

CEMPRA, INC.

FORM 10-K/A (Amended Annual Report)

Filed 06/17/16 for the Period Ending 12/31/15

Address	6320 QUADRANGLE DRIVE SUITE 360 CHAPEL HILL, NC 27517-8149
Telephone	919-576-2306
CIK	0001461993
Symbol	CEMP
SIC Code	2834 - Pharmaceutical Preparations
Industry	Major Drugs
Sector	Healthcare
Fiscal Year	12/31

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549**

**FORM 10-K/A
(Amendment No. 1)**

ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2015

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the Transition Period from _____ to _____

Commission File Number: 001-35405

CEMPRA, INC.

(Exact name of registrant specified in its charter)

Delaware
(State or Other Jurisdiction of
Incorporation or Organization)

2834
(Primary Standard Industrial
Classification Code Number)

45-4440364
(I.R.S. Employer
Identification No.)

**6320 Quadrangle Drive, Suite 360
Chapel Hill, NC 27517**
(Address of Principal Executive Offices)

(919) 313-6601
(Telephone Number, Including Area Code)

Securities Registered Pursuant to Section 12(b) of the Exchange Act:

Title of Each Class
Common Stock, \$0.001 Par Value

Name of Exchange on which Registered
Nasdaq Global Market

Securities Registered Pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Exchange Act. Yes No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes No

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes No

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

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

Large accelerated filer

Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company)

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes No

The aggregate market value of the voting stock held by non-affiliates of the registrant, as of June 30, 2015, was approximately \$1.2 billion. Such aggregate market value was computed by reference to the closing price of the common stock as reported on the Nasdaq Global Market on June 30, 2015. For purposes of making this calculation only, the registrant has defined affiliates as including only directors and executive officers and shareholders holding greater than 10% of the voting stock of the registrant as of June 30, 2015.

As of February 18, 2016 there were 48,169,733 shares of the registrant's common stock, \$0.001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the registrant's definitive Proxy Statement for its 2016 Annual Meeting of Stockholders are incorporated herein by reference, as indicated in Part III.

EXPLANATORY NOTE

Cempra, Inc. is filing this Amendment No. 1 (the "Amendment") to our Annual Report on Form 10-K for the fiscal year ended December 31, 2015, as originally filed with the Securities and Exchange Commission ("SEC") on February 25, 2016 (the "Original Form 10-K"), to (i) amend Item 5(a) of Part II to provide the high and low sales prices for our common stock for each quarter of 2014 and 2015 and (ii) amend Item 15(b) of Part IV to re-file two agreements that were filed as exhibits to the Original Form 10-K to reflect the inclusion of information that we had previously requested be treated confidentially. In addition, Item 15(b) of Part IV is being amended solely to file as exhibits certain new certifications in accordance with Rule 13a-14(a) promulgated by the SEC under the Securities Exchange Act of 1934.

Except as described above, no other changes have been made to the Original Form 10-K. This Amendment No. 1 continues to speak as of the date of the Original Form 10-K and we have not updated the disclosure herein to reflect any events that occurred at a later date other than as expressly stated herein. Accordingly, this Amendment No. 1 should be read in conjunction with the Original Form 10-K and with our filings made with the SEC subsequent to the filing of the Original Form 10-K.

PART II

Item 5. Market for Registrant’s Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

Our common stock is traded under the symbol “CEMP” and is quoted on the NASDAQ Global Market. The following table sets forth the high and low sale prices of our common stock, as reported on the NASDAQ Global Market in each quarter of 2015 and 2014.

	<u>High</u>	<u>Low</u>
2015		
Fourth quarter	\$ 34.79	\$ 15.43
Third quarter	\$ 46.99	\$ 24.00
Second quarter	\$ 39.68	\$ 31.15
First quarter	\$ 41.63	\$ 21.52
2014		
Fourth quarter	\$ 24.71	\$ 10.86
Third quarter	\$ 11.60	\$ 8.55
Second quarter	\$ 12.00	\$ 8.10
First quarter	\$ 15.39	\$ 10.60

PART IV

Item 15. Exhibits, Financial Statement Schedules

(3) Exhibits. The following exhibits are included herein or incorporated herein by reference:

<u>Exhibit No.</u>	<u>Description</u>	<u>Registrant's Form</u>	<u>Dated</u>	<u>Exhibit Number</u>	<u>Filed Herewith</u>
2.1	Form of Plan of Conversion of Cempra Holdings, LLC.	S-1	10/12/2011	2.1	
3.1	Certificate of Incorporation of Cempra, Inc.	S-1/A	1/13/2012	3.1	
3.2	Form of Bylaws of Cempra, Inc.	S-1	10/12/2011	3.2	
4.1	Specimen of Common Stock Certificate of Cempra, Inc.	S-1/A	11/22/2011	4.1	
4.2	Form of Registration Rights Agreement by and among Cempra, Inc. and certain of its stockholders, to be effective upon the corporate conversion.	S-1	10/12/2011	4.2	
10.1	Forms of Indemnification Agreements by and between Cempra, Inc. and its directors.	S-1	10/12/2011	10.1	
10.2	Cempra, Inc. Sixth Amended and Restated 2006 Stock Plan.	S-1/A	1/13/2012	10.2	
10.3	Cempra, Inc. 2011 Equity Incentive Plan and Form of Stock Option Agreement thereunder.	S-1/A	1/13/2012	10.3	
10.4*	Collaborative Research and Development and License Agreement dated March 31, 2006, by and between Cempra Pharmaceuticals, Inc. and Optimer Pharmaceuticals, Inc.	S-1	10/12/2011	10.4	
10.5*	Supply Agreement effective March 15, 2011, by and among CEM-102 Pharmaceuticals, Inc., Ercros S.A. and Gyma Laboratories of America, Inc.	S-1	10/12/2011	10.5	
10.6	Office Lease Agreement dated November 9, 2011 between Cempra Pharmaceuticals, Inc. and Property Reserve, Inc.	S-1/A	11/22/2011	10.6	
10.7	Loan and Security Agreement dated December 20, 2011 between Cempra Holdings, LLC and Hercules Technology Growth Capital, Inc.	S-1/A	12/22/2011	10.7	
10.8	Secured Promissory Note dated December 20, 2011, issued by Cempra Holdings, LLC to Hercules Technology Growth Capital, Inc.	S-1/A	12/22/2011	10.8	
10.9*	License Agreement, effective June 12, 2012, between The Scripps Research Institute and Cempra Pharmaceuticals, Inc.	10-Q	8/08/2012	10.9	
10.10	2011 Equity Incentive Plan, as amended May 23, 2013.	10-Q	7/31/2013	10.3	
10.11*	Exclusive License and Development Agreement by and between Cempra Pharmaceuticals, Inc. and Toyama Chemical Co., Ltd., dated May 8, 2013.	10-Q	7/31/2013	10.13	
10.12*	Supply Agreement by and between Cempra Pharmaceuticals, Inc. and Toyama Chemical Co., Ltd., dated May 8, 2013.	10-Q	7/31/2013	10.14	
10.13*	Contract by and between Cempra, Inc. and the Biomedical Advanced Research and Development Authority, dated May 24, 2013.	10-Q	7/31/2013	10.15	
10.14*	Development and Supply Agreement by and between Cempra Pharmaceuticals, Inc. and Hospira Worldwide, Inc. effective as of July 1, 2013.	10-Q/A	11/08/2013	10.18	

