it is necessary for a Party to perform a Clinical Study (or a portion of a Clinical Study) in its Commercial Territory for purposes of obtaining Regulatory Approval for a Licensed

Product in the Field in any country of such Party's Commercial Territory, which Clinical Study (or portion thereof) is not necessary for purposes of obtaining Regulatory Approval for such Licensed Product in any country of the other Party's Commercial Territory (i.e., Data from such Clinical Study (or portion thereof) shall not be submitted with any application for Regulatory Approval in any country of such other Party's Commercial Territory), such Party, in consultation with the JSC, shall have the right to include and perform such Clinical Study (or portion thereof) under the Development Plan pursuant to an amendment thereof made pursuant to this Section 3.10(c), notwithstanding anything to the contrary in this Agreement (including Section 3.3(c)(i)), and the Development Costs incurred in conducting such Clinical Study (or portion thereof) shall be shared by the Parties pursuant to Section 3.10(f)(i), unless the other Party elects not to share such costs by giving written notice of such election within [*] days following the JSC's approval of such amendment of the Development Plan, in which case (A) the Development Costs incurred in conducting such Clinical Study (or portion thereof) shall be paid for solely by the Party conducting such Clinical Study and (B) the royalties otherwise payable by such Party with respect to Net Sales of any Licensed Product sold by such Party and its Affiliates and Sublicensees in any country of such Party's Commercial Territory in which Data from such Clinical Study (or portion thereof) is necessary for purposes of obtaining Regulatory Approval for such Licensed Product in such country shall be reduced to [*] of the amount otherwise payable pursuant to this Agreement.

- (d) **Development Budget.** The Development Budget included in the Development Plan shall be a rolling [*] year budget setting forth the budgeted amounts for Development Costs with respect to activities allocated to the Parties under the Development Plan during the then-current Calendar Year and the succeeding Calendar Year thereafter, and shall include for each Party a budget for Development Costs for the Development activities allocated to such Party, broken down by Calendar Quarter with respect to the then-current Calendar Year. The Development Budget shall also include a breakout of costs by functional area or category as determined by the JSC. Concurrently with the annual update of the Development Plan in accordance with Section 3.10(c), the JSC shall also prepare and approve an updated [*] rolling Development Budget covering the next Calendar Year and the succeeding Calendar Year.
- (e) **Development Efforts.** Each Party shall use its Commercially Reasonable Efforts to perform, or cause to be performed, the activities assigned to it in the Development Plan.

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Each Party shall conduct its Development activities in good scientific manner and in compliance with Applicable Laws and all applicable requirements relating to the protection of human subjects. Notwithstanding anything to the contrary in this Agreement, a Party shall not be obligated to undertake or continue any Development activity with respect to a Compound or Licensed Product if such Party reasonably determines that performance of such Development activity would violate Applicable Laws or would pose an unacceptable safety risk for subjects participating in a Clinical Study.

(f) **Development Costs.**

- (i) **Cost Sharing.** Subject to Section 3.10(f)(iv) and except as otherwise expressly provided in this Agreement, Development Costs incurred during the Term by the Parties shall be borne sixty percent (60%) by Janssen and forty percent (40%) by Minerva.
- (ii) **Development Costs Reports.** Development Costs shall initially be borne by the Party incurring the cost or expense, subject to reimbursement as provided in Section 3.10(f)(iii). Each Party shall calculate and maintain records of Development Costs incurred by it and its Affiliates in accordance with procedures to be established by the Parties, and the procedures for quarterly reporting of actual results, quarterly review and discussion of potential discrepancies, quarterly reconciliation, reasonable cost forecasting, and other finance and accounting matters related to Development Costs will be determined by the Parties (the "**Development Reconciliation Procedures**"). Such procedures will provide the ability to comply with financial reporting requirements of each Party. The Development Reconciliation Procedures shall provide that within [*] days after the end of each Calendar Quarter, each Party shall submit to the JSC a report, in such reasonable detail and format as is established by the Parties, of all Development Costs incurred by such Party during such Calendar Quarter. Within [*] days following the receipt of such report, each Party shall have the right to request reasonable additional information related to the other Party's and its Affiliates' Development Costs during such Calendar Quarter in order to confirm that such other Party's spending is in conformance with the Development Budget. The Parties shall establish reasonable procedures for the Parties to share estimated Development Costs for each Calendar Quarter prior to the end of such Calendar Quarter, to enable each Party to appropriately accrue its share of Development Costs for financial reporting purposes.

(iii) Reimbursement of Development Costs.

(A) Each Calendar Quarter, the Party (with its Affiliates) that incurs more than its share of the total actual Development Costs during such Calendar Quarter shall be paid by the other Party an amount of cash sufficient to reconcile to the agreed percentage of actual Development Costs as set forth in Section 3.10(f)(i). Notwithstanding the foregoing, on a Calendar Year-to-date basis, the Parties shall not share any Development Costs in excess of the amounts allocated for such Calendar Year-to-date period in the Development Budget; provided, however, that Development Costs in excess of the Development Budget shall be included in the calculation of Development Costs to be shared by the Parties to the extent such excess Development Costs do not exceed by more than [*] the total Development Costs allocated to be incurred by such Party and its Affiliates in the applicable Calendar Year-to-date period in

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accordance with the applicable Development Budget for such Calendar Year (a "Permitted Cost Overrun").

(B) The Development Reconciliation Procedures shall provide for the JSC to develop a written report setting forth in reasonable detail the calculation of any net amount owed by Janssen to Minerva or by Minerva to Janssen, as the case may be, as necessary to accomplish the sharing of Development Costs set forth in Section 3.10(f)(i) and this Section 3.10(f)(iii), and to prepare such report promptly following delivery of the report described in Section 3.10(f)(ii) and in a reasonable time (to be defined in the Development Reconciliation Procedures) in advance of payment. The net

amount payable to accomplish the sharing of Development Costs as provided under this Agreement shall be paid by Janssen or Minerva or by Minerva to Janssen, as the case may be, within [*] days after the end of the applicable Calendar Quarter.

(iv) Cap on Minerva's Share of Development Costs; Other Adjustments to Cost Sharing.

- (A) In the event that Minerva's share of aggregate Development Costs incurred during the period from the Effective Date through the completion of Decision Point 2 (the "**Initial Stage**"), excluding any Development Costs payable solely by Minerva pursuant to Section 3.10(c) (ii) or 3.11(a) or reimbursed or paid by Minerva pursuant to Section 3.10(h), exceeds an aggregate of \$5,000,000 (inclusive of any Permitted Cost Overruns) (the "**Initial Stage Cap**"), then any such amounts for the Initial Stage that are in excess of the Initial Stage Cap shall be borne by Janssen, and not Minerva, and the reimbursement calculations set forth in Section 3.10(f)(iii) shall be adjusted accordingly.
- (B) In the event that Minerva's share of aggregate Development Costs incurred during the period from the Effective Date and up to completion of Decision Point 4 (the "Second Stage"), excluding any Development Costs payable solely by Minerva pursuant to Section 3.10(c)(ii) or 3.11(a) or reimbursed or paid by Minerva pursuant to Section 3.10(h), exceeds an aggregate of \$24,000,000 (inclusive of Minerva's share of aggregate Development Costs incurred in the Initial Stage and any Permitted Cost Overruns) (the "Second Stage Cap"), then any such amounts for the Second Stage that are in excess of the Second Stage Cap shall be borne by Janssen, and not Minerva, and the reimbursement calculations set forth in Section 3.10(f) (iii) shall be adjusted accordingly.

(g) Decision Points.

- (i) For purposes of this Agreement:
- (A) "Decision Point 1" shall mean completion of a single dose Phase I Trial, using a suspension formulation, in patients with major depression disorder as described in the Provisional Plan and Budget.
- (B) "Decision Point 2" shall mean completion of each of the following: (I) a four (4) week Phase Ib Trial in patients with primary and secondary insomnia,

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- (II) a three (3) month toxicology study in two (2) species and (III) a reproductive toxicology study in rodents, in each case as described in the Provisional Plan and Budget.
- (C) "Decision Point 3" shall mean completion of the interim analysis of an Adaptive Phase IIa/IIb Trial in patients with primary insomnia and adjunctive depression as described in the Provisional Plan and Budget and the protocol for such trial, including the distribution of the data and results pertaining to such interim analysis to the members of the JSC and a meeting of the JSC to discuss such data and results. Alternatively, if the Development Plan is amended to include a stand alone Phase IIa Trial in lieu of such Adaptive Phase IIa/IIb Trial, then Decision Point 3 shall instead mean completion of such Phase IIa Trial.
- (D) "Decision Point 4" shall mean completion of a Phase IIb Trial (including completion of an Adaptive Phase IIa/IIb Trial, as applicable) in patients with primary insomnia and adjunctive depression as described in the Provisional Plan and Budget.

For purposes of this Section 3.10(g)(i), "completion" of a trial or study (but, for clarity, excluding completion of the "interim analysis" referenced in Section 3.10(g)(i)(C)) is deemed to have occurred following the last to occur of: (I) database lock with respect to such trial, (II) the distribution of the data and results of such trial to the members of the JSC, and (III) a meeting of the JSC to discuss the data and results of such trial.

- (ii) Within [*] days following the completion of each of Decision Point 2 and Decision Point 3 and at any time following Decision Point 4, Minerva shall have the right, but not the obligation, to opt out of further joint Development of the Licensed Products for the Initial Indications and Initial Formulations by giving Janssen written notice of such election, which election shall be effective [*] days after providing such notice and shall constitute a termination of this Agreement pursuant to Section 11.5(a), subject to Section 11.6(b).
- (iii) Within [*] days following the completion of each of Decision Point 1, Decision Point 2 and Decision Point 3 and at any time following Decision Point 4, Janssen shall have the right, but not the obligation, to opt out of further joint Development of the Licensed Products by giving Minerva written notice of such election, which election shall be effective [*] days after providing written notice of such election. In the event that Janssen makes such election (and provided that Minerva does not make a corresponding election pursuant to Section 3.10(g)(ii)):
- (A) the Janssen Territory shall be deemed automatically amended to exclude all North American Countries and the Minerva Territory shall be deemed automatically amended to include all North American Countries;
- (B) the Parties shall promptly amend the Development Plan pursuant to Section 3.10(c) such that Janssen shall have no further responsibilities thereunder and, in this regard, notwithstanding Section 3.3(c)(i), Minerva shall thereafter have final decision making authority with respect to matters relating to the Development of Licensed Products in the Minerva Territory in the Field;

- (C) Janssen shall thereafter have no further obligation to share Development Costs pursuant to Section 3.10(f), other than with respect to Development Costs incurred prior to such election;

 (D) Janssen shall thereafter have no further diligence obligations with respect to the Development or Commercialization of Licensed Products;

 (E) Except as otherwise required under Section 4.3 with respect to Manufacture of Licensed Product and Section 3.11 with respect to certain Regulatory, Approvals, Janssen shall have the right, but not the obligation, to transfer control and responsibility to Minerya with respect to
 - (E) Except as otherwise required under Section 4.3 with respect to Manufacture of Licensed Product and Section 3.11 with respect to certain Regulatory Approvals, Janssen shall have the right, but not the obligation, to transfer control and responsibility to Minerva with respect to (1) the Manufacture of the Licensed Products for Development and Commercialization in the Field (in accordance with Section 4.3), (2) obtaining all Regulatory Approvals for the Licensed Products in the Field in the Minerva Territory and/or (3) transfer maintenance and operation of the Global Safety Database;
 - (F) the royalties payable by Minerva pursuant to Section 6.2(a) with respect to Net Sales of Licensed Products sold by Minerva and its Affiliates and Sublicensees in the Minerva Territory (as such territory is amended pursuant to Section 3.10(g)(iii)(A)) shall be reduced to [*] of such Net Sales, subject to potential further adjustment pursuant to Section 3.10(c)(ii), Section 6.2(b) or Section 6.2(c); and
 - (G) the royalties payable by Janssen pursuant to Section 6.3(a) with respect to Net Sales of Licensed Products sold by Janssen and its Affiliates and Sublicensees in the Janssen Territory (as such territory is amended pursuant to Section 3.10(g)(iii)(A)) shall be reduced to [*] of such Net Sales, subject to potential further adjustment pursuant to Section 3.10(c)(ii), Section 6.3(b) or Section 6.3(c); provided, however, that such royalty shall be increased to [*] for each country in which Janssen obtains Regulatory Approval of a Licensed Product by referencing Minerva's Regulatory Filings or Data without being required to conduct an independent Phase III Trial in order to obtain Regulatory Approval in such country.
 - (iv) If Janssen makes an election to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), except as otherwise expressly provided in Section 3.10(g)(iii), Janssen thereafter shall continue to have the right, but not the obligation, to Develop, Manufacture and Commercialize Licensed Products in accordance with this Agreement, provided that such Commercialization shall be limited to the Janssen Territory (as such territory is amended pursuant to Section 3.10(g)(iii)(A)). In this regard, (A) the Parties shall exchange reports and Data pursuant to Section 3.10(j); (B) the Parties shall continue to have rights of reference pursuant to Section 3.11(d); (C) the Parties shall continue to share Adverse Event information pursuant to Section 5.4(a) and the Pharmacovigilance Agreement; and (D) if Janssen has transferred control and responsibility to Minerva with respect to the Manufacture of Licensed Products, at Janssen's option, Minerva shall supply Janssen with Licensed Products pursuant to Section 4.3(b), except that Janssen shall no longer have the ROFN provided pursuant to Section 2.7(b).

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(h) **New Development Activities.**

- (i) If, at any time, Janssen desires to Develop a Product containing or comprised of a Compound, alone or in combination with one or more other APIs, for a New Indication or to Develop a New Formulation of such a Product, Janssen shall submit to Minerva a proposal for Janssen and Minerva to jointly Develop such New Indication or New Formulation under the terms and conditions of this Agreement. Such proposal shall contain, at a minimum, information supporting the rationale for Developing such New Indication or New Formulation from a scientific, regulatory and commercial standpoint, as well as an estimated developmental critical path and an estimate of the timeframe for and cost of such Development, including:
- (A) all major Development tasks to be accomplished prior to submission of filings for Regulatory Approvals for such New Indication or New Formulation;
- (B) key Development objectives, expected associated resources, risk factors, timelines, Go/No Go decision points and relevant decision criteria and, where appropriate, decision trees;
- (C) how resources are expected to be provided by Janssen and Minerva to support the Development for such New Indication or New Formulation; and
- (D) a reasonably detailed description and budget for the Development activities that are expected to be performed by Janssen and Minerva for such New Indication or New Formulation.
- (ii) If Janssen proposes the Development of a New Indication or New Formulation to Minerva, then Minerva shall, within [*] days following receipt of such proposal, give Janssen written notice of whether it elects to:
- (A) participate in the joint Development of such New Indication or New Formulation, in which case: (1) such New Indication or New Formulation, as the case may be, shall be deemed included within the scope of the licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4; (2) the Parties shall promptly amend the Development Plan and the Development Budget pursuant to Section 3.10(c) in order provide for the joint Development of such New Indication or New Formulation, as the case may be; and (3) the Development Costs incurred in connection with the Development of such New Indication or New Formulation, as the case may be, pursuant to the Development Plan (as so amended) shall be shared by the Parties pursuant to Section 3.10(f)(i) and shall not be subject to the Initial Stage Cap or the Second Stage Cap; or
- (B) opt out of joint Development of such New Indication or New Formulation, in which case Janssen shall have the right to Develop such New Indication or New Formulation, as the case may be, subject to the provisions of this Section 3.10(h)(ii)(B). If Minerva reasonably believes that Development of such New Indication or New Formulation, as the case may be, would be likely to (1) have a material negative impact on Minerva's business interest in a Licensed Product in the Minerva Territory or (2) raise material toxicity or drug safety concerns, Minerva may provide Janssen with a reasonably detailed written explanation of

the basis for its view. In the event that Janssen disagrees with Minerva's view, such dispute shall be referred to the JSC for resolution. In the event that the JSC agrees with Minerva's view, then Janssen shall not proceed with such Development activities. If the JSC does not agree with Minerva's view, then Janssen shall be entitled to proceed with Development of such New Indication or New Formulation, as the case may be, and such activities shall be outside of the Development Plan and Janssen shall be responsible for all costs and expenses for the Development of such New Indication or New Formulation, subject to Minerva's buy-in rights pursuant to Section 3.10(h)(iii). For the avoidance of doubt, unless Minerva exercises its buy-in rights pursuant to Section 3.10(h) (iii), such New Indication or New Formulation for which Minerva did not share in the Development Costs shall not be included in Janssen's Net Sales for purposes of calculating the royalties due from Janssen to Minerva pursuant to Section 6.3 and shall not be included within the scope of the licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4.