10.15	Amendment No. 1, effective as of September 26, 2013 to Exclusive License And Development Agreement by and between Cempra Pharmaceuticals, Inc. and Toyama Chemical Co., Ltd, dated May 8, 2013.	10-Q	10/29/2013	10.19
10.16	Amendment No. 2 to Loan and Security Agreement, dated May 31, 2013, by and among Cempra, Inc., and each of its subsidiaries signatory thereto, and Hercules Capital Funding Trust 2012-1, as a lender and Hercules Technology Growth Capital, Inc., as a lender and as an agent for the lenders.	8-K	6/06/2013	10.12
10.17	Form of Employment Agreement by and between Cempra, Inc. and Prabhavathi B. Fernandes, Ph.D.	8-K	8/13/2013	10.16
10.18	Form of Change in Control Severance Agreement by and between Cempra, Inc. and Prabhavathi B. Fernandes, Ph.D.	8-K	8/13/2013	10.17
10.19	First Amendment, dated May 17, 2013, to Office Lease Agreement dated November 9, 2011 between Cempra Pharmaceuticals, Inc., and Property Reserve, Inc.	10-K	2/28/2014	10.21
10.20	Second Amendment, dated August 13, 2013, to Office Lease Agreement dated November 9, 2011 between Cempra Pharmaceuticals, Inc., and Property Reserve, Inc.	10-K	2/28/2014	10.22
10.21	Amendment No. 3 to Loan and Security Agreement, dated March 27, 2014, by and among Cempra, Inc., and each of its subsidiaries signatory thereto, and Hercules Capital Funding Trust 2012-1, as a lender and Hercules Technology Growth Capital, Inc., as a lender and as an agent for the lenders.	8-K	10/17/2014	10.23
10.22	Third Amendment, dated March 31, 2014, to Office Lease Agreement dated November 9, 2011 between Cempra, Inc. and Property Reserve, Inc.	10-Q	4/29/2014	10.24
10.23	Change in Control Severance Agreement, dated May 23, 2014, by and between Cempra, Inc. and Mark W. Hahn.	8-K	5/29/2014	10.25
10.24	Amendment No. 4 to Loan and Security Agreement, dated June 30, 2014, by and among Cempra, Inc., and each of its subsidiaries signatory thereto, and Hercules Capital Funding Trust 2012-1, as a lender and Hercules Technology Growth Capital, Inc., as a lender and as an agent for the lenders.	10-Q	7/29/2014	10.25
10.25	Amendment, dated November 13, 2014, to Contract by and between Cempra Pharmaceuticals, Inc. and the Biomedical Advanced Research and Development Agency, dated May 24, 2013.	10-K	2/29/2015	10.27
10.26	Change in Control Severance Agreement, dated May 23, 2014, by and between Cempra, Inc. and David Moore	10-Q	4/30/2015	10.1
10.27	Loan and Security Agreement, dated as of July 10, 2015, by and among Comerica Bank and Cempra, Inc., Cempra Pharmaceuticals, Inc. and CEM-102 Pharmaceuticals, Inc.	8-K	7/16/2015	10.1
10.28	Form of Change in Control Severance Agreement by and between Cempra, Inc. and David W. Oldach, M.D.	8-K	10/19/2015	10.1
10.29	Amendment to Form of Employment Agreement by and between Cempra, Inc. and Prabhavathi B. Fernandes, Ph.D.	8-K	10/19/2015	10.2

10.30	Amendment to Form of Change in Control Severance Agreement by and between Cempra, Inc. and Prabhavathi Fernandes, Ph.D.	8-K	10/19/2015	10.3	
10.31	Amendment to Form of Change in Control Severance Agreement by and between Cempra, Inc. and Mark W. Hahn	8-K	10/19/2015	10.4	
10.32	Amendment to Form of Change in Control Severance Agreement by and between Cempra, Inc. and David Moore	8-K	10/19/2015	10.5	
10.34**	Option and License Agreement, dated January 29, 2016, between Cempra Pharmaceuticals, Inc. and Macrolide Pharmaceuticals, Inc.				X
10.35**	API Manufacturing and Supply Agreement, entered into January 18, 2016, by and between Cempra, Inc. and FUJIFILM Finechemicals Co., Ltd.				X
21.1	List of subsidiaries of Cempra Holdings, LLC.	S-1	10/12/2011	21.1	
23.1	Consent of Independent Registered Public Accounting Firm	10-K	2/25/2016	23.1	
31.1	Certification of the Chief Executive Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
31.2	Certification of the Chief Financial Officer Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.				X
32.1	Certification of the Chief Executive Officer Pursuant to 18 U.S. C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	10-K	2/25/2016	32.1	
32.2	Certification of the Chief Financial Officer Pursuant to 18 U.S. C. Section 1350 as Adopted Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.	10-K	2/25/2016	32.2	
101	Financials in XBRL format.	10-K	2/25/2016	101	

* The Registrant has received confidential treatment with respect to portions of this exhibit. Those portions have been omitted and filed separately with the Securities and Exchange Commission pursuant to a confidential treatment request.

** Confidential treatment has been requested with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

SIGNATURES

Pursuant to the requirements of the Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused this Amendment No. 1 on Form 10-K/A to be signed on its behalf by the undersigned, thereunto duly authorized.

CEMPRA, INC.

June 17, 2016

By: /s/ Prabhavathi Fernandes, Ph.D.
Prabhavathi Fernandes, Ph.D.
President and Chief Executive Officer

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

O P T I O N A N D L I C E N S E A G R E E M E N T

This **O P T I O N A N D L I C E N S E A G R E E M E N T** (the “Agreement”) is entered into as of January 29, 2016 (the “Effective Date”) by and between **Cempra Pharmaceuticals, Inc.**, a Delaware corporation having an address at 6320 Quadrangle Dr. #360, Chapel Hill, NC 27517 (“Cempra”), and **Macrolide Pharmaceuticals, Inc.**, a Delaware corporation having an address at 480 Arsenal St., Suite 130, Watertown, MA 02472 (“MP”). MP and Cempra may be referred to herein individually as a “Party” or collectively, as the “Parties.”

R E C I T A L S

W H E R E A S, MP owns or controls certain intellectual property rights with respect to Macrolides (as defined below) and/or the synthesis or manufacture thereof, and owns or controls certain know-how, technology, documentation, data, and other materials relating thereto; and

W H E R E A S, Cempra wishes to obtain an exclusive option to exclusively license certain of such intellectual property rights, and, during such option, a license to evaluate such rights and the technology covered thereby.

N O W , T H E R E F O R E, in consideration of the foregoing and the covenants and promises contained in this Agreement, the Parties agree as follows:

1. D E F I N I T I O N S. The following capitalized terms shall have the subsequent meanings when used in this Agreement.

1.1 “Affiliate” means, with respect to either Party or any other business entity, any person, corporation or other business entity which, directly or indirectly through one or more intermediaries, actually controls, is actually controlled by, or is under common control with such party. As used in this Section 1.1, “control” means to possess, directly or indirectly, the power to affirmatively direct the management and policies of such person, corporation or other business entity, whether through ownership of at least fifty percent (50%) of the voting securities or by contract relating to voting rights or corporate governance.

1.2 “Annual Net Sales” shall mean the cumulative Net Sales in the Territory of all Royalty Products in an applicable Calendar Year.

1.3 “API” means active pharmaceutical ingredient.

1.4 “Applicable Law” means all applicable laws, rules, regulations and guidelines that may apply to the development, marketing, manufacturing or sale of Products, the performance of either Party’s obligations, or the exercise of either Party’s rights, under this Agreement, including but not limited to all laws, regulations and guidelines governing the import, export, development, marketing, distribution and sale of Products in the Territory and, to the extent relevant, all GCP, GLP or GMP standards or guidelines promulgated by any Regulatory Authorities or the ICH.

1.5 “Approved Subcontractor” means a Third Party contractor selected or designated by a Party in good faith to perform one or more of the activities described or contemplated by the Evaluation Program on behalf of such Party on a fee-for-service or similar basis, pursuant to a contract that (a) assigns to such Party ownership of intellectual property rights created in the course of such subcontractor’s service in a manner reasonably sufficient to enable such Party’s compliance with the intellectual property-related provisions of this Agreement and (b) requires that Confidential Information of either Party be kept confidential on terms substantially as protective as those of this Agreement.

1.6 “BLA” means a Biologics License Application under the United States’ Public Health Services Act and Federal Food, Drug and Cosmetics Act, each as amended, and the regulations promulgated thereunder, or a comparable filing seeking Regulatory Approval in any country.

1.7 “Business Day” means any day other than Saturday, Sunday, or a day that is a federal legal holiday in the U.S.

1.8 “Calendar Day” means each of those seven (7) days in the week.

1.9 “Calendar Quarter” means each of those three (3) calendar month periods of each Calendar Year ending March 31, June 30, September 30 and December 31, provided, that (i) the initial Calendar Quarter shall begin on the Effective Date and end June 30, 2016 and (ii) the Calendar Quarter in which this Agreement expires or is terminated shall extend from the first Calendar Day of such Calendar Quarter until the effective date of such expiration or termination.

1.10 “Calendar Year” means (a) for the first Calendar Year, the period commencing on the Effective Date and ending on December 31 of the same year, (b) for the Calendar Year in which this Agreement expires or is terminated, the period beginning on January 1 of such Calendar Year and ending on the effective date of such expiration or termination, and (c) for all other years, each successive twelve (12) consecutive month period beginning on January 1 and ending December 31.

1.11 “Commercialize” or “Commercialization” means all activities that are undertaken after Regulatory Approval of a Product in a particular jurisdiction and that relate to the commercial marketing, sale, and/or distribution of such Product, including but not limited to advertising and/or promotional activities.

1.12 “Commercially Reasonable Efforts” means the carrying out of obligations or tasks in a manner consistent with the efforts a Party devotes to research, development, commercialization or marketing of a pharmaceutical product or products of similar market potential, profit potential or strategic value resulting from its own research efforts or for its own benefit, taking into account technical, regulatory and intellectual property factors, target product profiles, product labeling, past performance, costs, economic return, the regulatory environment and competitive market conditions in the therapeutic or market niche, all based on conditions

then prevailing, and subject to and in consideration of, in each case, the resources available to such Party and within such Party's organization for such efforts, provided that such efforts shall, no less than consistent with reasonable, customary practices within the U.S. pharmaceutical industry. "Commercially Reasonable" shall have a corresponding meaning.

1.13 "Compound" means solithromycin, which has the chemical structure set forth on Schedule 1.13, and any enantiomer, diastereomer, racemate, salt, hydrate, solvate, polymorph or co-crystal thereof.

1.14 "Confidential Information" means all information and know-how and any tangible embodiments thereof provided by or on behalf of one Party to the other Party either in connection with the discussions and negotiations pertaining to this Agreement or in the course of performing under this Agreement, which may include data, knowledge, practices, processes, ideas, research plans, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business; provided, that, information of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information: (a) was already known to the receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such receiving Party, as can be shown by written records; (b) was part of the public domain, at the time of its disclosure to such receiving Party; (c) became part of the public domain after its disclosure to such receiving Party through no fault of the receiving Party; (d) was disclosed to such receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the disclosing Party not to disclose such information or know-how to others, as can be shown by written records; or (e) was independently discovered or developed by such receiving Party, as can be shown by its written records, without the use or benefit of, or reliance on, Confidential Information belonging to the disclosing Party. Notwithstanding anything to the contrary, and regardless of which Party first discloses any Improvement(s) to the other Party, (y) any Cempra Improvements, any information related thereto (or to any intellectual property rights related thereto), and Compound Data shall be the Confidential Information of Cempra, and Cempra shall be deemed the disclosing Party, and MP the receiving Party, with respect to such Confidential Information and (z) any MP Improvements and any information related thereto (or to any intellectual property rights related thereto) shall be the confidential information of MP, and MP shall be deemed the disclosing party, and Cempra the receiving Party, with respect to such Confidential Information.

1.15 "Control" means, with respect to any intellectual property or right therein, the possession by a Party or an Affiliate thereof of the ability to grant a license or sublicense as provided for herein without violating the terms of any arrangement or agreements between such Party (or any Affiliate thereof) and any Third Party.

1.16 "Cover" means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

1.17 “Derivative” means any compound that can be synthetically prepared from or converted into a Compound, and any enantiomer, diastereomer, racemate, isomer, metabolite, salt, hydrate, solvate, polymorph, or co-crystal of the foregoing.

1.18 “Develop” or “Development” means, with respect to a Product, engaging in preclinical, clinical, and other research or development activities, which may include but is not limited to research, pre-clinical, clinical and regulatory activities directed towards obtaining Regulatory Approval of a Product in a particular jurisdiction.

1.19 “DMF” means a drug master file, as provided for in 21 CFR § 314.420 or similar submission to or file maintained with the FDA or other Governmental Authority or Regulatory Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs.

1.20 “Evaluation Program” means the research activities to be carried out by or on behalf of MP and the evaluation activities to be carried out by or on behalf of Cempra pursuant to this Agreement, as further described on Schedule 1.20.

1.21 “FDA” means the United States Food and Drug Administration, or any successor federal agency thereto.

1.22 “Field” means any and all uses in humans or non-human animals.

1.23 “GCP” means all applicable Good Clinical Practice standards for the design, conduct, performance, monitoring, auditing, recording, analyses and reporting of clinical trials, including, if and as applicable, (a) CFR Title 21, Parts 50 (Protection of Human Subjects), 56 (Institutional Review Boards), and 312 (Investigational New Drug Application), as may be amended from time to time, (b) as set forth in European Commission Directive 2001/20/EC relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use, and brought into law by European Commission Directive 2005/28/EC laying down the principles and detailed guidelines for good clinical practice for investigational medicinal products, (c) as set forth in the ICH Harmonised Tripartite Guideline for Good Clinical Practice (CPMP/ICH/135/95) and any other guidelines for good clinical practice for trials on medicinal products in the Territory, and (d) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time and in each case, that provide for, among other things, assurance that the clinical data and reported results are credible and accurate and protect the rights, integrity, and confidentiality of trial subjects.

1.24 “GLP” means all applicable Good Laboratory Practice standards, including, if and as applicable, (a) as set forth in the then-current good laboratory practice standards promulgated or endorsed by the FDA as defined in Title 21, Part 58 of the CFR, (b) as set forth in European Commission Directive 2004/10/EC relating to the application of the principles of good laboratory practices, as may be amended from time to time as well as any Rules Governing Medicinal Products in the European Community Vol. III, ISBN 92.825 9619-2 (ex—OECD principles of GLP), and (c) the Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.25 “GMP” means all applicable Good Manufacturing Practices including, if and as applicable, (a) the principles detailed in the U.S. Current Good Manufacturing Practices, Title 21, Parts 210, 211, 601 and 610 of the CFR, (b) the applicable part of quality assurance to ensure that products are consistently produced and controlled in accordance with the quality standards appropriate for their intended use, as defined in European Commission Directive 2003/94/EC laying down the principals and guidelines of good manufacturing practice, (c) the principles detailed in the ICH Q7A guidelines, (d) the Rules Governing Medicinal Products in the European Community, Volume IV Good Manufacturing Practice for Medicinal Products, and (e) the equivalent Applicable Laws in any relevant country, each as may be amended and applicable from time to time.