- (iii) If Minerva wishes to Commercialize a New Indication or New Formulation in the Minerva Territory with respect to which Minerva elected to opt out of joint Development pursuant to Section 3.10(h)(ii)(B), then, within thirty (30) days following database lock with respect to the first Phase IIb Trial for such New Indication or New Formulation, as the case may be, Minerva may request an itemized invoice of the Development Costs incurred by or on behalf of Janssen in connection with the Development of such New Indication or New Formulation, as the case may be (which invoice Janssen shall provide within [*] days following such request), and Minerva shall have the right to Commercialize such New Indication or New Formulation, as the case may be, in the Minerva Territory in accordance with the terms and conditions of this Agreement effective upon payment to Janssen of the amount equal to [*] of such Development Costs within ninety (90) days following [*], in which case: (A) such New Indication or New Formulation, as the case may be, shall be deemed included within the scope of the licenses granted to Minerva pursuant to Sections 2.1, 2.2, 2.3 and 2.4; (B) the Development Costs incurred in connection with the further Development of such New Indication or New Formulation, as the case may be, shall be shared by the Parties pursuant to Section 3.10(f)(i) and shall not be subject to the Initial Stage Cap or the Second Stage Cap; and (C) such New Indication or New Formulation, as the case may be, shall be included in Janssen's Net Sales for purposes of calculating the royalties due from Janssen to Minerva pursuant to Section 6.3.
- (i) **Supply of Clinical Trial Material.** Janssen will be responsible for the Manufacture of all Clinical Trial Material for Development activities under this Agreement, either by Manufacturing such Clinical Trial Material itself or through Affiliates, or through one or more Contract Manufacturers selected by Janssen, subject to Section 4.3. In the case of Clinical Studies performed by Janssen pursuant to the Development Plan, the costs for such Clinical Trial Material shall be incurred by Janssen as a Development Cost and allocated pursuant to Section 3.10(f). In the case of Clinical Studies performed by Minerva pursuant to the Development Plan, such Clinical Trial Material shall be supplied by Janssen at the cost set forth in Section 4.2, and such cost shall be treated as a Development Cost and allocated pursuant to Section 3.10(f). Promptly following either Party's request, the Parties shall negotiate in good faith and enter into an appropriately detailed supply and quality agreement (the "**Development Supply Agreement**") governing such supply of Clinical Trial Material by, or on behalf of, Janssen to Minerva with terms and conditions typical for such agreements and consistent with the terms set forth in this Agreement.

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- (j) Reports and Data. If Janssen makes an election to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), each Party then engaged in Development activities shall thereafter prepare and provide to the other Party, within [*] days after the end of June and December of each Calendar Year, a written report that summarizes the Development activities performed, and any Program Inventions and Data generated, by such Party hereunder during the preceding two (2) Calendar Quarters and identifies any issues or circumstances of which it is aware that may prevent or adversely affect in a material manner the future performance of activities under the Development Plan. The Parties may agree that minutes or presentations from Committee meetings may be used to satisfy the foregoing reporting requirement. Each Party shall maintain records in sufficient detail as will properly reflect all work done, and Development Costs expended, in the performance of activities arising out of, in conducting, or otherwise in connection with the Development Plan. In addition, each Party, at the request of the other Party, or upon instruction by the JSC, shall promptly provide to the other Party in a prompt manner all Data (including all reports related to any Clinical Studies) developed by or on behalf of such Party in connection with the Development of the Licensed Products in the Field under this Agreement. The format of, and media for exchanging, such Data shall be determined by the JSC.
- (k) **Use of Contractors.** Each Party shall have the right to use the services of Third Party contractors, including clinical research organizations and the like, to assist such Party in fulfilling its Development obligations under this Agreement, subject to the following terms and conditions: (i) none of the rights of the other Party hereunder are diminished or otherwise adversely affected as a result of such subcontract; (ii) such Third Party contractor is bound by a written agreement that is consistent with the terms of this Agreement, including applicable confidentiality and intellectual property ownership provisions; and (iii) such Party shall remain responsible under this Agreement for ensuring, and shall be liable to the other Party for, the compliance of such Third Party contractor with this Agreement.
- (l) **Clinical Studies.** Any Clinical Studies under the Development Plan will be conducted in accordance with GCP and involve investigators of recognized competence. Each Party shall have the right, at its own expense and subject to the terms and conditions of any applicable agreements, to audit all Clinical Study sites used by the other Party to ensure that any necessary compliance standards are upheld. Any such audit shall be conducted at a reasonable time during regular business hours and upon at least [*] Business Days prior written notice to such other Party and the Clinical Study site.
- (m) **Competing Products.** During the Term, Minerva shall not, directly or indirectly, and shall not assist, fund or cause any Third Party to, Develop, Manufacture or Commercialize a Competing Product.

3.11. Regulatory Activities.

(a) **Regulatory Responsibilities.** Janssen or its Affiliate shall be responsible for seeking and attempting to obtain all Regulatory Approvals for the Licensed Products in the Field in the Territory in accordance with the Development Plan, including managing related relationships and communications with applicable Regulatory Authorities, and the

Development Costs incurred in connection therewith shall be shared by the Parties pursuant to Section 3.10(f)(i), except that: (i) Janssen shall bear [*] of the Development Costs incurred in preparing and filing each MAA in the Janssen Territory; (ii) Minerva shall bear [*] of the Development Costs incurred in preparing and filing each MAA in the Minerva Territory; and (iii) the reimbursement calculations set forth in Section 3.10(f)(iii) shall be adjusted accordingly. Upon request, Minerva shall provide reasonable cooperation and support in regard to the foregoing activities. Notwithstanding the foregoing, if Janssen has elected to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), then Janssen shall transfer control and responsibility to Minerva with respect to seeking and attempting to obtain all MAAs for the Licensed Products in the Field in the Minerva Territory, at Minerva's expense, and, upon request, Janssen shall provide reasonable cooperation and support in regard to the foregoing activities.

- (b) **Ownership of Regulatory Approvals.** Except as otherwise provided for in Section 3.11(a), Janssen or its Affiliate shall own all Regulatory Approvals, including related Regulatory Filings and applications, for the Licensed Products in the Field in the Territory, to the extent permitted by Applicable Laws, except that, following approval of any MAA for a Licensed Product in the Field from the applicable Regulatory Authority in a country within the Minerva Territory, Janssen or its Affiliate shall (to the extent Minerva is not already the holder of such MAA pursuant to Section 3.11(a)) promptly, subject to applicable regulatory procedures, assign to Minerva all right, title and interest in and to such MAA, and thereafter Minerva shall be responsible for maintaining such MAA, at Minerva's expense. Following any such assignment of an MAA to Minerva, if Janssen controls the Manufacture of such Licensed Product, Janssen shall thereafter provide Minerva with such information and documentation related to such Manufacture as necessary in connection with the maintenance of such MAA by Minerva.
- (c) **Regulatory Cooperation.** Subject to Section 3.11(a), Applicable Laws and attendance limitations established by applicable Regulatory Authorities, each Party shall have the right to attend and observe (but not participate in unless specifically agreed to by the other Party in advance) all material meetings, conferences and discussions by the other Party or its Affiliate with Regulatory Authorities pertaining to the Development of the Licensed Products in the Field or Regulatory Approvals. Each Party shall provide the other Party with reasonable advance notice of all such meetings and other contact and advance copies of material documents and other relevant information relating to such meetings or other contact. Each Party shall provide the JSC with advance drafts of any material documents or other material correspondence pertaining to Regulatory Approvals, including any proposed labeling, that such Party plans to submit to any Regulatory Authority. The JSC may provide comments regarding such documents and other correspondence prior to their submission, which comments the submitting Party shall consider in good faith. Each Party shall provide the other Party with copies of all material submissions it makes to, and all material correspondence it receives from, a Regulatory Authority pertaining to a Regulatory Approval. Notices, copies of submissions and correspondence, and other materials to be given in advance as provided in this Section 3.11(c) shall be provided at least [*] Business Days in advance unless circumstances necessitate a shorter time period.

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- Rights of Reference and Access to Data. Each Party shall have the right to cross-reference the other Party's or its Affiliate's DMF, if any, and other Regulatory Filings anywhere in the world related to the Licensed Products, and to access such Regulatory Filings and any Data and Know-How therein and use such Data and Know-How, in each case in connection with the performance of its obligations and exercise of its rights under this Agreement, including inclusion of such Data and Know-How in its own Regulatory Filings for the Licensed Products. Each Party hereby grants to the other Party a "Right of Reference," as that term is defined in 21 C.F.R. § 314.3(b) in the United States, or an equivalent right of access/reference in any other jurisdiction, to any Data, including such Party's or its Affiliates' Regulatory Dossiers, Controlled by such Party or such Affiliates that relate to a Licensed Product for use by such other Party to Develop and Commercialize the Licensed Products in the Field pursuant to this Agreement. Each Party or such Affiliate shall provide a signed statement to this effect, if requested by the other Party, in accordance with 21 C.F.R. § 314.50(g)(3) or the equivalent as required in any other jurisdiction or otherwise provide appropriate notification of such right of the other Party to the applicable Regulatory Authority.
- (e) **Regulatory Inspections.** The Parties shall cooperate in good faith with respect to Regulatory Authority inspections of any site or facility where Clinical Studies or Manufacturing of the Licensed Products in the Field are conducted by or on behalf a Party pursuant to this Agreement (each an "Audited Site"). Each Party shall be given a reasonable opportunity (taking into account the timing and notice provided by the applicable Regulatory Authority) to attend any inspection by any Regulatory Authority of the other Party's Audited Sites, and the summary, or wrap-up, meeting with a Regulatory Authority at the conclusion of such inspection if such inspection relates to the Manufacture of Licensed Products. If such attendance would result in the disclosure to the other Party of Confidential Information unrelated to the subject matter of this Agreement, the Parties shall enter into a confidentiality agreement covering such unrelated subject matter. The rights under this Section 3.11(e) shall be subject to any access restrictions imposed by any applicable permitted contractor which owns or operates any Audited Site, provided, however, that each Party shall use Commercially Reasonable Efforts to include in any contract or other written arrangement with its permitted contractors a clause permitting the other Party to exercise its rights under this Section 3.11(e).
- (f) **Pricing and Reimbursement Approvals.** Notwithstanding anything to the contrary in this Agreement, (i) Janssen or its Affiliate shall be responsible for and have the exclusive right to seek and attempt to obtain pricing and reimbursement approvals for the Licensed Products in the Field in the Janssen Territory, at Janssen's expense, and (ii) Minerva shall be responsible for and have the exclusive right to seek and attempt to obtain pricing and reimbursement approvals for the Licensed Products in the Field in the Minerva Territory, at Minerva's expense.

ARTICLE 4

SUPPLIES OF LICENSED PRODUCTS

4.1. Janssen Rights. Subject to Section 4.3, Janssen shall have the right and responsibility to obtain supply of the Licensed Products in the Field, including supplies for Clinical Studies and Commercialization, either by Manufacturing the Licensed Products itself or

through Affiliates, or through one or more Contract Manufacturers selected by Janssen. Subject to Section 4.3, Janssen shall (a) supply such quantities of Licensed Products in final packaging, ready for distribution to end-users, as are necessary on a worldwide basis to support the Development activities under the Development Plan, including clinical supply to Minerva in accordance with the Development Supply Agreement as set forth in Section 3.10(i), and (b) supply Licensed Products on a worldwide basis for Commercialization, including commercial supply to Minerva in accordance with the Commercial Supply Agreement. Prior to filing of the first MAA for a Licensed Product in the Field with a Regulatory Authority in the Minerva Territory, the Parties shall in good faith negotiate and enter into commercial supply and quality agreements for Licensed Products for Commercialization, containing provisions for the price of Licensed Products to be determined as set forth in Section 4.2, and containing other terms and conditions typical in such agreements and consistent with the terms of this Agreement (collectively, the "Commercial Supply Agreement"). The Parties agree and acknowledge that the Commercial Supply Agreement shall contain a reasonable and customary provision such that, in the event that Janssen or its applicable Affiliate commits an uncured material failure to supply Licensed Product in accordance with such agreement, Janssen or its applicable Affiliate shall, upon Minerva's request, transfer to Minerva control and responsibility with respect to the Manufacture of Minerva's requirements for such Licensed Product in the Field, itself or through its designated Affiliate or through one or more Contract Manufacturers selected by Minerva, in accordance with Section 4.3.