1.26 “Governmental Authority” means any court, agency, department or other instrumentality of any foreign, federal, state, county, city or other political subdivision (including any supra-national agency such as in the European Union).

1.27 “Harvard License” means the License Agreement between the President and Fellows of Harvard College (“Harvard”) and MP, dated February 10, 2015, as amended pursuant to that certain Amendment to License Agreement and Waiver between Harvard, MP, and Cempra, dated as of January 29, 2016 (the “Harvard Waiver”).

1.28 “Harvard Patents” means the Patent Rights (as defined in the Harvard License), which shall include, but not be limited to, (i) those Patents identified as Harvard Patents on Schedule 1.40 and (ii) any Improvement Patent Rights (as defined in the Harvard License) that may be included in the rights granted under the Harvard License as contemplated by Section 2.4 thereof.

1.29 “Harvard Product” means any Product Covered by any Valid Claim of any Harvard Patent in the country in which such Product is manufactured, used, or sold.

1.30 “ICH” means the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use.

1.31 “Improvements Date” means the date that is six (6) months following the earlier of (i) the termination or expiration of this Agreement, (ii) MP’s satisfaction of the condition corresponding to the last of the milestones set forth on Schedule 3.3-1 (i.e., delivery to Cempra of between 3-5 kilograms of MP Materials satisfying the specifications described in Schedule 3.3-2B), or (iii) Cempra’s termination of MP’s obligations under the Evaluation Program pursuant to Section 2.1.b(vii).

1.32 “IND” means an Investigational New Drug Application filed with the FDA or the equivalent application or filing filed with any Regulatory Authority outside of the United States (including any supra-national agency such as in the European Union) necessary to commence human clinical trials in such jurisdiction, and including all regulations at 21 CFR § 312 et. seq., and equivalent foreign regulations.

1.33 “Infringed Patent” means an issued and unexpired patent with a priority date prior to the Effective Date (a) that has not been abandoned, held invalid, revoked, held or rendered unenforceable or lost through interference and (b) the claims of which Cover methods

to Manufacture or synthesize the Compound or any Product and are infringed by Cempra's, any of its Affiliate's, any Sublicensee's, or any of Cempra's, its Affiliates', or Sublicensees' contract manufacturers' making, using, selling, offering for sale or importing the Compound or a Product in a particular country.

1.34 "Know-How" means all technical, scientific and other know-how and information, trade secrets, knowledge, technology, inventions, means, methods, processes, practices, formulas, instructions, skills, techniques, procedures, experiences, ideas, technical assistance, designs, drawings, assembly procedures, computer programs, apparatuses, specifications, data, results and other material, and other drug discovery and development technology, pre-clinical and clinical trial results, manufacturing procedures, test procedures and purification and isolation techniques, (whether or not confidential, proprietary, patented or patentable) in written, electronic or any other form now known or hereafter developed, and all improvements, whether to the foregoing or otherwise, and other discoveries, developments inventions and other intellectual property (whether or not confidential, proprietary, patented or patentable), provided that Know-How shall not include Patents.

1.35 "Macrolide" means any macrolide or ketolide, including but not limited to any 14-, 15-, or 16-membered lactone-ring-based compound, which shall include but not be limited to (i) any 14-, 15-, or 16-membered lactone containing a 1,2,3 triazole, including but not limited to solithromycin, (ii) any aza-macrolide, including but not limited to azithromycin, and (iii) any derivatives of any of the foregoing.

1.36 "Manufacture" means, with respect to the Compound, a Derivative or a Product, all activities related to the production, manufacture, processing, filling, finishing, packaging, labeling, release, shipping, holding, conduct of Manufacturing Process Development, stability testing, quality assurance and quality control of such Compound, Derivative or Product.

1.37 "Manufacturing Process Development" means the process development, process qualification and validation and scale-up of the process to manufacture the Compound, a Derivative or a Product and analytic development and product characterization with respect thereto.

1.38 "MP Know-How" means all Know-How Controlled by MP or its Affiliates as of the Effective Date or coming under MP's or its Affiliates' Control prior to the Improvements Date that is necessary for the research, Development, manufacture, or Commercialization of the Compound or a Product, which shall include, but not be limited to, any Know-How concerning any MP Improvements.

1.39 "MP Materials" means (a) the tangible supply of Compound that will be (x) manufactured or synthesized by the application, to a material extent, of any MP Technology and (y) provided by MP to Cempra pursuant to the Evaluation Program (which shall include but not be limited to the amounts of Compound described on Schedule 3.3-1) and (b) any additional tangible amount of Compound that is manufactured or synthesized by the application, to a material extent, of any MP Technology and to be delivered under this Agreement by MP that may be added after the Effective Date by the mutual written agreement of the Parties.

1.40 “MP Patents” means (a) those Patents set forth on Schedule 1.40 attached hereto (the “Initial MP Patents”); (b) any other Patents that are Controlled by MP or any Affiliate thereof as of the Effective Date, or come under MP’s or any of its Affiliates’ Control following the Effective Date and, solely in the case of Patents included under this clause (b) through the application of the following clauses (ii), (iii), and (iv), prior to the Improvements Date, and Cover (i) any of the subject matter described in or Covered by the Initial MP Patents and pertaining to the manufacture or synthesis of the Compound or a Product, (ii) the Compound, (iii) any Product, or (iv) the use, manufacture, or synthesis of the Compound or a Product; (c) any divisionals, continuations, continuations-in-part, conversion, extensions, term restorations, registrations, re-instatements, amendments, reissues, corrections, substitutions, re-examinations, registrations, revalidations, supplementary protection certificates, renewals, and foreign counterparts of any Patents described in clause (a) or (b) above, and any other Patents Controlled by MP or any Affiliate thereof claiming priority to any of the foregoing or any of the Patents referenced in clause (a) or (b) above; (d) all patents issuing from any of the Patents mentioned in clause (a), (b), or (c) above and any foreign counterparts of any such Patents; and (e) any MP Improvement Patents included in “MP Patents” pursuant to Section 8.2 of this Agreement.

1.41 “MP Technology” means the MP Know-How and the MP Patents.

1.42 “NDA” means a new drug application (as defined in Title 21 of the United States Code of Federal Regulations, as amended from time to time) submitted to the FDA seeking regulatory approval to market and sell any Product for human therapeutic use in the United States (including a new drug application submitted under Section 505(b)(2) of the Act).

1.43 “Net Sales” means gross amounts invoiced or otherwise received for Cempra’s, its Affiliates’, Sublicensees’, and Product Partners’ sales of Royalty Products, less the sum of the following, to the extent related to the sale of such Royalty Products: (1) discounts in amounts reasonable or customary in the trade, including but not limited to trade, cash, consumer, and quantity discounts, and credits, price adjustments or allowances for damaged Royalty Products, returns, defects, recalls or rejections of Royalty Products or retroactive price reductions; (2) reasonable rebates, credits, and chargeback payments granted to federal, state/provincial, local and other governments or managed health care organizations, including their agencies, purchasers, and/or reimbursers, under programs available under or required by Applicable Law, or reasonably entered into to sustain and/or increase market share for Royalty Products; (3) sales, value added, use, excise, and similar taxes; (4) amounts allowed or credited on returns for defective, damaged, expired, or otherwise unuseable or unsaleable Royalty Products; (5) freight, shipping, handling, and insurance charges; (6) import or export duties, tariffs, or similar charges incurred with respect to the import or export of Royalty Products into or out of any country; (7) distribution commissions/fees (including fees related to services provided pursuant to distribution service agreements with wholesalers) payable to any Third Party providing distribution services with respect to Royalty Products; and (8) amounts repaid or credited or provisions made for uncollectible amounts. Such amounts shall be determined from the books and records of Cempra, its Affiliates, Sublicensees, and Product Partners maintained in accordance with such reasonable accounting principles as may be consistently applied by Cempra, its Affiliates, Sublicensees, and Product Partners.

Royalty Products are considered “sold” when billed out or invoiced or, in the event such Royalty Products are not billed out or invoiced, when the consideration for sale of the Royalty Products is received. Notwithstanding the foregoing, Net Sales shall not include, and shall be deemed zero with respect to, (i) Royalty Products used by Cempra, its Affiliates, Sublicensees, or Product Partners for their internal use, (ii) the distribution of reasonable quantities of promotional samples of Royalty Products, (iii) Royalty Products provided for clinical trials or research, development, or evaluation purposes, (iv) Royalty Products provided by or on behalf of Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner to Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner for purposes of resale, provided such resale is subject to or triggers payments due MP under Section 3.6 of this Agreement, (v) Royalty Products provided in a compassionate use program, and (vi) Royalty Products, not themselves constituting finished Products, provided by or on behalf of Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner to Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner for purposes of manufacturing Royalty Products, provided (x) the sale of such finished Royalty Products is subject to or triggers payments due MP under Section 3.6 of this Agreement or (y) such finished Royalty Products are (I) used by Cempra, its Affiliates, Sublicensees, or Product Partners for internal purposes, (II) distributed in reasonable quantities as promotional samples or in a compassionate use program, (III) provided for clinical trials or research, development, or evaluation purposes, or (IV) provided by or on behalf of Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner to Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner for purposes of resale, provided such resale is subject to or triggers payments due MP under Section 3.6 of this Agreement.

Notwithstanding anything to the contrary, in the event that any Royalty Product includes, in addition to any Royalty Compound, one or more APIs that are not a Royalty Compound (such Royalty Product, a “Combination Product”), Net Sales of such Combination Product in a particular country, for the purposes of determining royalty payments due to MP hereunder, shall be determined by multiplying the Net Sales of the Combination Product in such country by the fraction $A/(A+B)$, where A is the weighted average sale price(s) of the Royalty Product(s) including Royalty Compound(s) included in such Combination Product (and not any of the other APIs included in the Combination Product) (the “Basic Product”) when sold separately in finished form in such country (if there is more than one Basic Product sold in such country, A shall equal the sum of all such Basic Products’ weighted average sale prices in such country), and B is the weighted average sale price(s) of product(s) including the other API(s) (and not the Royalty Compound(s) incorporated in such Combination Product) (such products, “Other Products”) sold separately in finished form in such country (if there is more than one Other Product sold in such country, B shall equal the sum of all such Other Products’ weighted average sale prices in such country).

In the event that, with respect to any Combination Product sold in a particular country, the weighted average sale price of the Basic Product in such country can be determined but the weighted average sale price(s) of the Other Product(s) in such country cannot be determined, Net Sales for purposes of determining royalty payments for such Combination Product in such country shall be calculated by multiplying the Net Sales of the Combination Product in such country by the fraction A/C where A is the weighted average sale price(s) of the Basic Product(s) when sold separately in finished form in such country (if there is more than one Basic Product sold in such country, A shall equal the sum of all such Basic Products’ weighted average sale prices in such country) and C is the weighted average sale price of the Combination Product in such country.

In the event that, with respect to any Combination Product sold in a particular country, the weighted average sale price(s) of the Other Product(s) in such country can be determined but the weighted average sale price of the Basic Product cannot be determined, Net Sales for purposes of determining royalty payments shall be calculated by multiplying the Net Sales of the Combination Product by the formula one (1) minus (B/C) (which may also be written as $1 - (B/C)$), where B is the weighted average sale price(s) of the Other Product(s) when sold separately in finished form in such country and C is the weighted average sale price of the Combination Product in such country (if there is more than one Other Product sold in such country, B shall equal the sum of all such Other Products' weighted average sale prices in such country).

In the event that, with respect to any Combination Product sold in a particular country, the weighted average sale price(s) in such country of neither the Basic Product nor the Other Product(s) in the Combination Product can be determined, the Net Sales of the Combination Product shall, for the purposes of determining royalty payments with respect to such Combination Product, be commercially reasonable and determined by good faith negotiation between Cempra and MP consistent with the ratios and related principles referenced above and based on the relative value of the Royalty Compound(s) incorporated in such Combination Product (and/or MP Technology used to synthesize or manufacture such Royalty Compound(s)) and the other API(s) to such Combination Product.

The weighted average sale price for a Basic Product, Other Product, or Combination Product in a particular country shall be calculated once for each Calendar Year and such price shall be used during all applicable royalty reporting periods for such Calendar Year. When determining the weighted average sale price of a Basic Product, Other Product, or Combination Product in a particular country, the weighted average sale price shall be calculated by dividing the sales dollars by the units of Basic Product, Combination Product, or Other Product sold in such country during the twelve (12) months (or the number of months sold in a partial Calendar Year) of that Calendar Year for the respective Basic Product, Other Product, or Combination Product. For each Calendar Year, a reasonably forecasted weighted average sale price will be used for the Basic Product, Other Product, or Combination Product, which forecasted weighted average sale price will be, for each Calendar Year other than the initial Calendar Year (or portion thereof) during which the Combination Product is sold, no less than the weighted average sale price for the Basic Product, Other Product, or Combination Product in a particular country calculated for the preceding Calendar Year. Any over or under payment due to a difference between forecasted and actual weighted average sale prices will be paid or credited in the payment due with respect to the first Calendar Quarter of the following Calendar Year. For the avoidance of doubt, excipients shall not be considered APIs for the purpose of this definition of Net Sales.

Notwithstanding anything to the contrary, in the case of discounts on "bundles" of separate products or services which include Royalty Products (such "bundles" including but not limited to (i) contingent arrangements involving drugs that share the same NDC (whether the same or different package sizes), drugs with different NDCs, or drugs and other products or

services, (ii) circumstances in which a discount is conditioned on the achievement of some other performance requirement for the Royalty Product or other product or service (e.g. achievement of market share or placement on a formulary tier), or (iii) otherwise where the resulting price concessions or discounts are greater than those which would have been available had the bundled products or services been purchased separately or outside the bundled arrangement), Cempra may calculate Net Sales and royalties due hereunder by applying a discount to the price of a Royalty Product equal to the average percentage discount of all products or services of Cempra, its Affiliate(s), or Sublicensee(s) in a particular “bundle”, calculated as follows:

$$\begin{array}{l} \text{Average percentage} \\ \text{discount on a} \\ \text{particular “bundle”} \end{array} = [1 - (X/Y)] \times 100$$

where X equals the total discounted price of a particular “bundle” of products or services, and Y equals the sum of the undiscounted bona fide list prices of each unit of every product or service in such “bundle”. Cempra shall provide MP documentation reasonably supporting such average discount with respect to each “bundle.” If a Royalty Product in a “bundle” is not sold separately, and no bona fide list price exists for such Royalty Product, Cempra and MP shall, for purposes of calculating Net Sales and royalties due hereunder, negotiate in good faith a reasonable imputed list price for such Royalty Product and Net Sales with respect thereto shall be based on such imputed list price.