- **4.2. Supply Price.** If Janssen has not elected to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), the price of Clinical Trial Material Manufactured by or on behalf of Janssen hereunder shall be [*] of the Manufacturing Cost of Janssen or its Affiliate(s) and included in Development Costs shared by the Parties pursuant to Section 3.10(f)(i). If Janssen has elected to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), the price of Clinical Trial Material Manufactured by or on behalf of Janssen and supplied to Minerva shall be [*] of the Manufacturing Cost of Janssen or its Affiliate(s) and paid for by Minerva. The price of any supplies of Licensed Product for Commercialization Manufactured by or on behalf of Janssen and supplied to Minerva shall be [*] of the Manufacturing Cost of Janssen or its Affiliate(s) on a pro rata basis reflecting the proportion of the total production batch that Minerva receives, except that such transfer price shall be increased to [*] of the Manufacturing Cost of Janssen or its Affiliate(s) in the event that Janssen makes an opt out election pursuant to Section 3.10(g)(iii). All Finished Product supplied by, or on behalf of, Janssen to Minerva shall be supplied in final packaging, ready for distribution to end-users, except as otherwise agreed by the Parties in writing.
- **4.3. Transfer of Manufacturing Rights.** Notwithstanding anything to the contrary in this Agreement, in the event that (a) Minerva receives approval of an MAA for a Licensed Product in the Field from the applicable Regulatory Authority in a country within the Minerva Territory, or (b) Janssen elects to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii) and thereafter fails to supply a Licensed Product to Minerva for Development in accordance with this Agreement and the applicable product specifications for a period of at least [*] months and fails to cure such supply failure within [*] months following the agreed upon delivery schedule or date, then upon each such case, upon written request by Minerva, Janssen shall transfer control and responsibility to Minerva with respect to the Manufacture of Minerva's requirements of such Licensed Product for Development and

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Commercialization in the Field in accordance with this Section 4.3. In addition, notwithstanding anything to the contrary in this Agreement, in the event that Janssen elects to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), Janssen shall have the right, but not the obligation, to transfer control and responsibility to Minerva with respect to the Manufacture of Licensed Products for Development and Commercialization in the Field in accordance with this Section 4.3, which right may be exercised by Janssen in whole or in part (e.g., Janssen may retain control and responsibility with respect to the Manufacture of the applicable API, while responsibility with respect to the Manufacture of the corresponding Finished Product is transferred to Minerva). In the event of a transfer of Manufacturing pursuant to this Section 4.3:

(i) The Party requesting such transfer of Manufacturing shall give the other Party written notice of such request; (ii) the Parties shall promptly negotiate in good faith a reasonable technology transfer plan with respect to such transfer of Manufacturing; and (iii) Janssen shall thereafter transfer to Minerva or its designated Affiliate or Contract Manufacturer, and reasonably assist Minerva or its designated Affiliate or Contract Manufacturer in implementing, the Janssen Manufacturing IP (including applicable Manufacturing processes) in accordance with such technology transfer plan, at Minerva's expense, with the understanding that the implementation of such technology transfer plan may take approximately [*] years if the applicable Licensed Product (or the applicable component thereof) was previously Manufactured by Janssen or its Affiliate or approximately [*] months if the applicable Licensed Product (or the applicable component thereof) was previously Manufactured by a Contract Manufacturer. In addition, to the extent provided in such technology transfer plan, Janssen or its Affiliate shall: (A) provide to Minerva or its designated Affiliate or Contract Manufacturer copies of the physical embodiment of processes, protocols, procedures, methods, and tests relating to the Manufacturing of Licensed Product (or any component thereof); (B) make available to Minerva or its designated Affiliate or Contract Manufacturer a reasonable number of appropriately trained Janssen personnel to provide, on a mutually convenient timetable, technical assistance with respect to the Manufacture of Licensed Product (or any component thereof); (C) allow a reasonable number of representatives of Minerva or its designated Affiliate or Contract Manufacturer to observe the Manufacturing process at the Manufacturing facilities of Janssen (or its applicable Affiliate or Contract Manufacturer), on a mutually convenient timetable, provided that each such representative enters into a reasonable access and confidentiality agreement acceptable to Janssen; (D) promptly assist Minerva or its designated Affiliate or Contract Manufacturer in obtaining all necessary Regulatory Approvals and/or modifying existing Regulatory Approvals for the Manufacture of such Licensed Product (or any component thereof) by Minerva or its designated Affiliate or Contract Manufacturer; (E) supply analytical test methods and other testing Know-How, including method validation reasonably required to perform release testing or other testing as may be required by the applicable Regulatory Authority; and (F) upon request by Minerva, provide Minerva or its designated Affiliate or Contract Manufacturer with appropriate quantities of reference standards and samples related to Licensed Product (or any component thereof) in order to facilitate its testing. For the avoidance of doubt, Minerva or its designated Affiliate or Contract Manufacturer shall have the right to reference the DMF and other Regulatory Filings of Janssen or its applicable Affiliates as reasonably necessary or useful for the Manufacture of Licensed Product (or any component thereof), in accordance with Section 3.11(d).

- (b) Minerva may perform such Manufacturing either by Manufacturing the applicable Licensed Product(s) (or the applicable component thereof) itself or through its designated Affiliate, or through one or more Contract Manufacturers selected by Minerva, and shall supply Janssen with (i) such quantities of the applicable Licensed Product(s) (or the applicable component thereof) in final packaging, ready for distribution to end-users, as are necessary on a worldwide basis to support Janssen's Development activities and (ii) the applicable Licensed Product(s) (or the applicable component thereof) on a worldwide basis for Commercialization by Janssen and its Affiliates and Sublicensees in the Janssen Territory. The transfer price of Clinical Trial Material Manufactured by or on behalf of Minerva hereunder shall be [*] of the Manufacturing Cost of Minerva or its Affiliate(s) on a pro-rata basis reflecting the proportion of the total production batch that Janssen receives; and the transfer price of any supplies of Licensed Product for Commercialization Manufactured by or on behalf of Minerva shall be [*] of the Manufacturing Cost of Minerva or its Affiliate(s) on a pro-rata basis reflecting the proportion of the total production batch that Janssen receives. All Finished Product supplied by, or on behalf of, Minerva to Janssen shall be supplied in final packaging, ready for distribution to end-users, except as otherwise agreed by the Parties in writing.
- (c) Upon either Party's request, the Parties shall in good faith negotiate and enter into supply and quality agreements for the applicable Licensed Product(s) (or the applicable component(s) thereof) for Development and Commercialization, containing provisions for the price thereof to be determined as set forth in Section 4.3(b), and containing other terms and conditions typical in such agreements and consistent with the terms of this Agreement. In addition, Minerva shall keep the JMC informed on a periodic basis of its plans and activities relating to Manufacture of the applicable Licensed Product(s) in the Field.

ARTICLE 5

COMMERCIALIZATION

- **5.1. General.** Janssen and Minerva shall use Commercially Reasonable Efforts to Commercialize Licensed Products (for which Regulatory Approval has been received) in the Field in the Janssen Territory and Minerva Territory, respectively, on the terms and conditions set forth in this Agreement.
- **5.2. Janssen Commercialization Role.** Janssen shall use Commercially Reasonable Efforts to Commercialize the Licensed Products (for which Regulatory Approval has been received) in the Field in the Janssen Territory. Subject to the terms and conditions of this Agreement, Janssen will have the sole authority and the exclusive right to Commercialize the Licensed Products in the Field in the Janssen Territory and will have sole authority and responsibility in all matters relating to the Commercialization of the Licensed Products in the Field in the Janssen Territory. In such role, Janssen shall be responsible for marketing, detailing, order processing, establishing all terms of sale, invoicing and collection, inventory, warehousing, distributing, and handling all returns of the Licensed Products in the Field in the Janssen Territory, and performing all related services, including the allocation and coordination of sales representatives. Janssen shall be solely responsible for all decisions regarding the prices charged for the Licensed Products in the Field, as well as discounts and rebates, in the Janssen Territory. Sales of the Licensed Products in the Field in the Janssen Territory shall be booked by Janssen

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(or its Affiliates or Sublicensees). All business decisions, including the sale, price and promotion of the Licensed Products in the Field in the Janssen Territory and the decisions whether to market a Licensed Product in any country in the Janssen Territory shall be within the sole discretion of Janssen, subject to the terms and conditions of this Agreement. Subject to its obligation to use Commercially Reasonable Efforts to Commercialize the Licensed Products (for which Regulatory Approval has been received) in the Field in the Janssen Territory, any marketing of a Licensed Product in the Field in one market or country in the Janssen Territory shall not obligate Janssen to market such Licensed Product in the Field in any other market or country in the Janssen Territory. The Parties agree and acknowledge that Commercialization of at least one Licensed Product for at least one indication in at least one North American Country will be deemed to satisfy in full Janssen's obligations under this Agreement to use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products in the Janssen Territory. Janssen retains all Commercialization rights outside the Field both inside and outside the Janssen Territory.

Minerva Commercialization Role. Minerva shall use Commercially Reasonable Efforts to Commercialize the Licensed Products (for which Regulatory Approval has been received) in the Field in the Minerva Territory. Subject to the terms and conditions of this Agreement, Minerva will have the sole authority and the exclusive right to Commercialize the Licensed Products in the Field in the Minerva Territory and will have sole authority and responsibility in all matters relating to the Commercialization of the Licensed Products in the Field in the Minerva Territory. In such role, Minerva shall be responsible for marketing, detailing, order processing, establishing all terms of sale, invoicing and collection, inventory, warehousing, distributing, and handling all returns of the Licensed Products in the Field in the Minerva Territory, and performing all related services, including the allocation and coordination of sales representatives. Minerva shall be solely responsible for all decisions regarding the prices charged for the Licensed Products in the Field, as well as discounts and rebates, in the Minerva Territory. Sales of the Licensed Products in the Field in the Minerva Territory shall be booked by Minerva (or its Affiliates or Sublicensees). All business decisions, including the sale, price and promotion of the Licensed Products in the Field in the Minerva Territory and the decisions whether to market the Licensed Products in any country in the Minerva Territory shall be within the sole discretion of Minerva, subject to the terms and conditions of this Agreement. Subject to its obligation to use Commercially Reasonable Efforts to Commercialize the Licensed Products (for which Regulatory Approval has been received) in the Field in the Minerva Territory, any marketing of a Licensed Product in the Field in one market or country in the Minerva Territory shall not obligate Minerva to market such Licensed Product in the Field in any other market or country in the Minerva Territory. The Parties agree and acknowledge that Commercialization of at least one Licensed Product for at least one indication in at least France, Germany and the United Kingdom will be deemed to satisfy in full Minerva's obligations under this Agreement to use Commercially Reasonable Efforts to Develop and Commercialize Licensed Products in the Minerva Territory.

5.4. Pharmacovigilance and Global Safety Database.

(a) **Pharmacovigilance Agreement.** Upon Janssen's request, the Parties shall meet to negotiate in good faith and agree on processes and procedures for sharing Adverse Event information not later than thirty (30) days prior to the commencement of the first Clinical Study

to be performed by or on behalf of Minerva to the extent set forth in the Development Plan. The agreed-upon processes and procedures shall be set forth in a pharmacovigilance agreement (the "**Pharmacovigilance Agreement**") containing mutually agreed terms and conditions that are customary for agreements of such type. Each Party shall be responsible for submitting Adverse Event reports to the applicable Regulatory Authority for any Clinical Study sponsored by such Party, including annual safety reports, periodic update safety reports and quarterly line listings.

- (b) **Global Safety Database.** Janssen shall, at its sole cost and expense and not as a Development Cost, establish and maintain a global safety database for the Licensed Products, including Adverse Events tracking and pregnancy reports (the "**Global Safety Database**") for the Licensed Products. Minerva shall transfer all Adverse Events information in its possession or control to Janssen for entry and validation into the Global Safety Database in a manner and time so as to enable Janssen to comply with all applicable reporting requirements. Janssen will provide Minerva with online, read-only access to the Global Safety Database and will train an appropriate number of Minerva employees in the use of such database.
- 5.5. Recalls and Market Withdrawals. In the event that either Party determines that an event, incident or circumstance has occurred that may result in the need for a recall or market withdrawal in the Territory, or in the event that any Regulatory Authority issues or requests a recall or takes a similar action in connection with a Licensed Product, the Party that has determined the need for such recall or similar action, or the Party notified of such recall or similar action, shall, within [*], advise the other Party thereof by telephone or facsimile. Minerva, in consultation with Janssen, shall decide whether to conduct a recall in the Minerva Territory (except in the case of a government mandated recall, in which case Minerva may act without such advance consultation, but shall notify Janssen as soon as possible) and the manner in which any such recall shall be conducted. Janssen, in its sole discretion, shall decide whether to conduct a recall in the Janssen Territory and the manner in which any such recall shall be conducted. Each Party will make available to the other Party, upon request, all of such Party's (and its Affiliates') pertinent records that such other Party may reasonably request to assist such other Party in effecting any recall. The costs and expenses of any such recall shall be borne by the Party whose actions or omissions caused the recall to be necessary or deemed advisable.
- 5.6. Medical Inquiries. Minerva shall handle all medical questions or inquiries from members of the medical profession in the Minerva Territory regarding the Licensed Products and Janssen shall, and shall cause its sales representatives to, refer to Minerva all such questions and inquiries within [*] of receipt and shall respond to all inquiries from Minerva and follow the directives of Minerva in connection therewith. Janssen shall handle all medical questions or inquiries from members of the medical profession in the Janssen Territory regarding the Licensed Products and Minerva shall, and shall cause its sales representatives to, refer to Janssen all such questions and inquiries within [*] of receipt and shall respond to all inquiries from Janssen and follow the directives of Janssen in connection therewith. Janssen and its sales representatives shall not respond to any such medical question or inquiry in the Minerva Territory, and Minerva and its sales representatives shall not respond to any such medical question or inquiry in the Janssen Territory, except those received by either Party from a Regulatory Authority.

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5.7. Branding of the Licensed Products.

- (a) **Product Trademarks.** The JSC shall be responsible for establishing a global branding strategy for the Licensed Products and identifying and selecting Product Trademarks consistent with such global branding strategy; provided that Janssen shall have the right to select alternative trademarks on a country-by-country basis in the Janssen Territory and Minerva shall have the right to select alternative trademarks on a country-by-country basis in the Minerva Territory in the event that the Product Trademarks selected by the JSC present any linguistic, cultural or legal issues in such country; provided, further, that any such alternative trademarks shall be consistent with such global branding strategy to the extent practicable. For the avoidance of doubt, Product Trademarks shall not include the corporate names and logos of Janssen or Minerva ("**Party Name Marks**"). The Product Trademarks shall be owned, on a country-by-country basis, by the Party responsible for Commercializing the Licensed Products in such country and such Party shall control the filing, prosecution and maintenance of the Product Trademarks in such country, and shall be responsible for all costs related thereto, including the search and clearance of the Product Trademarks.
- (b) **Enforcement of Product Trademarks.** If a Party has a reasonable basis to believe that a Third Party is engaging in infringement of a Product Trademark, such Party shall promptly notify the other Party in writing and provide it with any evidence of such infringement that is reasonably available. As between the Parties, the Party owning the infringed Product Trademark, or its designee, shall have the sole right and option, at its sole expense, to respond to any infringement or potential infringement with respect to such Product Trademark by appropriate steps, including filing an infringement suit or taking other similar action. The non-owning Party shall provide reasonable assistance to the other Party, or the other Party's designee, at such other Party's expense, with respect to any enforcement activities with respect to such Product Trademark, including providing access to relevant documents and other evidence, making its employees reasonably available during business hours, and joining the action to the extent necessary to maintain the action. Any amounts recovered pursuant to this Section 5.7(b), whether by settlement or judgment, shall first be used to reimburse the applicable Party(ies) for their costs and expenses in making such recovery, and any remaining recovery shall be the property of the Party owning the infringed Product Trademark. Trademark or trade-dress infringement claims by Third Parties shall be governed by Section 8.3(e).
- (c) **Party Name Marks.** The Party Name Marks shall be displayed on the packaging, labeling and promotional materials for the Licensed Products in the Field in the Territory as required by Applicable Laws on a country-by-country basis, and may include appropriate trademark notices (e.g., TM or ®, as the case may be), as directed by each Party with respect to its own Party Name Marks. Each Party shall retain all right, title and interest in and to its respective Party Name Marks, except to the extent expressly licensed to the other Party in this Section 5.7(c), and each Party hereby grants to the other a royalty-free, revocable license to use and exploit its Party Name Marks solely as set forth in the preceding sentence in connection with the Commercialization of the Licensed Products in the Field under this Agreement.

Products in the Field shall be subject to guidelines established by the JSC and consistent with the Parties' usage guidelines with respect to such marks.

5.8. Ex-Territory Sales; Export Monitoring.

- (a) **Ex-Territory Sales.** Subject to Applicable Laws, neither Party shall engage in any advertising or promotional activities relating to any Licensed Product directed primarily to customers or other buyers or users of such Licensed Product located outside its Commercial Territory or accept orders for Licensed Products from or sell Licensed Products into the other Party's Commercial Territory for its own account, and if a Party receives any order for any Licensed Product in the other Party's Commercial Territory, it shall refer such orders to the other Party. The Parties agree and acknowledge that Applicable Laws may prevent or limit a Party from taking action to prevent exports from one European Union country to another.
- (b) **Export Monitoring.** Each Party shall use Commercially Reasonable Efforts to monitor and prevent exports of Licensed Products from its own Commercial Territory for Commercialization in the other Party's Commercial Territory using methods permitted under Applicable Laws that are commonly used in the industry for such purpose (if any), and shall promptly notify the other Party of any such exports of Licensed Products from its Commercial Territory, and any actions taken to prevent such exports. Each Party agrees to take reasonable actions requested in writing by the other Party that are consistent with Applicable Laws to prevent exports of Licensed Products from its Commercial Territory for Commercialization in the other Party's Commercial Territory. The Parties agree and acknowledge that Applicable Laws may prevent or limit a Party from taking action to prevent exports from one European Union country to another.

ARTICLE 6

FINANCIAL TERMS

6.1. Upfront Payment. As partial consideration for the rights granted to Minerva under this Agreement, Minerva shall pay a one-time, non-refundable, non-creditable, upfront payment of twenty-two million dollars (\$22,000,000) to Janssen (the "**Upfront Payment**"), within two Business Days of the date of the IPO Closing.

6.2. Minerva Royalties.

(a) **Royalty Rate and Royalty Term.** In accordance with the terms of this Section 6.2, Minerva shall pay to Janssen royalties in the amount of [*] of Net Sales of all Licensed Products sold by Minerva and its Affiliates and Sublicensees in the Minerva Territory, subject to any royalty rate reduction made pursuant to Section 3.10(c)(ii), Section 3.10(g)(iii), Section 6.2(b) or Section 6.2(c). Such royalties shall be payable, on a country-by-country and Licensed Product-by-Licensed Product basis, beginning upon First Commercial Sale of a Licensed Product in a particular country in the Minerva Territory until the latest of (i) the ten (10) year anniversary of the First Commercial Sale of such Licensed Product in such country, (ii) the expiration of the last to expire Janssen Patent or Program Patent Covering the Compound of the Licensed Product as a composition of matter or labeled use of such Licensed Product in such

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country in the Minerva Territory, or (iii) the end of the period during which such Licensed Product is subject to Regulatory Exclusivity in such country (such period for a particular Licensed Product in a particular country, the "Minerva Royalty Term").

- (b) **Loss of Patent Coverage and Regulatory Exclusivity.** In any country in the Minerva Territory where no Janssen Patents or Program Patents Cover the composition or use of a Licensed Product and where such Licensed Product is not subject to Regulatory Exclusivity, the royalty rate applicable to Net Sales of such Licensed Product in such country shall be reduced by [*], effective with respect to sales of such Licensed Product in such country occurring on or after the date upon which there are no such Patents or no such Regulatory Exclusivity.
- (c) **Generic Competition.** If a Licensed Product is sold in a country in the Minerva Territory where a product that is an AB Rated Product with respect to such Licensed Product is sold or marketed by a Third Party, then the royalty rate applicable to Net Sales of such Licensed Product in such country shall be reduced by [*], effective with respect to sales of such Licensed Product in such country occurring on or after the first day of the first calendar month following the month during which such AB Rated Product is first sold in such country. In the event that such AB Rated Product subsequently ceases to be sold or marketed in such country, the reduction of the royalty rate with respect to such Licensed Product in such country under this Section 6.2(c) shall no longer apply, effective with respect to sales of such Licensed Product in such country occurring after the last day on which such AB Rated Product is sold or marketed in such country.
- (d) **Maximum Royalty Adjustment.** Notwithstanding anything to the contrary in this Agreement, unless subject to further reduction pursuant to Section 3.10(c)(ii), the royalty rate applicable to Net Sales of a Licensed Product sold by Minerva or its Affiliates or Sublicensees in any country of the Minerva Territory during the applicable Minerva Royalty Term shall not, in any event, be less than [*] of the maximum royalty rate applicable pursuant to Section 3.10(g)(iii) or Section 6.2(a), regardless of any subsequent adjustments thereof.

6.3. Janssen Royalties.

(a) **Royalty Rate and Royalty Term.** In accordance with the terms of this Section 6.3, Janssen shall pay to Minerva royalties in the amount of [*] of Net Sales of all Licensed Products sold by Janssen and its Affiliates and Sublicensees in the Janssen Territory, subject to any royalty rate reduction made pursuant to Section 3.10(c)(ii), Section 3.10(g)(iii), Section 6.3(b), Section 6.3(c) or Section 11.6(b). Such royalties shall be payable, on a country-by-country and Licensed Product-by-Licensed Product basis, beginning upon First Commercial Sale of a Licensed Product in a particular country in the Janssen Territory until the latest of (i) the ten (10) year anniversary of the First Commercial Sale of such Licensed Product in such country, (ii) the expiration of the last to expire Program Patent or Minerva Patent Covering the Compound of the Licensed Product as a composition of matter or labeled use of such Licensed Product in such country in the Janssen Territory, or (iii) the end of the period during which such Licensed Product is subject to Regulatory Exclusivity in such country (such period for a particular Licensed Product in a particular country, the "Janssen Royalty Term").

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- (b) **Loss of Patent Coverage and Regulatory Exclusivity.** In any country in the Janssen Territory where no Program Patents or Minerva Patents Cover the composition, manufacture or use of a Licensed Product and where such Licensed Product is not subject to Regulatory Exclusivity, the royalty rate applicable to Net Sales of such Licensed Product in such country shall be reduced by [*], effective with respect to sales of such Licensed Product in such country occurring on or after the date upon which there are no such Patents or no such Regulatory Exclusivity.
- (c) **Generic Competition.** If a Licensed Product is sold in a country in the Janssen Territory where a product that is an AB Rated Product with respect to such Licensed Product is sold or marketed by a Third Party, then the royalty rate applicable to Net Sales of such Licensed Product in such country shall be reduced by [*], effective with respect to sales of such Licensed Product in such country occurring on or after the first day of the first calendar month following the month during which such AB Rated Product is first sold in such country. In the event that such AB Rated Product subsequently ceases to be sold or marketed in such country, the reduction of the royalty rate with respect to such Licensed Product in such country under this Section 6.3(c) shall no longer apply, effective with respect to sales of such Licensed Product in such country occurring after the last day on which such AB Rated Product is sold or marketed in such country.
- (d) **Maximum Royalty Adjustment.** Notwithstanding anything to the contrary in this Agreement, unless subject to further reduction pursuant to Section 3.10(c)(ii), the royalty rate applicable to Net Sales of a Licensed Product sold by Janssen or its Affiliates or Sublicensees in any country of the Janssen Territory during the applicable Janssen Royalty Term shall not, in any event, be less than [*] of the maximum royalty rate applicable pursuant to Section 3.10(g)(ii) or Section 6.3(a), regardless of any subsequent adjustments thereof.

ARTICLE 7

RECORDS, REPORTS AND PAYMENTS

7.1. Payment Method; Reports.

- (a) **Wire and Currency.** All payments to a Payee pursuant to Article 6 shall be made by Federal Reserve electronic wire transfer in immediately available funds to an account designated by such Payee.
- (b) **Royalty Payments.** All royalty payments by Minerva or Janssen, as the case may be, will be made in United States dollars. If sales were made in a currency other than United States dollars, then such amounts shall be converted into United States dollars in accordance with Section 7.4.
- (c) **Financial Reports and Records.** Within sixty (60) days after the close of each Calendar Quarter in which there are any Net Sales subject to the payment of royalties or other amounts under this Agreement, Payor shall furnish to Payee a statement of Net Sales of each Licensed Product for such Calendar Quarter setting forth the Net Sales for each country in which Licensed Products were sold during such Calendar Quarter, and a calculation of royalties

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due pursuant to Article 6 (including any currency conversions). Payor will mail such report to Payee pursuant to Section 14.4. The amount of the royalty payment due to Payee with respect to such Calendar Quarter shall be paid by Payor concurrently with the remittance of each royalty report. Interest shall accrue on any payments due under this Agreement (including royalties) not paid when due through and including the date upon which Payee is paid the funds in accordance herewith at a rate equal to the lesser of (i) [*], or (ii) the maximum interest rate allowed by Applicable Laws.

7.2. Taxes.

- (a) Payor will make all payments to Payee under this Agreement without deduction or withholding for taxes except to the extent that any such deduction or withholding is required by Applicable Laws in effect at the time of payment.
- (b) Any tax required to be withheld on amounts payable under this Agreement will promptly be paid by Payor on behalf of Payee to the appropriate governmental authority, and Payor will furnish Payee with proof of payment of such tax. Any such tax required to be withheld will be an expense of and borne by Payee.
- (c) Payor and Payee will cooperate with respect to all documentation required by any governmental authority or reasonably requested by Payor to secure a reduction in the rate of applicable withholding taxes.

- (d) If Payor had a duty to withhold taxes in connection with any payment it made to Payee under this Agreement but Payor failed to withhold, and such taxes were assessed against and paid by Payor, then Payee will indemnify and hold harmless Payor from and against such taxes (including interest). If Payor makes a claim under this Section 7.2(d), it will comply with the obligations imposed by Section 7.2(b) as if Payor had withheld taxes from a payment to Payee.
- **7.3. Blocked Currency.** In each country where the local currency is blocked and cannot be removed from the country, royalty payments pursuant to Article 6 arising from Net Sales made in that country shall be paid to Payee in the country in local currency by deposit in a local bank designated by Payee, unless the Parties otherwise agree in writing.
- **7.4. Foreign Exchange.** With respect to Net Sales invoiced or expenses incurred in a currency other than United States dollars, such Net Sales invoiced or expenses incurred will be converted into the United States dollars equivalent using (a) in the case of Minerva, a rate of exchange that corresponds to the rate used to record such receipt or expenditure for GAAP reporting purposes for the respective reporting period and (b) in the case of Janssen, the following method: For the upcoming Calendar Year, Janssen shall provide (i) a Currency Hedge Rate to be used for the local currency of each applicable country of the Territory and (ii) the details of such Currency Hedge Rates in writing to Minerva not later than ten (10) Business Days after such Currency Hedge Rates are available from the GTSC or an Affiliate of Janssen, which is customarily at the end of October. Such Currency Hedge Rates shall remain constant throughout the upcoming Calendar Year. Janssen shall use such Currency Hedge Rates to

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convert the applicable Net Sales or expenses to United States dollars for the purpose of calculating royalties and other payments under this Agreement.

Records; Inspection. Payor shall keep, and shall require its Affiliates and Sublicensees to keep, complete, true and accurate books of 7.5. accounts and records for the purpose of determining the basis and accuracy of payments to be made under this Agreement, including royalties and reimbursement of Development Costs. Such records shall be kept in accordance with GAAP and such entity's usual internal practices and procedures (which shall be commercially reasonable) consistently applied, showing Net Sales on a country-by-country and Licensed Product-by-Licensed Product basis and Development Costs on an itemized basis, as applicable. Such books and records shall be kept for at least [*] years following the end of the Calendar Quarter to which they pertain. Such records will be open for inspection by Payee during such [*] year period by independent accountants reasonably acceptable to Payor, solely for the purpose of verifying the basis and accuracy of amounts in the payment statements hereunder. Such inspections shall be made no more than once each Calendar Year, at a reasonable time and on reasonable notice, and shall be limited to information related to Licensed Products. Results of any such inspection shall be deemed to be Confidential Information of Payor, and any such independent accountant shall be required to enter into a customary confidentiality agreement with Payor. If any errors in favor of Payor are discovered in the course of such inspection, then within thirty (30) days of written request by Payee, Payor shall pay Payee those amounts that Payee would have received in the absence of such errors, plus interest pursuant to and in accordance with Section 7.1(c). Inspections conducted under this Section 7.5 shall be at the expense of Payee, unless a variation or error in favor of Payor exceeding [*] of the amount due for the period covered by the inspection is established in the course of such inspection, whereupon all reasonable, documented out-of-pocket costs relating to the inspection for such period will be paid promptly by Payor. In the event of overpayment to Payee, any amount of such overpayment shall be fully creditable against amounts payable in any succeeding Calendar Quarter.

ARTICLE 8

INFORMATION, INVENTIONS AND INTELLECTUAL PROPERTY

8.1. Ownership.

- (a) **Inventorship.** Inventorship for all inventions arising under the Agreement, including Program Inventions, will be determined under the patent laws of the United States.
- (b) **Ownership of Program Inventions.** Each Party shall own an undivided one-half interest in and to any and all Program Inventions and Program Patents, and each Party hereby assigns, and agrees to assign, to the other Party an undivided one-half interest in and to any and all Program Inventions and Program Patents of which such Party would otherwise be the sole owner. Subject to the terms of, and the rights granted under, this Agreement, each of Janssen and Minerva as joint owners shall each have the right to exploit and to grant licenses under such Program Inventions and Program Patents (without an accounting or obligation to, or consent required from, the other Party).

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8.2. Patent Prosecution and Maintenance.

- (a) **Inventions.** Each Party shall notify the other Party promptly in writing of each Program Invention made by such Party.
- (b) **Janssen Patents.** Janssen shall have the primary responsibility for Prosecuting Janssen Patents. The costs and expenses incurred as a result of such Prosecution shall be borne by Minerva to the extent such Prosecution is related to the Minerva Territory and by Janssen to the extent such Prosecution is related to the Janssen Territory; provided, however, that the cost and expense of Prosecuting any PCT application shall be borne by Janssen. Janssen shall provide to Minerva, at least on an annual basis, a detailed list accurately identifying the status of all Janssen Patents. Janssen shall provide Minerva with a reasonable opportunity to review and comment upon draft patent applications and office action responses in the Minerva Territory for such Janssen Patents. If Janssen decides not to file, prosecute, or maintain any Janssen Patents in the Minerva Territory, Janssen shall give Minerva reasonable notice of same (such notice to be provided reasonably in advance of any statutory, response, maintenance fee, or similar deadlines); and after receipt of such notice, Minerva may, upon written election to Janssen, file, prosecute, or maintain such Janssen Patents in its sole discretion at its own expense and shall be made the exclusive attorney of record for such Janssen Patents and Janssen shall promptly assign to Minerva any such Janssen Patents as a result of

Minerva's assumption of any such responsibility. Minerva shall continue to keep Janssen reasonably informed with respect to the status of such Janssen Patents and their Prosecution in the Minerva Territory.