1.44 “Option” has the meaning set forth in Section 2.2.

1.45 “Option Period” means the period commencing on the Effective Date and ending at 5:00 pm Eastern Time on the date that is the later to occur of (A) the earlier of (i) the date that Cempra, its Affiliate(s) or Sublicensee(s) first obtains Regulatory Approval from the FDA with respect to any product incorporating the Compound as an API or (ii) the third (3rd) anniversary of the Effective Date or (B) the date that is six (6) months following the earlier of (I) MP’s satisfaction of the condition corresponding to the last of the milestones set forth on Schedule 3.3-1 (i.e., delivery to Cempra of between [*] kilograms of MP Materials satisfying the specifications described in Schedule 3.3-2B) or (II) Cempra’s termination of MP’s obligations under the Evaluation Program pursuant to Section 2.1.b(vii).

1.46 “Patent(s)” means any granted patents and pending patent applications, together with all additions, divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, revalidations, supplementary protection certificates, and renewals of any of the foregoing, and all foreign applications and patents corresponding to or claiming priority from any of the foregoing.

1.47 “Pricing Approval” means any pricing and reimbursement approvals which must be obtained before placing a Product on the market for sale in a particular jurisdiction.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

1.48 “Product” means a product that incorporates or comprises a Compound as an API (alone or in combination with any other API(s)) and (i) utilizes, incorporates, or is Developed, Manufactured, or Commercialized using any MP Technology or (ii) is Covered by one or more Valid Claims of any MP Patents in any country in which such product or any part thereof is made, used, or sold.

1.49 “Product Partner” means a Third Party, other than a Sublicensee, that (i) is granted a license by Cempra or an Affiliate thereof under Patents or Know-How owned, licensed, or controlled by Cempra or an Affiliate thereof, other than MP Technology, to sell a Royalty Product and (ii) supplied by Cempra or an Affiliate thereof with Royalty Product or Royalty Compound for use as an API in the Manufacture of finished Royalty Products.

1.50 “Regulatory Approval” means any and all approvals (including supplements, amendments, and pre- and post-approvals), licenses, registrations, clearances, 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 or, in Cempra’s reasonable judgment, sale of a Product for human therapeutic use in a particular jurisdiction, provided that Regulatory Approval shall not include any Pricing Approval.

1.51 “Regulatory Authority” means any Governmental Authority with responsibility for granting any licenses or approvals necessary for the marketing and sale of human pharmaceutical or biological products in a particular jurisdiction, including the FDA with respect to the United States, and where applicable any ethics committee or any equivalent review board.

1.52 “Regulatory Filing” means, with respect to the United States, an NDA, BLA, or IND, any foreign counterparts or equivalents of any of the foregoing, any DMFs, and any other filings or submissions required by or provided to Regulatory Authorities relating to the Manufacture, Development or Commercialization of any Product, including any supporting documentation, data, correspondence, meeting minutes, amendments, supplements, registrations, licenses, regulatory drug lists, advertising and promotion documents, adverse event files, complaint files, and manufacturing, shipping, or storage records with respect to any of the foregoing.

1.53 “Royalty Compound” means a Compound that is actually synthesized or Manufactured using a method or process that is Covered by a Valid Claim of an MP Patent in the country in which the Product incorporating such Compound as an API is actually sold. For purposes of clarity, Compound, as incorporated as an API into a particular Product, that is not actually synthesized or Manufactured using any methods or processes Covered by a Valid Claim of a MP Patent in the country in which such Product is actually sold shall not be considered a Royalty Compound for purposes of this Agreement, even if such Compound could have been so Manufactured or synthesized.

1.54 “Royalty Product” means a particular Product that incorporates, as an API (alone or in combination with any other API(s)), a Compound constituting a Royalty Compound in the country in which such Product is actually sold and, with respect to Products sold by Product Partners, which Royalty Compound incorporated into such particular Product is supplied to such Product Partner by Cempra or an Affiliate thereof for use as an API in the Manufacture of such Product.

1.55 “Sublicensee” means a Third Party granted a sublicense to any of the rights granted to Cempra and its Affiliates under this Agreement.

1.56 “Territory” means the world, other than the member nations of the Association of Southeast Asian Nations as of March 31, 2006 (such member nations, “ASEAN Countries”), subject to any further reduction in the Territory (or later expansion thereof) as set forth in Section 2.2.

1.57 “Third Party” means any entity other than (a) MP, (b) Cempra, or (c) any Affiliate of either Party.

1.58 “United States” shall mean the United States of America and its territories and protectorates.

1.59 “Valid Claim” means a claim of any pending patent application or any issued, unexpired United States or granted 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 to be invalid or unenforceable or of a scope not Covering a particular Product or Compound through reissue, disclaimer or otherwise, provided that, notwithstanding the foregoing, if a particular claim has been pending longer than seven (7) years from the date of issuance of the first substantive patent office action considering patentability of such claim by the relevant patent office in the country or territory in which such claim is pending, such pending claim shall, upon the conclusion of such seven (7) year period, cease to be a Valid Claim in a particular country for purposes of this Agreement unless and until such claim is the claim of an issued patent in such country.

2. EVALUATION ; OPTION ; LICENSE .

2.1 Evaluation Program .

a. Purpose of Evaluation Program. The purpose of the Evaluation Program shall be (i) research and Development by MP of methods to Manufacture or synthesize the Compound using methods or processes Covered by the Existing MP Patents and (ii) the evaluation by Cempra of (A) the Manufacture and synthesis of the MP Materials (and the MP Materials themselves) and (B) the MP Technology, to permit Cempra to evaluate its interest in exercising the Option. Except as set forth in Section 3, each Party shall be solely responsible for all of its own costs and expenses associated with this Agreement.

b. Conduct of Evaluation Program.

(i) MP Responsibilities. MP shall use Commercially Reasonable Efforts during the Option Period to perform its obligations under the Evaluation Program, which shall include but not be limited to supplying Cempra, in accordance with the delivery schedule set forth on Schedule 1.20 attached hereto, with the MP Materials in the quantities set forth on

Schedules 1.20 and 3.3-1 attached hereto to a facility designated in writing by Cempra, subject to the restrictions set forth herein, including, without limitation, Section 2.1.b.(iv). MP shall not use any Third Parties (other than Approved Subcontractors) in the course of performing its obligations under the Evaluation Program, unless such Third Party is approved in advance in writing by Cempra.

(ii) Cempra Responsibilities. Cempra shall use Commercially Reasonable Efforts during the Option Period to evaluate the Manufacture and synthesis of the MP Materials (and the MP Materials themselves) and the MP Technology, for purposes of eventually determining whether or not to exercise the Option, and commit such resources as are reasonably necessary to perform such evaluation.

(iii) Compliance. Both Parties shall perform their obligations under this Agreement, and Cempra shall use the MP Materials, in compliance with all Applicable Laws.

(iv) Restrictions on Use of MP Materials. Cempra hereby agrees that, notwithstanding anything to the contrary in this Agreement, Cempra shall not use MP Materials for any purpose other than in the conduct of the Evaluation Program. Cempra shall transfer MP Materials only to its Affiliates or those employees, consultants, or Approved Subcontractors of Cempra or its Affiliates who are conducting Cempra's portion of the Evaluation Program and who are bound by obligations of confidentiality and non-use comparable in scope to those set forth in this Agreement, and Cempra shall not transfer, distribute or release any MP Materials to any Third Party (other than Approved Subcontractors) without the prior written consent of MP.