- (c) Minerva Patents. Minerva shall have the primary responsibility for, using outside counsel mutually agreeable to the Parties, Prosecuting Minerva Patents. The costs and expenses incurred as a result of such Prosecution shall be borne by Minerva to the extent such Prosecution is related to the Minerva Territory and by Janssen to the extent such Prosecution is related to the Janssen Territory; provided, however, that the cost and expense of Prosecuting any PCT application shall be borne by Minerva. Minerva shall provide to Janssen, at least on an annual basis, a detailed list accurately identifying the status of all Minerva Patents. Minerva shall provide Janssen with a reasonable opportunity to review and comment upon draft patent applications and office action responses in the Janssen Territory for such Minerva Patents. If Minerva decides not to file, prosecute, or maintain any Minerva Patents in the Janssen Territory, Minerva shall give Janssen reasonable notice of same (such notice to be provided reasonably in advance of any statutory, response, maintenance fee, or similar deadlines); and after receipt of such notice, Janssen may, upon written election to Minerva, file, prosecute, or maintain such Minerva Patents in its sole discretion at its own expense and shall be made the exclusive attorney of record for such Minerva Patents and Minerva shall promptly assign to Janssen any such Minerva Patents as a result of Janssen's assumption of any such responsibility. Janssen shall continue to keep Minerva reasonably informed with respect to the status of such Minerva Patents and their Prosecution in the Janssen Territory.
- (d) **Program Patents.** The Parties shall work in good faith to establish the strategy for Prosecuting Program Patents, and shall use outside counsel mutually agreeable to the Parties in connection with such Prosecution. The costs and expenses incurred as a result of Prosecuting any such Program Patents shall be borne equally by the Parties. The Parties shall

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- (i) exchange (A) drafts of any new application with respect to any Program Patent prior to filing that application, allowing adequate time for review and comment by the other Party if possible, and each Party shall take into account any reasonable comments or consideration of the other Party and (B) copies of all correspondence from any and all patent offices concerning applications with respect any Program Patents and have an opportunity to comment on any proposed responses, voluntary amendments and submissions of any kind to be made to any and all such patent offices; and (ii) with respect to any Program Patents, use Commercially Reasonable Efforts to cooperate and work together in good faith to Prosecute such Program Patents in a manner reasonably consistent with the Development and Commercialization of Licensed Products under this Agreement. If at any time either Party decides not to file, prosecute, or maintain any Program Patent in the other Party's Commercial Territory, such Party (the "Abandoning Party") shall give the other Party reasonable notice of same (such notice to be provided reasonably in advance of any statutory, response, maintenance fee, or similar deadlines); and after receipt of such notice, the other Party may, upon written election to the Abandoning Party, file, prosecute, or maintain such Program Patents in its sole discretion at its own expense and shall be made the exclusive attorney of record for such Program Patents and the Abandoning Party shall promptly assign to the other Party any such Program Patents as a result of the other Party's assumption of any such responsibility. A Party assuming control of Program Patents shall continue to keep the Abandoning Party reasonably informed with respect to the status of such Program Patents and their prosecution in the Abandoning Party's Commercial Territory.
- (e) **General.** Each Party acknowledges that the Party responsible for Prosecution of Patents licensed or jointly owned under this Agreement does not guarantee the issuance, validity, or enforceability of any such Patent or any claim resulting from its efforts hereunder. Neither Party shall have any liability to the other Party for any negligent acts or misconduct of internal or outside legal counsel utilized in connection with such Prosecution, provided that, in the case of outside counsel, the other Party was notified of the selection of such outside counsel and gave consent thereto, not unreasonably withheld.
- (f) **Assignment Documents**. Each Party will take all reasonable actions requested by the other Party to perfect or separately document each or both of the Parties' (as the case may be) ownership rights in any invention as provided for in this Agreement, including causing its, and its Affiliates' and Third Party contractors', representatives, employees, and agents to execute appropriate assignment documents and technology transfer and technology export documents, and the requesting Party shall not be required to pay any remuneration to the other Party or its Affiliates or Third Party contractors, or any of their representatives, employees, or agents, for the execution of any assignments or other papers in connection with this Section 8.2(f). Each Party shall be solely responsible for all compensation due to it and its Affiliates' and Third Party contractors' representatives, employees, and agents in connection with the assignment of rights to inventions pursuant to this Agreement or in connection with such Party's exercise of rights in relation to any such inventions hereunder.

8.3. Enforcement of Patent Rights.

(a) **Infringement of Patent Rights.** Each Party shall notify the other Party in writing promptly of any actual, potential or suspected infringement of Janssen Patents, Program

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Patents, or Minerva Patents by a Third Party commercially manufacturing, using, offering for sale, selling, or importing a product competitive with any Licensed Product (collectively "Alleged Infringement") of which such Party becomes aware and shall promptly provide the other Party with available evidence of such Alleged Infringement. In such event, the Parties shall discuss the most appropriate action to take.

(b) **Right to Pursue Infringers.** With respect to any Alleged Infringement of Janssen Patents, Minerva Patents or Program Patents in any country in the Territory as they relate to Licensed Products, the Party having the right to Commercialize Licensed Products in such country hereunder (the "**Marketing Party**") shall have the first and primary right, but not the obligation, in its sole discretion, to initiate, prosecute, and control any action or legal proceedings by counsel of its choice and at its own expense, such as by Janssen in connection with the submission by any Third Party of an abbreviated new drug application or a 505(b)(2) application under the U.S. Drug Price Competition and Patent Term Restoration Act of 1984. If, within six (6) months of the

notice above, the Marketing Party (i) shall have been unsuccessful in persuading the alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement action, or (iii) is not engaged in settlement discussions with respect to such infringement, or if such Marketing Party notifies the other Party that it has decided not to undertake any of the foregoing against any such alleged infringer, then, unless the Marketing Party provides the other Party with a commercially reasonable justification for not doing so, the Party having any ownership rights in such Patents shall have the right to bring suit to enforce such Patents upon notice to the Marketing Party. If either Party brings any infringement action or proceeding hereunder (such Party, the "Enforcing Party"), the other Party agrees to be joined as a plaintiff if necessary for standing and, at the expense of the Enforcing Party, to give the Enforcing Party reasonable cooperation, assistance and authority to control, file and prosecute the suit as necessary.

- (c) **Litigation Control.** The Enforcing Party shall bear all of its costs and expenses of the suit and shall keep the other Party reasonably informed, and reasonably consult with the other Party, as to the strategy and progress of the suit and all settlement discussions. The Enforcing Party shall not approve a settlement or consent judgment or other final voluntary disposition of a suit brought by such Enforcing Party under Section 8.3(b) (i) in a manner that would admit the unenforceability or invalidity of Patents Controlled by the other Party, or of Program Patents, or (ii) to the extent pertaining specifically to Patents in the other Party's Commercial Territory, in each case without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed.
- (d) Allocation of Recoveries. Any settlements, damages or monetary awards ("Recovery") recovered by the Enforcing Party pursuant to a suit brought by such Enforcing Party under Section 8.3(b) will be allocated first to reimburse the Enforcing Party for the costs and expenses incurred by it in connection with such suit (including any expenses or costs incurred by such Party to reimburse the other Party pursuant to Section 8.3(b)), and then to reimburse the other Party for the costs and expenses incurred by it in connection with such suit to the extent not previously reimbursed. If [*] is the Enforcing Party in the [*], any remaining Recovery shall be retained by [*]. If [*] is the Enforcing Party in the [*], any remaining Recovery shall be retained by [*]. If [*] is the Enforcing Party in the [*],

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any remaining Recovery [*] and any other remaining Recovery shall be retained by [*]. If [*] is the Enforcing Party in the [*], any remaining Recovery shall be retained by [*].

- (e) **Infringement of Third Party Patent Rights.** If a Party's conduct or exercise of its rights under this Agreement becomes the basis of a claim of infringement of any Patent or other proprietary right of any Third Party, such Party shall promptly give notice to the other Party and the Parties shall confer to consider the claim and an appropriate course of action. Unless the Parties agree otherwise, each Party shall have the right to control the defense of any such Third Party claim brought against it, by counsel of its own choice, except such Party shall not approve a settlement or consent judgment or other final voluntary disposition of such claim in a manner that would admit the unenforceability or invalidity of Patents Controlled by the other Party, or of Program Patents, without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. The Party defending any such Third Party claim shall bear all of its costs and expenses and shall retain any damages or other monetary awards recovered in connection therewith. The other Party shall cooperate with the defending Party, as reasonably requested by it, in connection with the defense against such claim or action, at the defending Party's expense.
- **8.4. Patent Term Extensions.** Janssen shall have sole discretion, after consultation with Minerva, to determine which Janssen Patents, Program Patents and Minerva Patents, as the case may be, shall be extended pursuant to patent term extensions, patent term restorations, pediatric data package exclusivity extensions, supplementary protection certificates, any functional equivalents of any of the foregoing, or similar means of extending market exclusivity or patent protection for any Licensed Product in the Territory. Upon Janssen's written request specifying the extension(s) to be applied for and the time period(s) in which to apply, Minerva shall apply for any such extension(s) and shall provide Janssen with all information and data in Minerva's possession reasonably needed to enable Janssen to request, prepare or apply for any such extension(s) with respect to the applicable Patents or Licensed Product. Janssen shall have the right to (a) identify in any list of Patents in an MAA the applicable Janssen Patents, Program Patents and Minerva Patents, as Janssen reasonably believes are appropriate, and (b) exercise any rights that may be exercisable by a patent owner in order to apply for a patent term extension in accordance with this Section 8.4.
- **8.5. Patent Marking.** To the extent permitted by Applicable Laws, the Party Commercializing any Licensed Product agrees to mark, and to cause any Affiliates and Sublicensees Commercializing such Licensed Product to mark, such Licensed Product (through a marking on containers, packaging or labels, or an Orange Book or like listing) made, sold, or otherwise disposed of by it or them with any notice of patent rights reasonably necessary, in any country where such Licensed Product is sold, to (a) enable Patents (to the extent, in each case, relating to such Licensed Product) to be enforced to their full extent or (b) ensure the availability of all potential legal or equitable remedies with respect to any infringement of any Patents (to the extent, in each case, relating to such Licensed Product) by any Third Party.

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ARTICLE 9

CONFIDENTIAL INFORMATION

9.1. Nondisclosure of Confidential Information. All Information disclosed by one Party to the other Party pursuant to this Agreement shall be the "**Confidential Information**" of the disclosing Party. The Parties agree that, during the Term and for a period of [*] years thereafter, a Party receiving Confidential Information of the other Party will (a) maintain in confidence such Confidential Information to the same extent such Party maintains its own proprietary information of similar kind and value (but at a minimum each Party shall use Commercially Reasonable Efforts to do so), (b) not publish or otherwise disclose such Confidential Information to any Third Party without prior written consent of the other Party, and (c) not use such Confidential Information for any purpose except those permitted by this Agreement.

- **9.2. Exceptions.** The obligations in Section 9.1 shall not apply with respect to any portion of the Confidential Information that the receiving Party can show by competent written proof:
 - (a) Was generally available to the public or otherwise part of the public domain at the time it was disclosed to the receiving Party hereunder;
 - (b) Was known to the receiving Party or its Affiliate, without obligation to keep it confidential, prior to disclosure by the disclosing Party;
 - (c) Is subsequently disclosed to the receiving Party or its Affiliate without obligation to keep it confidential by a Third Party lawfully in possession thereof and having the right to so disclose such Confidential Information without breach of any obligation of confidentiality to the disclosing Party;
- (d) Became generally available to the public or otherwise part of the public domain after its disclosure and other than through any act or omission of the receiving Party; or
- (e) Has been or was independently developed or discovered by employees of the receiving Party or its Affiliates without the aid or use of all or any part of such Confidential Information.
- **9.3. Authorized Disclosure.** A Party may disclose the other Party's Confidential Information to the extent such disclosure is reasonably necessary in the following instances:
 - (a) Prosecuting Patents pursuant to the rights granted in Section 8.2;
 - (b) Making Regulatory Filings and applying for Regulatory Approvals;
 - (c) Prosecuting or defending litigation;
 - (d) To the extent such disclosure is required by Applicable Laws, valid court order or legal process, provided, however, that such Party gives the other Party advance notice of such

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required disclosure, limits the disclosure to that actually required, and cooperates, at the other Party's expense, in the other Party's attempts to obtain a protective order or confidential treatment of the Confidential Information required to be disclosed; or

(e) Disclosure, in connection with the performance of, or exercise of rights under, this Agreement, to Sublicensees, manufacturers, collaborators, contractors, employees, consultants, or other agents or representatives of a Party or its Affiliates, each of whom prior to disclosure must be bound by obligations of confidentiality and non-use at least as protective as those set forth in this Article 9.

The Parties acknowledge that the terms of this Agreement shall be treated as Confidential Information of both Parties. Such terms may be disclosed by a Party to investment bankers, counsel, accountants, financial advisors, potential or actual investors, potential or actual lenders, potential or actual acquirers, acquisition targets, or merger targets, actual or potential Sublicensees, or actual or potential other strategic partners, provided that they are bound by obligations of confidentiality and non-use at least as protective as those set forth in this Article 9. In addition, a copy of this Agreement or a notification thereof may be filed or registered by either Party with any Regulatory Authority, including the Federal Trade Commission, the Justice Department, or the Securities and Exchange Commission (or any similar foreign agency), if such filing is required by Applicable Laws. In connection with any such filing, such Party shall (i) provide the other Party a reasonable opportunity to review and comment on any potential disclosure and (ii) use Commercially Reasonable Efforts to obtain confidential treatment of economic, trade secret, and other confidential or proprietary information to the extent permitted by Applicable Laws and the applicable governmental agency(ies). In any event, the Parties agree to take all reasonable action to avoid disclosure of Confidential Information except as permitted hereunder.

9.4. Publicity. No written publication, news release or other written public announcement relating to this Agreement, or to the execution or effectiveness hereof or performance hereunder, shall be made without the other Party's written consent. Notwithstanding the foregoing, any disclosure which is required by stock exchange regulation or by Applicable Laws (including Regulation FD and any duties to disclose material information or known trends and uncertainties, and duties to update financial guidance or other disclosure) as advised by the disclosing Party's counsel may be made without the prior consent of the other Party, provided that the other Party shall be given prompt notice of any such legally required written disclosure and the disclosing Party, to the extent reasonably practicable, shall provide the other Party an opportunity to comment on the proposed written disclosure prior to its disclosure or release.

9.5. Publications.

(a) **Publication Strategy.** The JSC shall develop and approve a global publication strategy for the Development activities related to the Licensed Products in the Field (the "**Publication Strategy**") that is consistent with the Development Plan and the Parties' applicable internal policies. The JSC may also from time to time develop and approve substantive amendments to such Publication Strategy and, upon approval by the JSC of any such amendment, the Publication Strategy shall be amended accordingly.

- (b) **Review of Publications.** Except as required by Applicable Laws, and subject to Section 9.6, any proposed scientific or medical publications or public scientific or medical presentations related to the Licensed Products, other than publications or presentations of Janssen related to the use of Licensed Products outside the Field, shall be subject to the provisions of this Section 9.5(b). In the event a Party desires to publish such a scientific or medical publication or to make such a public scientific or medical presentation related to any Licensed Product, such Party shall provide the other Party a reasonable advance opportunity, but no less than [*] days prior to its intended submission for publication presentation, to review and comment on such proposed publication or presentation prior to its submission. Further, the reviewing Party shall have the right to require a delay of up to [*] days in publication or presentation in order to enable patent applications protecting each Party's rights in such information to be filed, and the reviewing Party shall have the right to prohibit disclosure of any of its Confidential Information in any such proposed publication or presentation. In any permitted publication or presentation by a Party, the other Party's contribution shall be duly recognized, and co-authorship shall be determined, in accordance with customary standards.
- **9.6. Publication of Clinical Studies.** Minerva has read and understands the Johnson & Johnson Clinical Trial Data Transparency Statement as in effect from time to time (the "**Policy**"), a copy of which in its then current form has been provided to Minerva prior to the Execution Date, and agrees that the Development and Commercialization of Licensed Products contemplated herein is subject to the Policy. In connection with the Development and Commercialization of Licensed Products contemplated hereunder, Minerva agrees that it will, and it will cause any of its Affiliates to agree to, permit Janssen to register and publish the resulting Data in accordance with the Policy, and otherwise comply with all terms therein. Minerva further agrees to provide, or to cause any of its Affiliates to provide, to Minerva such reasonable assistance as Janssen may require in connection with fulfilling the requirements set forth in the Policy. Notwithstanding anything to the contrary in this Agreement, Janssen's compliance with the terms of the Policy will not result in a breach of any provision of this Agreement, including Section 9.1.
- **9.7. Prior Agreements.** This Agreement supersedes the Confidentiality Agreements between Janssen and Minerva dated April 24, 2013 (F/K/A Cyrenaic Pharmaceuticals, Inc.), May 14, 2013 (Mind-NRG SA) and May 14, 2013 (Sonkei Pharmaceuticals, Inc., predecessor of Minerva) (collectively, the "**Prior Agreements**"), provided, however, that the foregoing shall not limit any remedies available to either Party with respect to any breach of the Prior Agreements which occurred prior to the Effective Date. All information disclosed under the Prior Agreements shall be deemed to have been disclosed under this Agreement and shall be subject to the terms of this Article 9.

ARTICLE 10

REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1. Mutual Representations and Warranties. Janssen and Minerva each represents and warrants to the other, as of the Effective Date, that: (a) it is duly incorporated and validly existing under the laws of the state or jurisdiction of its incorporation and has full corporate power and authority to enter into this Agreement and to carry out the provisions hereof; (b) it has

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taken all corporate action necessary to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement; (c) 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 or other debtor's rights laws and regulations; (d) it has the authority and right to enter into and perform this Agreement; (e) its execution, delivery and performance of this Agreement will not conflict in any material respect with the terms of any other agreement to which it is a Party or by which it is bound; and (f) it has not been debarred and is not the subject of debarment proceedings by any Regulatory Authority.

10.2. Representations and Warranties of Janssen.

- (a) Janssen represents and warrants to Minerva that Janssen has disclosed in writing to Minerva any Adverse Events that have arisen, as of the Execution Date, after administration of the study drug in the Phase I Trial of the Licensed Product identified as [*].
- (b) Janssen represents and warrants to Minerva that, as of the Execution Date, Janssen, to the best of its knowledge, does not Control Patents Covering [*]as a composition of matter, other than those set forth on <u>EXHIBIT C</u>.
- **10.3. Representation and Warranty of Minerva.** Minerva represents and warrants to Janssen that, as of the Execution Date, Minerva, to the best of its knowledge, does not Control Patents Covering [*] as a composition of matter, other than those set forth on <u>EXHIBIT E</u>. If there are no Patents set forth on <u>EXHIBIT E</u>, then Minerva represents and warrants to Janssen that, as of the Execution Date, Minerva, to the best of its knowledge, does not Control any Patents Covering any Compound as a composition of matter, such as [*] or any isomer, tautomer, enantiomer, diastereomer, prodrug, ester, salt, hydrate, solvate, racemate, metabolite, polymorph, or isotopic substitution thereof.
- **10.4. Performance by Affiliates.** Each Party may perform some or all of its obligations under this Agreement through such Party's Affiliates, provided, however, that each Party shall remain responsible for the payment and performance by its Affiliates and shall cause its Affiliates to comply with the provisions of this Agreement in connection with such performance.
 - **10.5. Mutual Covenants.** Janssen and Minerva each covenants to the other that:
- (a) **No Conflicting Agreements.** It shall not enter into any agreement, or grant any rights to any Third Party, which would conflict with the rights granted to the other Party hereunder.
- (b) **Invention Assignment Agreements.** It shall maintain valid and enforceable agreements with all persons and entities acting by or on behalf of such Party or its Affiliates under this Agreement which require such persons and entities to assign to such Party their entire right, title and interest in and to all Know-How made by such persons and entities in connection with their activities under this Agreement and any and all Patents Covering any such Know-How.

- (c) **Compliance.** It shall comply with all Applicable Laws in performing its obligations and exercising its rights under this Agreement, and shall ensure that all of its Affiliates and Sublicensees and all Third Parties conducting activities on its behalf, comply with all Applicable Laws in their Development, Manufacture and Commercialization of Licensed Products.
- (d) **Debarment.** It shall not knowingly use in connection with the Development, Manufacture or Commercialization of the Licensed Products in the Field any employee, consultant, agent, contractor or investigator that has been debarred or is the subject of debarment proceedings by any Regulatory Authority.
- (e) **FCPA.** Neither it, nor any of its Affiliates or Sublicensees, in performing any of its obligations or activities under this Agreement, shall engage in any activities (such as offering a bribe to any government official), directly or indirectly (e.g., through use of an agent), that would subject the other Party to liability under the U.S. Foreign Corrupt Practices Act. Without limiting the foregoing, Minerva and each of its Affiliates and Sublicensees shall conduct their respective activities hereunder in accordance with the provisions of <u>EXHIBIT D</u>.
- 10.6. Disclaimer of Warranties. EXCEPT AS SET FORTH IN SECTION 10.1, EACH PARTY EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE, AND NON-INFRINGEMENT OF THIRD PARTY RIGHTS. IN PARTICULAR, THE COMPOUNDS, LICENSED PRODUCTS AND INFORMATION OF JANSSEN ARE PROVIDED "AS IS" AND WITHOUT ANY REPRESENTATION OR WARRANTY, EXPRESS OR IMPLIED, INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR OF FITNESS FOR ANY PARTICULAR PURPOSE OR ANY WARRANTY THAT THE USE OF COMPOUNDS OR LICENSED PRODUCTS WILL NOT INFRINGE OR VIOLATE ANY PATENT OR OTHER INTELLECTUAL PROPERTY RIGHTS OF ANY THIRD PARTY.

ARTICLE 11

EFFECTIVE DATE; TERM; AND TERMINATION

11.1. Effective Date. This Agreement shall not become effective, and the Parties shall not commence the performance of this Agreement (other than Section 9.1), unless and until Minerva completes the closing, on or before September 30, 2014 (the "Outside Date"), of a firm-commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended (the "IPO Closing") and makes the Upfront Payment in accordance with Section 6.1 (the date on which both such conditions have been satisfied being referred to herein as the "Effective Date"). If such IPO Closing does not occur on or before the Outside Date, then this Agreement shall be deemed to be null and void, and of no further force or effect, as of the Outside Date, except that (a) the Parties shall continue to comply with Section 9.1 for a period of [*] years following the Execution Date and (b) Article 13 shall apply to any dispute, controversy or claim arising out of or related to this Agreement, or the interpretation, application, breach, termination or validity thereof.

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- **11.2. Term.** Unless sooner terminated as hereinafter provided, this Agreement shall become effective upon the Effective Date and continue in full force and effect on a Licensed Product-by-Licensed Product and country-by-country basis until the date no further payment obligations of Payor to Payee relating to such Licensed Product are due under Article 6 in such country (the "**Term**"). At such time, all licenses granted to the Party Commercializing such Licensed Product under this Agreement in such country shall survive, but shall be non-exclusive, fully paid-up, and royalty-free, with rights of sublicense.
- 11.3. Early Termination for Material Breach. Notwithstanding anything to the contrary in this Agreement, if either Party is in material breach of this Agreement (including any material breach of a representation or warranty made in this Agreement), then the other Party may deliver notice of such breach to the breaching Party. In such notice, the non-breaching Party shall identify the specific nature of default, require the breaching Party to cure the breach, and state its intention to terminate the Agreement if such breach is not cured. The breaching Party shall have [*] days to either cure such breach or, if cure cannot be reasonably affected within such [*] day period, to deliver to the non-breaching Party a plan for curing such breach which is reasonably sufficient to effect a cure. Such a plan shall set forth a program for curing such breach as rapidly as practicable and specify a commercially reasonable date for achieving such cure consistent with the foregoing, which shall not, in any event, exceed [*] days. Following delivery of such plan, the breaching Party shall use Commercially Reasonable Efforts to carry out the plan and cure the breach by such date. If the breaching Party fails to cure such breach within the [*] day cure period (or such later date set forth in the plan provided by the breaching Party in accordance with the preceding sentence, which shall not in any event exceed [*] days following notice of such breach), or the non-breaching Party reasonably determines that (a) the proposed corrective plan or the actions being taken to carry it out is/are not commercially practicable by the specified date or (b) the specified date for cure in such plan does not represent a commercially reasonable date to achieve such cure as rapidly as practicable through the application of the breaching Party's Commercially Reasonable Efforts, the non-breaching Party may, upon written notice, terminate this Agreement in its entirety. Notwithstanding the foregoing, the cure period for any failure to pay amounts due
- 11.4. Early Termination for Bankruptcy. Notwithstanding anything to the contrary in this Agreement, upon the Bankruptcy of either Party (or its successor in interest in the event this Agreement is assigned as permitted hereunder), the other Party may, upon written notice, terminate this Agreement in its entirety. For the purposes of this Section 11.4, "Bankruptcy" means, with respect to a Party, that: (a) such Party has been declared insolvent or bankrupt by a court of competent jurisdiction; (b) a voluntary or involuntary petition in bankruptcy is filed in any court of competent jurisdiction against such Party and such petition has not been dismissed within ninety (90) days after filing; or (c) such Party has made or executed an assignment of all or substantially all of its assets for the benefit of creditors.

11.5. Early Termination by Minerva.

(a) **Decision Points.** Commencing upon, and within [*] days following each of Decision Point 2 and Decision Point 3, and at any time following Decision Point 4, Minerva may, upon at least [*] days prior written notice, terminate this Agreement in its entirety.

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(b) **Janssen Opt Out.** If Janssen makes an election to opt out of further joint Development of the Licensed Products pursuant to Section 3.10(g)(iii), Minerva thereafter may, upon prior written notice, terminate this Agreement in its entirety.

11.6. Effects of Termination.

- Termination by Janssen pursuant to Section 11.3 or Section 11.4. If Janssen terminates this Agreement pursuant to Section 11.3 or (a) Section 11.4, then (i) any and all licenses granted to Minerva by Janssen under this Agreement, and any and all sublicenses granted thereunder, shall terminate and (ii) Minerva shall, without additional consideration (except as otherwise expressly provided below) to the extent requested by Janssen in writing, (A) assign and transfer to Janssen or its designee all right, title, and interest in and to all quantities of Clinical Trial Material and Finished Product in Minerva's control (subject to Janssen reimbursing Minerva's reasonable cost) and all Regulatory Filings, Regulatory Documentation, Regulatory Approvals, Product Trademarks and Product-Related Materials, (B) irrevocably and perpetually grant Janssen the rights described in Sections 2.5 and 2.6 with respect to Minerva Patents and Minerva Know-How, (C) assign (or use diligent efforts to assign if the applicable contract does not freely permit assignment) to Janssen any manufacturing, supplier, distributor, clinical study, or other contracts concerning the Development or Commercialization of Licensed Products entered into by Minerva with Third Parties or otherwise facilitate Janssen's establishment of similar relationships with such Third Parties, (D) continue to comply with Sections 8.4, 9.5 and 9.6, and (E) cooperate, at Janssen's request, in undertaking a reasonable wind-down and/or orderly transition to Janssen of Minerva's Development and/or Commercialization activities, consistent with Janssen's continuing rights and interest in the Licensed Products following such termination (including taking such reasonable actions in regard to Regulatory Approvals as may be directed by Janssen or its designee pending the assignment and transfer of such Regulatory Approvals pursuant to clause (ii)(A) above), provided, however, that Minerva shall not be obligated to initiate any new substantive activity, distinct from any previously ongoing substantive activity, that would itself create any new obligations on the part of Minerva that would continue following such termination. If Minerva has registered any Product Trademarks for any Licensed Product(s), upon Janssen's request, Minerva will cooperate with and execute any reasonable assignment and transfer documents prepared by Janssen to effectuate an assignment of such Product Trademarks to Janssen or its designee, at Janssen's cost for the assignment and transfer documents and any governmental fees for effecting such assignment.
- (b) **Termination by Minerva pursuant to Section 11.5.** If Minerva terminates this Agreement pursuant to Section 11.5(a), then (i) the terms and conditions of Section 11.6(a) shall apply to such termination, (ii) if such termination occurs within forty-five (45) days following the completion of Decision Point 2, then Minerva shall pay a one-time, non-refundable, non-creditable termination fee of \$3,000,000 to Janssen, within ten (10) Business Days after the effective date of such termination, and (iii) if such termination occurs on or any time following Decision Point 4, then Janssen shall thereafter pay to Minerva royalties with respect to worldwide Net Sales of Licensed Products sold by Janssen and its Affiliates and Sublicensees pursuant to Section 6.3(a) at the reduced rate of [*] of such Net Sales (excluding New Indications and New Formulations unless Minerva had paid its allocation of the Development Costs thereof pursuant to Section 3.10(h)), subject to potential further adjustment

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pursuant to Section 3.10(c)(ii), Section 6.3(b) or Section 6.3(c); provided that in no event shall the royalties on Net Sales be reduced to an amount less than [*] of Net Sales. If Minerva terminates this Agreement pursuant to Section 11.5(b), then the terms and conditions of Section 11.6(a) shall apply to such termination.