(v) Cooperation; Scientific Contact. The Parties shall reasonably cooperate in the conduct of the Evaluation Program and, subject to the terms of this Agreement and any confidentiality obligations to third parties, shall provide such information and materials as are reasonably necessary for the performance of the Evaluation Program. The respective scientific contacts (each, a "Scientific Contact") of the Parties for purposes of this Agreement are as follows:

MP: [*]
Macrolide Pharmaceuticals, Inc.
480 Arsenal St., Suite 130
Watertown, MA 02472
Email: [*]
Phone: [*]

Cempra: [*]
Vice President, CMC
Cempra Pharmaceuticals, Inc.
6320 Quadrangle Dr. #360
Chapel Hill, NC 27517
Email: [*]
Phone: [*]

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(vi) Reporting. Each Party shall (i) keep the other Party reasonably informed of the progress of the Evaluation Program by oral reports to the respective Scientific Contact not less than once each thirty (30) day period during the Option Period (which can occur by telephone) and (ii) provide written summary reports to the respective Scientific Contact of the results of the Evaluation Program as are reasonably requested, no more frequently than once per Calendar Quarter. In addition to the foregoing, the Parties' Scientific Contacts shall attend in-person meetings, at a location to be mutually agreed on by the Parties, at least once per Calendar Quarter. Each Party shall bear its own expenses of complying with the provisions of this Section 2.1.b.(vi).

(vii) Termination of MP Responsibilities Under Evaluation Program. Cempra shall be entitled to terminate MP's performance of MP's remaining, unfulfilled research, development, synthesis, and manufacturing obligations under the Evaluation Program (and corresponding obligations under Section 2.1.b(i)) upon written notice to MP given at any time following the second (2nd) anniversary of the Effective Date or, if earlier, Cempra's exercise of its Option in whole or in part. Upon such notice, MP shall, without limitation of any of its obligations under this Agreement except those set forth in Section 2.1(b)(i), cease (and cause its Affiliates to cease) all of its and its Affiliates' research, development, synthesis, and manufacturing activities with respect to the Evaluation Program or the Compound.

2.2 Option. MP hereby grants to Cempra the exclusive option to be granted (and to have Cempra's Affiliates be granted) the exclusive license set forth in Section 2.3.b. below (the "Option"). Cempra may exercise such Option, at its sole discretion, at any time during the Option Period by providing written notice of such exercise to MP; provided that Cempra shall automatically be deemed to have exercised the Option for any and all purposes of this Agreement if, and as of the date that, Cempra, its Affiliate(s) or Sublicensee(s) makes a Regulatory Filing with any Regulatory Authority that covers a Royalty Product manufactured using or incorporating Royalty Compound and includes, as part of such Regulatory Filing's chemistry, manufacturing, and controls section(s), a description of the relevant manufacturing process(es) Covered by the MP Patents. If, and only if, Cempra indicates in such exercise notice, or by providing written notice to MP within sixty (60) days of any deemed exercise of its Option pursuant to the preceding sentence's proviso, that it wishes to exercise such Option only with respect to a reduced portion of the Territory and/or a reduced portion of the rights to MP Technology described in Section 2.3.b below, the Territory and/or scope of rights to MP Technology to be licensed to Cempra and its Affiliates under Section 2.3.b. upon exercise of the Option shall be so reduced as described in such notice, unless Cempra, within sixty (60) months of providing such notice of such reduced rights, provides MP with a subsequent notice indicating that Cempra wishes to increase the scope of such rights and/or portion of the Territory applicable to the rights granted under Section 2.3.b. and describing the extent to which Cempra wishes to do so (such a notice, a "Restoration Notice"), in which case, effective upon receipt of such Restoration Notice, the portion of the Territory and/or scope of such rights licensed to Cempra under Section 2.3.b. shall be increased to the extent requested in such subsequent notice, provided that a Restoration Notice shall not in any case be construed to expand Cempra's and its Affiliates' rights under Section 2.3.b. beyond the potential maximum scope originally contemplated thereby. The Parties further agree that Cempra shall be entitled to provide more than one Restoration Notice, and thereby increase the scope of rights granted under Section 2.3.b. to the extent described in any such Restoration Notice(s) at any time prior to the expiration of the above-referenced sixty (60) month period following the initial Option exercise notice.

During the Option Term, and, if the Option is not exercised by Cempra with respect to the entirety of rights potentially available under Section 2.3.b., prior to the expiration of the above-referenced sixty (60) month period following the initial exercise of the Option, MP will not (and will ensure that its Affiliates do not), on its (or their) own or with any Third Party, conduct any research or development directly and specifically related to the Compound, Products, or the synthesis or manufacture of either of the foregoing, except to the extent such activities are undertaken solely by MP (y) in the performance of its obligations under this Agreement or (z) in using a Compound as a comparator in its in vitro or in silico (i.e., non-clinical and non-animal) research, or incidentally in non-commercial, internal, in vitro or in silico (i.e., non-clinical and non-animal) research, focused in each case under this clause (y) on any compound other than the Compound, provided that nothing in this paragraph shall be construed to create or include a grant of any rights by Cempra or any Affiliate thereof to MP or any Affiliate thereof under any Patents, Know-How, or other intellectual property rights.

2.3 Licenses; Retained Rights.

a. Subject to the other terms and conditions of this Agreement, MP hereby grants to Cempra and its Affiliates an exclusive license (transferable in accordance with Section 12.2), without the right to grant sublicenses, during the Option Period under the MP Technology to conduct the Evaluation Program or otherwise evaluate, test, or analyze the MP Materials, provided that, notwithstanding the foregoing prohibition on sublicensing, Cempra and its Affiliates shall be entitled to engage Approved Subcontractors to perform Cempra's portion of the Evaluation Program or otherwise evaluate, test, or analyze the MP Materials. Cempra shall not acquire any additional right, title or interest in or to the MP Materials as a result of MP's supply, or Cempra's use, of the MP Materials in the Evaluation Program.

b. Upon Cempra's exercise or deemed exercise of the Option pursuant to Section 2.2, MP hereby grants to Cempra and its Affiliates an exclusive license (transferable in accordance with Section 12.2), with the right to sublicense as set forth in Section 2.4, under the MP Technology to:

(i) engage in clinical and regulatory activities directed towards obtaining Regulatory Approval, make, have made, Manufacture, use, sell, offer for sale, import, export and otherwise Commercialize the Compound and Products in the Field in the Territory, subject to any reductions in such rights which may be indicated by Cempra in its exercise notice (or later restored, in whole or in part) as contemplated by Section 2.2; and

(ii) Manufacture, make, have made, use, sell, offer for sale, import, and export Derivatives solely and exclusively for the purposes of (A) making, having made, or Manufacturing the Compound or a Product under the foregoing clause (i) or (B) activities that are necessary to seek or obtain Regulatory Approval of or for the Compound or a Product, provided that (x) the rights to sell or offer for sale Derivative referenced above in this clause (ii) shall only be exercised with respect to sales of Derivatives (or offers for the sale thereof) to Third Parties to whom Cempra, an Affiliate thereof, or a Sublicensee has granted rights under

Know-How or Patents owned, licensed, or controlled by Cempra or an Affiliate thereof to make, use, and sell Compound or Product and (y) the right to sell Derivative referenced above in this clause (ii) shall further only be exercised pursuant to a written agreement containing provisions explicitly limiting the use of such Derivative solely to the manufacture of Compound or Product or activities that are necessary to seek or obtain Regulatory Approval of or for the Compound or Product.