- (c) **Other Effects of Termination.** Except as expressly set forth this Section 11.6 and Section 11.8, upon the expiration or termination of this Agreement for any reason, all rights and obligations of the Parties under this Agreement shall terminate.
- 11.7. Accrued Obligations; Additional Remedies. Expiration or termination of this Agreement for any reason whatsoever will not release or discharge Janssen or Minerva from the performance of any obligation, the payment of any debt or responsibility for any liability which may have previously accrued and remains to be performed, paid or discharged as of the date of such expiration or termination. In addition, termination of this Agreement under this Article 11 or any other provision of this Agreement providing any right of termination shall not be exclusive or prejudicial to any legal or equitable rights or remedies each Party may have on account of any breach or default of this Agreement.
- **11.8. Survival.** The following provisions of this Agreement shall, in addition to any provisions specified elsewhere in this Agreement as surviving expiration or termination of this Agreement in certain circumstances, survive any expiration or termination or expiration of this Agreement: Articles 6 and 7 (each only with respect to any payment obligation surviving termination), 12, 13 and 14 and Sections 5.4(a), 8.1, 9.1, 9.2, 9.3, 9.4 and 9.7.

ARTICLE 12

INDEMNIFICATION, INSURANCE; LIMITATION OF LIABILITY

12.1. Indemnification.

(a) **Indemnification by Each Party.** Each Party (such Party, the "**Indemnitor**") hereby agrees to indemnify, defend and hold harmless the other Party, its Affiliates, and such Party's and its Affiliates' directors, officers, employees, agents, and other representatives (each, an "**Indemnitee**" and, collectively, the "**Indemnitees**") from and against any and all damages, liabilities, expenses and losses, including reasonable legal expenses and reasonable

attorneys' fees ("Losses") resulting from suits, claims, proceedings or causes of action brought by a Third Party (each, a "Claim") against such Indemnitee based on any of the following performed or committed by the indemnifying Party or its Affiliates, agents or, to the extent applicable, Sublicensees: (i) breach of a representation or warranty contained in this Agreement; (ii) breach of this Agreement or failure to comply with any Applicable Laws in connection with this Agreement; (iii) negligence, fraud or willful misconduct in connection with this Agreement; or (iv) Development, Manufacture or Commercialization of Licensed Products (which shall include but not be limited to any liability based on product liability or any personal injury or death resulting from the administration of any Licensed Product to any human subject or patient prior to or following Regulatory Approval thereof), except, in each case, to the extent such Losses result from any matter with respect to which the other Party is obligated to indemnify the Indemnitor pursuant to this Section 12.1(a).

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- (b) **Indemnification Procedure.** In the event that an Indemnitee is seeking indemnification under this Section 12.1, it shall inform the Indemnitor in writing of the relevant claim as soon as reasonably practicable after it receives notice of the Claim, shall permit the Indemnitor to assume direction and control of the defense of the Claim, including the right to select defense counsel, which counsel shall be reasonably satisfactory to the Indemnitee, and shall cooperate as reasonably requested by the Indemnitor (at the expense of the Indemnitor) in the defense of the Claim. The failure or delay to so notify the Indemnitor shall not relieve the Indemnitor of any obligation or liability that it may have to the Indemnitee except to the extent that the Indemnitor demonstrates that its ability to defend or resolve such Claim is adversely affected thereby. In no event may the Indemnitor compromise or settle any Claim in any manner that admits fault or wrongdoing on the part of any Indemnitee, incurs non-indemnified liability on the part of any Indemnitee, adversely affects any of the intellectual property rights subject to this Agreement or otherwise adversely affects either Party's ability to Develop or Commercialize Licensed Products hereunder, without the prior written consent of the Indemnitor with respect thereto.
- 12.2. Limitation of Liability. EXCEPT IN CIRCUMSTANCES OF NEGLIGENCE, FRAUD, WILLFUL MISCONDUCT, PATENT INFRINGEMENT BY A PARTY OR ITS AFFILIATES, OR BREACH OF ARTICLE 9 BY A PARTY OR ITS AFFILIATES OR WITH RESPECT TO THE INDEMNIFICATION PROVIDED UNDER SECTION 12.1, IN NO EVENT SHALL EITHER PARTY, OR ITS AFFILIATES, DIRECTORS, OFFICERS, EMPLOYEES OR AGENTS, BE LIABLE TO THE OTHER PARTY FOR ANY PUNITIVE, EXEMPLARY, MULTIPLIED, INDIRECT, CONSEQUENTIAL OR LOST PROFITS/REVENUES DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT. For clarification, the foregoing sentence shall not be interpreted to limit or to expand the express rights specifically granted in this Agreement.
- 12.3. Insurance. The JSC shall determine the appropriate amount of clinical trial insurance required in connection with conducting Clinical Studies performed under this Agreement and each Party shall procure such insurance for the clinical trials it sponsors in amounts suggested by the JSC and in compliance with local regulations. Such insurance shall cover bodily harm or personal injury resulting from any such Clinical Study. The premiums with respect to any such clinical trial insurance shall be a Development Cost. In addition, Minerva shall maintain in full force and effect during the Term of this Agreement, and for a period of not less than [*] years after the time the products are no longer commercialized, commercial general liability insurance and other appropriate insurance (including product liability insurance when and if Minerva or its Affiliates commercialize a pharmaceutical product) in amounts that are customary in the pharmaceutical business taking into consideration all relevant factors; however, in no event shall such product liability insurance be in amounts less than [*] per occurrence and annual aggregate. Such insurance shall include worldwide coverage where appropriate. Minerva shall furnish to Janssen certificates evidencing the insurance coverage within [*] Business Days of Janssen's written request. Each of the certificates shall provide that the coverage will not be

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canceled or materially reduced until at least [*] days after written notice has been given to Janssen.

ARTICLE 13

DISPUTE RESOLUTION

- 13.1. 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 (each, a "Dispute"). It is the objective of the Parties to establish procedures to facilitate the resolution of Disputes in an expedient manner by mutual cooperation and good faith negotiation and without resort to litigation. To accomplish this objective, the Parties agree to follow the procedures set forth in this Article 13 if and when a Dispute arises under this Agreement, except as otherwise provided with respect to certain Committee Deadlocks under Section 3.3(c). If after negotiating in good faith pursuant to the foregoing sentence, the Parties fail to enter into a written agreement resolving the Dispute within [*] days, then the CEO of Minerva and the Therapeutic Head for Neuroscience at Janssen (or another appropriate executive of Janssen) and their respective legal counsel shall discuss in good faith an appropriate resolution to the Dispute. If these executives fail, after good-faith discussions undertaken within reasonable promptness, to reach an amicable agreement within [*] days, then either Party may upon notice to the other submit the Dispute to mediation and binding arbitration for final resolution pursuant to Sections 13.3 and 13.4 below. No statements made by either Party during such discussions will be used by the other Party or be admissible in arbitration or any other subsequent proceeding for resolving the Dispute.
- **13.2. Governing Law; Service of Process.** This Agreement shall be governed by and construed under the substantive laws of the State of New York, without regard to conflicts of law or choice of law rules that would provide for application of the law of a jurisdiction outside New York. The Parties agree that service of process upon them in any legal action may be made if delivered in person, by courier service, by telegram, by facsimile or by first class mail, and shall be deemed effectively given upon receipt.

13.3. Mediation.

- (a) The Parties shall first attempt in good faith to resolve any Dispute by confidential mediation in accordance with the then current Mediation Procedure of the International Institute for Conflict Prevention and Resolution (the "CPR Mediation Procedure") (www.cpradr.org) before initiating arbitration. The CPR Mediation Procedure shall control, except where it conflicts with these provisions, in which case these provisions control. The mediator shall be chosen pursuant to CPR Mediation Procedure. The mediation shall be held in New York, New York.
- (b) Subject to Section 13.1, either Party may initiate mediation by written notice to the other Party of the existence of a Dispute. The Parties agree to select a mediator within [*] days of the notice and the mediation will begin promptly after the selection. The mediation will continue until the mediator, or either Party, declares in writing, no sooner than after the conclusion of [*] full day of a substantive mediation conference attended on behalf of each

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Party by a senior business person with authority to resolve the Dispute, that the Dispute cannot be resolved by mediation. In no event, however, shall mediation continue more than [*] days from the initial notice by a Party to initiate mediation unless the Parties agree in writing to extend that period.

(c) Any period of limitations that would otherwise expire between the initiation of mediation and its conclusion shall be extended until [*] days after the conclusion of the mediation.

13.4. Arbitration.

- (a) If the Parties fail to resolve the Dispute in mediation, and a Party desires to pursue resolution of the Dispute, the Dispute shall be submitted by either Party for resolution in arbitration pursuant to the then current CPR Non-Administered Arbitration Rules (the "CPR Rules") (www.cpradr.org), except where they conflict with these provisions, in which case these provisions control. The arbitration will be held in New York, New York. All aspects of the arbitration shall be treated as confidential.
- (b) The arbitrators will be chosen from the CPR Panel of Distinguished Neutrals, unless a candidate not on such panel is approved by both Parties. Each arbitrator shall be a lawyer with at least fifteen (15) years experience with a law firm or corporate law department of over twenty-five (25) lawyers or who was a judge of a court of general jurisdiction. To the extent that the Dispute requires special expertise, the Parties will so inform CPR prior to the beginning of the selection process.
- (c) The arbitration tribunal shall consist of three (3) arbitrators, of whom each Party shall designate one (1) in accordance with the "screened" appointment procedure provided in CPR Rule 5.4. The chair will be chosen in accordance with CPR Rule 6.4.
- (d) If, however, the aggregate award sought by the Parties is less than [*] and equitable relief is not sought, a single arbitrator shall be chosen in accordance with the CPR Rules.
- (e) Candidates for the arbitrator position(s) may be interviewed by representatives of the Parties in advance of their selection, provided that all Parties are represented.
- (f) The Parties agree to select the arbitrator(s) within [*] days of initiation of the arbitration. The hearing will be concluded within [*] months after selection of the arbitrator(s) and the award will be rendered within [*] days of the conclusion of the hearing, or of any post hearing briefing, which briefing will be completed by both Parties within [*] days after the conclusion of the hearing. In the event the Parties cannot agree upon a schedule, then the arbitrator(s) shall set the schedule following the time limits set forth above as closely as practical.
- (g) The hearing will be concluded in [*] hearing days or less. Multiple hearing days will be scheduled consecutively to the greatest extent possible. A transcript of the testimony adduced at the hearing shall be made and shall be made available to each Party.

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- (h) The arbitrator(s) shall be guided, but not bound, by the CPR Protocol on Disclosure of Documents and Presentation of Witnesses in Commercial Arbitration (www.cpradr.org) (the "**Protocol**"). The Parties will attempt to agree on modes of document disclosure, electronic discovery, witness presentation, and the like within the parameters of the Protocol. If the Parties cannot agree on discovery and presentation issues, the arbitrator(s) shall decide on presentation modes and provide for discovery within the Protocol, understanding that the Parties contemplate reasonable discovery.
- (i) The arbitrator(s) shall decide the merits of any Dispute in accordance with the law governing this Agreement, without application of any principle of conflict of laws that would result in reference to a different law. The arbitrator(s) may not apply principles such as "amiable compositeur" or "natural justice and equity."
- (j) The arbitrator(s) are expressly empowered to decide dispositive motions in advance of any hearing and shall endeavor to decide such motions as would a United States District Court Judge sitting in the jurisdiction whose substantive law governs.
- (k) The arbitrator(s) shall render a written opinion stating the reasons upon which the award is based. The Parties consent to the jurisdiction of the United States District Court for the district in which the arbitration is held for the enforcement of these provisions and the entry of judgment on any award rendered hereunder. Should such court for any reason lack jurisdiction, any court with jurisdiction may act in the same fashion.

- (l) Each Party has the right to seek from the appropriate court provisional remedies, such as attachment, preliminary injunction or replevin, to avoid irreparable harm, maintain the status quo, or preserve the subject matter of the Dispute. Rule 14 of the CPR Rules does not apply to this Agreement.
- (m) EACH PARTY HERETO WAIVES ITS RIGHT TO TRIAL OF ANY ISSUE BY JURY AND ANY CLAIM FOR ATTORNEY FEES, COSTS AND PREJUDGMENT INTEREST.
- **13.5. Tolling of Time Periods.** In the event that a controversy or claim has been raised and is in the process of dispute resolution in accordance with Sections 13.1, 13.3 or 13.4, any applicable time period governing the underlying controversy or claim shall be tolled pending the outcome of the resolution process after which the time period shall again begin to run.

ARTICLE 14

MISCELLANEOUS

14.1. Entire Agreement; Amendment. This Agreement, along with the Exhibits hereto and the Development Supply Agreement and the Commercial Supply Agreement, sets forth the complete and final agreement, and all covenants, promises, agreements, warranties, representations, conditions and understandings, between the Parties regarding the subject matter hereof and supersedes and terminates all prior agreements and understandings between the Parties regarding such subject matter. There are no covenants, promises, agreements, warranties,

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representations, conditions or understandings, either oral or written, between the Parties other than as are set forth herein and therein. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties unless reduced to writing and signed by an authorized officer of each Party.

- 14.2. Bankruptcy. All rights and licenses granted under or pursuant to any section of this Agreement are, and shall otherwise be deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of rights to "intellectual property" as defined under Section 101(35A) of the U.S. Bankruptcy Code. The Parties shall retain and may fully exercise all of their respective rights and elections under the U.S. Bankruptcy Code. The Parties agree that a Party that is a licensee of such rights under this Agreement shall retain and may fully exercise all of its rights and elections under the U.S. Bankruptcy Code, and that upon commencement of a bankruptcy proceeding by or against the licensing Party (such Party, the "Involved Party") under the U.S. Bankruptcy Code, the other Party (such Party, the "Noninvolved Party") shall be entitled to a complete duplicate of or complete access to (as such Noninvolved Party deems appropriate) any such intellectual property and all embodiments of such intellectual property, provided the Noninvolved Party continues to fulfill its payment or royalty obligations as specified herein in full. Such intellectual property and all embodiments thereof shall be promptly delivered to the Noninvolved Party (a) upon any such commencement of a bankruptcy proceeding upon written request therefor by the Noninvolved Party, unless the Involved Party elects to continue to perform all of its obligations under this Agreement, or (b) if not delivered under clause (a) above, following the rejection of this Agreement by or on behalf of the Involved Party upon written request therefor by the Noninvolved Party. The foregoing is without prejudice to any rights the Noninvolved Party may have arising under the U.S. Bankruptcy Code or other Applicable Laws.
- 14.3. Force Majeure. Both Parties shall be excused from the performance of their obligations under this Agreement to the extent that such performance is prevented by force majeure and the nonperforming Party promptly provides notice of the prevention to the other Party (which notice shall specify the nature and extent of the force majeure event, its anticipated duration and any action being taken to avoid or minimize its effect). Such excuse shall be continued so long as the condition constituting force majeure continues and the nonperforming Party takes reasonable efforts to remove the condition. For purposes of this Agreement, "force majeure" shall mean conditions beyond the reasonable control of the Parties, including an act of God, government or regulatory acts or restrictions, change in any standard of medical care, war, acts of terrorism, civil commotion, labor strike or lock-out, epidemic, failure or default of public utilities or common carriers, destruction of facilities or materials by fire, earthquake, flood, storm or like catastrophe; provided, however, the payment of invoices due and owing hereunder shall not be delayed by the Payor because of a force majeure affecting the Payor.
- **14.4. Notices.** Any notice required or permitted to be given under this Agreement shall be in writing, shall specifically refer to this Agreement and shall be deemed to have been sufficiently given for all purposes if transmitted by facsimile transmission (with transmission confirmed), mailed by first class certified or registered mail, postage prepaid (which shall be deemed received by the other Party on the fifth (5th) Business Day following deposit in the mail), sent by express delivery service with tracking (e.g., FedEx) (which shall be deemed

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received by the other Party upon delivery) or personally delivered. Unless otherwise specified in writing, the mailing addresses of the Parties shall be as follows.

For Janssen: Janssen Pharmaceutica, N.V.

Turnhoutseweg 30, 2340

Beerse, Belgium

Fax: [*]

Attention: Chairman and Managing Director

With a copy to: Johnson & Johnson

1 Johnson & Johnson Plaza

New Brunswick, NJ 08933

Telephone: [*]
Fax: [*]

Attention: Philip Johnson, Esq., Chief Intellectual Property Counsel

With a copy to: Janssen Pharmaceutica, N.V. (for royalty reporting) Turnhoutseweg 30, 2340

Beerse, Belgium

Fax: [*]

Attention: Royalty Group

For Minerva: Minerva Neurosciences, Inc.

245 First Street

Cambridge, Massachusetts

Attention: Chief Executive Officer

With a copy to: Morgan, Lewis & Bockius

502 Carnegie Center Princeton, NJ 08540-6241

Fax: [*]

Attention: Denis Segota, Esq.

- 14.5. United States Dollars. References in this Agreement to "Dollars" or "\$" shall mean the legal tender of the United States of America.
- 14.6. No Strict Construction. This Agreement has been prepared jointly and shall not be strictly construed against either Party.
- **14.7. Assignment.** Except as expressly provided herein, and without limitation of the Parties' right to license or sublicense their rights to Licensed Products to Third Parties, as expressly provided in this Agreement, neither Party may assign or transfer (collectively "assign") this Agreement, or any rights or obligations under this Agreement, without the prior written consent of the other, which consent may be withheld in the consenting Party's discretion; provided, however, that a Party may make such an assignment without the other Party's consent (a) to an Affiliate, provided that such Affiliate agrees in writing to be bound by the terms and conditions of this Agreement and that the assigning Party remains liable for the full and complete

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performance of its obligations arising hereunder prior to such assignment; or (b) to its successor in conjunction with a Change of Control of such Party, provided that such assignee agrees in writing to be bound by the terms and conditions of this Agreement. This Agreement shall be binding upon the successors and permitted assigns of the Parties. Any assignment or attempted assignment by either Party in violation of the terms of this Section 14.7 shall be null and void and of no legal effect.

- **14.8. Counterparts.** This Agreement may be executed in two or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile signatures, including signatures in a fixed electronic format such as PDF, shall have the same effect as originals.
- **14.9. Further Actions.** Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other reasonable acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- **14.10. Severability.** If any one or more of the provisions of this Agreement is held to be invalid or unenforceable by any court of competent jurisdiction from which no appeal can be or is taken, the provision shall be considered severed from this Agreement and shall not serve to invalidate any remaining provisions hereof. The Parties shall make a good faith effort to replace any invalid or unenforceable provision with a valid and enforceable provision such that the objectives contemplated by the Parties when entering this Agreement may be realized.
- **14.11. Ambiguities.** Ambiguities, if any, in this Agreement shall not be construed against any Party, irrespective of which Party may be deemed to have authored the ambiguous provision.
- **14.12. Headings.** The headings for each Article and Section in this Agreement have been inserted for convenience of reference only and are not intended to limit or expand on the meaning of the language contained in the particular article or section.
- **14.13. No Waiver.** Any delay in enforcing a Party's rights under this Agreement or any waiver as to a particular default or other matter shall not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, excepting only as to an express written and signed waiver as to a particular matter for a particular period of time. 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.
- **14.14. Relationship of the Parties.** Nothing herein shall be construed to create any relationship of employer and employee, agent and principal, partnership or joint venture or any other legal entity, between the Parties or to constitute one Party as the agent of the other. Each Party is an independent contractor. Neither Party shall assume, either directly or indirectly, any liability of or for the other Party. Neither Party shall have the authority to bind or obligate the other Party and neither Party shall represent that it has such authority.

- **14.15. No Use of Name.** Except as set forth in Article 9 hereof, neither Party shall use in writing the name of the other Party without the other Party's prior written consent, unless such writing simply refers to the existence of this Agreement or other information concerning this Agreement that has been previously publicly disclosed in a manner permitted under this Agreement.
- **14.16. No Implied Licenses.** Except as expressly and specifically provided under this Agreement, the Parties agree that neither Party is granted any implied rights to or under any of the other Party's current or future patents, trade secrets, copyrights, moral rights, trademarks, service marks, trade dress, or other intellectual property rights.
- 14.17. Interpretation. Unless specified to the contrary, references to Articles, Sections or Exhibits mean the particular Articles, Sections or Exhibits to this Agreement and references to this Agreement include all Exhibits hereto. Unless the context otherwise clearly requires, whenever used in this Agreement: (a) the words "include", "includes" or "including" shall be construed as incorporating, also, "but not limited to" or "without limitation;" (b) the word "notice" means notice in writing (whether or not specifically stated) and shall include notices, consents, approvals and other written communications contemplated under this Agreement; (c) the words "hereof," "herein," "hereby" and derivative or similar words refer to this Agreement (including any Exhibits); (d) the word "or" shall be construed as the inclusive meaning identified with the phrase "and/or;" (e) provisions that require that a Party, the Parties or any Committee hereunder "agree," "consent" or "approve" or the like shall require that such agreement, consent or approval be specific and in writing, whether by written agreement, letter, approved minutes or otherwise; (f) words of any gender include the other gender; (g) words using the singular or plural number also include the plural or singular number, respectively; (h) references to any specific law or article, section or other division thereof shall be deemed to include the then-current amendments thereto or any replacement law thereof; (i) the word "will" shall be construed to have the same meaning and effect as the word "shall"; and (j) the word "any" means "any and all".

(*The remainder of this page is intentionally left blank. The signature page follows.*)

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IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the Execution Date.

MINERVA NEUROSCIENCES, INC.

JANSSEN PHARMACEUTICA, N.V.

Campus Business Services

By: /s/ Rogerio Vivaldi Coelho By: /s/ Tom Heyman Name: Rogerio Vivaldi Coelho, MD, MBA Name: Tom Heyman Title: Co-Founder, President, CEO Title: Managing Director Chairman Board of Directors /s/ Hilde Claes By: Name: Hilde Claes Title: VP Personeelsaangelegenheder

[Signature Page to Co-Development and License Agreement]

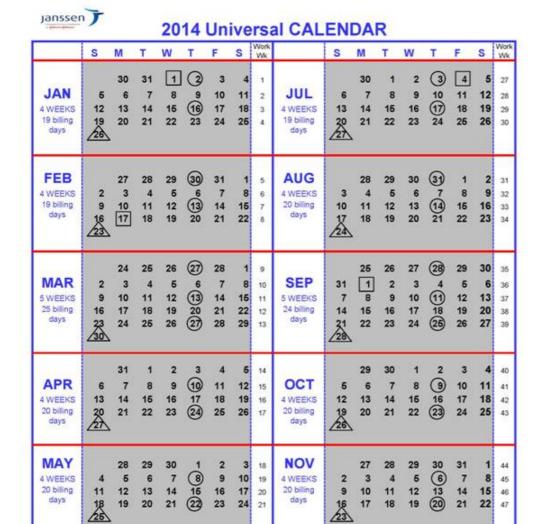
A request for confidential treatment has been made with respect to portions of the following document that are marked with [*]. The redacted portions have been filed separately with the SEC.

EXHIBIT A

Johnson & Johnson Universal Calendar

A-1

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*NOTE: Payroll work week numbers refer to Monday thru Saturday of the line shown plus the Sunday of the next line. The calendar reflects the accounting closes, paydays and holidays. There are 9 Company Holidays plus three (3) personal choice holidays for each employee in 2014. There are 52 weeks and 251 billing days in 2014.

22

23

24

21 25

☐ HOLIDAY ☐ PAY PERIOD ☐ MONTHLY ACCOUNTING CLOSE

DEC

5 WEEKS

21 billing

days

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EXHIBIT B

2

27 28 29

3 (4)

(18)

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17

5 6

12

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25 26

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22 23 24 26 26 27 52

30

7 8

14

Provisional Development Plan and budget for Orexin-2 Antagonist [*]

Provisional Development Plan

JUN

5 WEEKS

24 billing

days

26

2 3

23 24 25 26 27 28 26

8

15 16 17 18

27 28 29 30 31

10

(6)

12 13

(19)

6

20

4

Estimated Timeframe: [*]

- 1) [*]
- 2) [*]
- 3) [*]
- 4) [*]
- 5) [*]

It is expected that the results of item 4 along with any available data from items 1-3 and 5 would be presented to the [*] and form the basis for the first decision point (Decision Point 1). With a positive decision by the [*], additional activities are planned to be undertaken.

Estimated Timeframe: [*]

7) [*] 8) [*] 9) [*] 10) [*]

It is expected that the results of items 9 and 8 along with any available data from items 6, 7 and 10 would be presented to the [*] and form the basis for the second decision point (Decision Point 2). With a positive decision by the [*] to continue, additional activities would be expected to be undertaken.

Estimated Timeframe: [*] 11) [*]

It is expected that the results of interim analysis from item 11 would be presented to the [*] and form the basis for the third decision point (Decision Point 3). With a positive decision by the [*] to continue, additional activities would be expected to be undertaken.

Estimated Timeframe: [*]

12) [*]

It is expected that the results of item 12 would be presented to the [*] and form the basis for the fourth decision point (Decision Point 4).

B-1

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Provisional Budget

Budget Estimates

Total Cost to Launch by Phase

in USD Millions	Adjunctive MDD	Primary Insomnia	Total	Notes
Phase 1A	[*]	[*]	[*]	2
Phase 1B	[*]	[*]	[*]	2
Phase 2A	[*]	[*]	[*]	4
Phase 2B	[*]	[*]	[*]	4
Phase 3	[*]	[*]	[*]	5
Registration	[*]	[*]	[*]	6
Total Cost to Launch	[*]	[*]	[*]	

2013-2016 Cost by Decision Point

in USD Millions	2013	2014	2015	2016	Total	Notes
Decision Point 1	[*]	[*]	_	_	[*]	1
Decision Point 2	_	[*]	[*]	_	[*]	2
Decision Point 3				[*]	[*]	3
Total	[*]	[*]	[*]	[*]	[*]	

Notes to Budget Estimates:

- 1) [*]
- 2) [*]
- 3) [*]
- 4) [*]
- 5) [*]
- 6) [*]

Provisional Gantt Chart

[*]

2

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EXHIBIT C

Janssen Patents

Country [W]	Title	Filing Number	Filing Date
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]

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		C-2	

EXHIBIT D

Compliance

- 1.1 Minerva acknowledges that Janssen aims to perform its activities, and to have parties such as Minerva who enter into business arrangements with Janssen perform their activities under such arrangements, in accordance with the highest ethical standards and best industry practices, including without limitation any voluntary codes of practice applicable in the industry for the research. Minerva agrees to use commercially reasonable efforts to help ensure that Janssen does not fail to meet such aim with respect to activities hereunder through any violation of the FCPA.
- 1.2 Minerva shall comply with all laws and regulations concerning its efforts in any country or jurisdiction where it is providing work hereunder or otherwise applying to any of its activities under this Agreement. Minerva shall use reasonable efforts to ensure that its personnel performing under this Agreement become reasonably familiar with the U.S. Foreign Corrupt Practices Act (the "FCPA"), its prohibitions and purposes, and that they will not undertake any actions in connection with the Agreement and the business resulting therefrom that would violate the FCPA. Accordingly, Minerva hereby certifies that:
 - (i) no person employed by it is an official or employee of any government or any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government);
 - (ii) no payment or offer to pay, or the giving or offering to give, anything of value to an official or employee of any department, agency or instrumentality thereof (including, but not limited to, any health or medical providers owned or controlled by the government), or to any political party or any candidate for political office, shall be made with the purpose of influencing any decisions favorable to Janssen and its Affiliates in connection with this Agreement and the business resulting therefrom in contravention of the FCPA or the laws of the country in which it is providing work;
 - (iii) it has not paid, nor offered or agreed to pay, nor caused to be paid, directly or indirectly, any political contributions, fees or commissions to any governmental employee or representative (including, but not limited to, any employee of any health or medical provider owned or controlled by the government) in connection with this Agreement and the business resulting therefrom that would appear to cause a violation of the FCPA;
 - (iv) it will not, directly or indirectly, in connection with the Agreement and the business resulting therefrom, offer, pay, promise to pay, or authorize the

D-1

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giving of money or anything of value to any governmental official or representative, to any political party or official thereof, or to any candidate for political office, or to any person, while knowing or having received an indication or evidence that all or any portion of such money or thing of value will be offered, given, or promised, directly or indirectly, to any government official, to any political party or official thereof, or to any candidate to political office, for the purpose of:

a. influencing any act or decisions of such official, political party, party official, or candidate in its official capacity, including a decision to fail to perform official functions in connection with this Agreement and the business resulting therefrom; or

b. inducing such official, political party, party official, or candidate to use influence with the government or instrumentality thereof to affect or influence any act or decision of such government or instrumentality, in order to assist Janssen or Minerva in obtaining or retaining business for or with, or directing business to, any Affiliate or Third Party.

Minerva further agrees that if subsequent developments cause the certifications and information reported herein to be no longer accurate or complete, Minerva will promptly so advise Janssen in writing.

- 1.3 In the event of a claim or investigation, or an official request for Janssen to cooperate with respect to any such claim or investigation, by a Regulatory Authority, government agency, or other legal authority having jurisdiction over either Party, of an alleged violation of the FCPA arising from any activities conducted by Minerva relating to this Agreement or any Licensed Products, Minerva shall provide Janssen and its agents and representatives (collectively, "Agents"), as well as any such Regulatory Authority or government agency, or other legal authority having jurisdiction over Janssen, with access to Minerva's facilities, records (financial and otherwise), and supporting documentation, as reasonably requested by Janssen or Janssen's Agents in order to cooperate in connection with such claim or investigation. Minerva acknowledges that the provisions of this EXHIBIT D granting Janssen certain audit rights shall in no way relieve Minerva of any of its obligations under the Agreement, nor shall such provisions require Janssen to conduct any such audits.
- During the Term, Minerva shall maintain true and accurate records: (i) documenting its efforts made pursuant to Paragraph 1.1 of this EXHIBIT D; (ii) of payments made to any officials or employees of any government or any department, agency or instrumentality thereof; and (iii) of political contributions.
- 1.5 Minerva acknowledges and agrees that any breach of its obligations under Section 10.5(e) will constitute a material breach of the Agreement.

D-2

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1.6 Notwithstanding anything to the contrary in the Agreement, Janssen may disclose its terms and conditions (including any financial terms) to any party that Janssen determines in good faith has a legitimate need for access to such information for purposes of investigating or determining either Party's compliance with Applicable Laws (including, but not limited to, any governmental authorities in the U.S. or those in the country where research is being provided).

D-3

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EXHIBIT E

Minerva Patents

None

E-1