For purposes of clarity, the license under this Section 2.3.b. shall not include any right to research, Develop, Manufacture, make, have made, sell, offer for sale, use, import, export or otherwise Commercialize any Macrolide other than (y) the Compound and (z) subject to the provisions of Section 2.3.b(ii), Derivatives.

c. Cempra acknowledges and agrees that, notwithstanding the rights granted in Sections 2.3.a. and 2.3.b. above with respect to the Harvard Patents or the exclusivity thereof:

(i) the United States Government has certain rights arising out of its sponsorship of the research that led to the conception or reduction to practice of technology Covered by the Harvard Patents and, therefore, the United States federal government retains rights in the Patent Rights pursuant to 35 U.S.C. §§ 200-212 and 37 C.F.R. § 401 et seq., and any right granted in this Agreement greater than that permitted under 35 U.S.C. §§ 200-212 or 37 C.F.R. § 401 et seq. will be deemed modified as may be required to conform to the provisions of those statutes and regulations; and

(ii) Harvard retains the right, for itself and for other not-for-profit research organizations, to practice the Harvard Patents within the scope of the license granted above, solely for non-commercial research, educational and scholarly purposes; provided, that, nothing herein or in the Harvard License shall be construed as permitting Harvard or any such not-for-profit research organization to grant any rights to any third party, including any for-profit sponsor, to practice or exploit any of the Harvard Patents for any commercial purpose that would be inconsistent with the terms of the exclusive license granted hereunder or under the Harvard License, including any right to develop, Manufacture, market or sell Harvard Products for use in the Field.

d. Other than as expressly set forth in this Section 2.3, Cempra shall not acquire any right, title, interest or license in or to the MP Materials or MP Technology.

2.4 Sublicensing.

a. Cempra and its Affiliates shall, upon prior written notice to MP describing the territory and/or scope of rights within which Cempra and/or its Affiliates wish to be entitled to grant one or more sublicenses of rights granted under this Agreement (such a notice, a “Sublicense Notice”), have the right to sublicense any rights granted under Section 2.3.b. to one or more Third Parties within the scope described in such Sublicense Notice, through multiple tiers of sublicenses. The Parties further agree that Cempra shall be entitled to provide more than one Sublicense Notice, and thereby increase the scope of rights that may be sublicensed hereunder, at any time. Cempra shall, as promptly as practicable after execution thereof, provide MP a written copy of each such sublicense executed with respect to the rights

granted under this Agreement (and each amendment thereto, if any), which may be redacted to the extent reasonably necessary to protect the confidentiality of the applicable Sublicensee's confidential or proprietary information, promptly following its execution. Each such sublicense shall (i) be consistent with this Agreement and (ii) contain terms and conditions reasonably sufficient to enable Cempra to comply with the terms of this Agreement.

b. Notwithstanding anything to the contrary, however, and without limiting Cempra's, its Affiliates', and Sublicensees' rights to engage Third Party contract manufacturers to Manufacture the Compound, Derivatives, or Products on behalf of Cempra, its Affiliates, and Sublicensees as permitted in the exercise of the rights granted above, neither Cempra nor any Affiliate thereof shall, during the five (5) years following Cempra's exercise of the Option, be entitled to sublicense to any Third Party the rights granted under this Agreement to make or have made Compound or Derivative in the People's Republic of China (excluding Hong Kong) ("China"), other than for supply to Cempra, any Affiliate(s) thereof, or any Sublicensee pursuant to a manufacturing, supply, or similar agreement, unless (i) MP consents in writing to the grant of such sublicense, such consent not to be unreasonably withheld, or (ii) the agreement under which such sublicense is granted (x) includes rights to sell finished Product in China and (y) contains reasonable contractual provisions prohibiting any Compound made in China pursuant to such sublicense from being sold or commercialized outside of China or used in the manufacture of any product other than Product to be used or sold in China pursuant to such agreement.

c. Cempra shall ensure, and shall ensure that its Affiliates ensure, that any Third Party contract manufacturers engaged to manufacture the Compound, Derivatives or Products on behalf of Cempra or its Affiliates through the practice of MP Technology are subject to commercially reasonable contractual obligations that prohibit the use of MP's Confidential Information for any other purpose, and Cempra shall, and shall ensure that its Affiliates shall, either (i) use Commercially Reasonable Efforts to enforce such obligations or (ii) make MP a third party beneficiary entitled to enforce such obligations. Cempra shall, and shall ensure that its Affiliates shall, with respect to any sublicense agreement executed without MP's consent as permitted pursuant to Section 2.4(b), either (1) use Commercially Reasonable Efforts to enforce the contractual provisions referenced in clause (y) of the last sentence of Section 2.4(b) or (2) make MP a third party beneficiary entitled to enforce such obligations.

2.5 Section 365(n). All licenses granted under this Agreement are deemed to be, for purposes of Section 365(n) of the U.S. Bankruptcy Code, licenses of right to “intellectual property” as defined in Section 101 of such Code. The Parties agree that Cempra and its Affiliates may fully exercise all of its and their rights and elections under the U.S. Bankruptcy Code and any foreign equivalent thereto in any country having jurisdiction over a Party, any Affiliate thereof, or any of its or their assets. The Parties further agree that, in the event Cempra or any Affiliate(s) thereof elect to retain its rights as a licensee under such Code, Cempra and/or such Affiliate(s), as applicable, shall be entitled to complete access to any technology or intellectual property licensed to them hereunder and all embodiments of such technology and intellectual property. Such embodiments of the technology and intellectual property shall be delivered to Cempra and its Affiliates not later than:

a. the commencement of bankruptcy proceedings against MP, upon written request, unless MP elects to perform its obligations under this Agreement, or

b. if not delivered above under this Section 2.5, upon the rejection of this Agreement by or on behalf of MP, upon Cempra’s written request.

2.6 Restrictive Covenants.

(a) Until the earlier of (i) the expiration of this Agreement in all countries of the world or (ii) the termination of this Agreement in its entirety, MP and its Affiliates shall not, and MP shall cause its Affiliates not to, (A) manufacture, have manufactured, use, sell, market, distribute, or import the Compound or enter into any agreement with any Third Party regarding the manufacture, sale, marketing, distribution, or import of the Compound; (B) grant any Third Party any rights under any MP Technology to manufacture, sell, market, distribute, or import the Compound; or (C) enable any Third Party, directly or indirectly, to manufacture the Compound; or (D) grant any Third Party any rights under any MP Technology, or enable any Third Party directly or indirectly, in each case to manufacture, sell, market, distribute or import any Derivative if MP or any of its Affiliates possess actual knowledge that such Derivative is being or will be used by or on behalf of such Third Party to manufacture, sell, or otherwise commercialize the Compound; provided that, notwithstanding the foregoing, the obligations of MP and its Affiliates under this Section 2.6 shall not apply (x) to the extent reasonably necessary to enable MP to satisfy its obligations under this Agreement or (y) to the incidental use thereof in non-commercial internal in vitro or in silico (i.e., non-clinical and non-animal) research, or use of the same as a comparator in its in vitro or in silico (i.e., non-clinical and non-animal) research, focused in each case under this clause (y) on any compound other than the Compound (and provided that nothing in this paragraph shall be construed to create or include a grant of any rights by Cempra or any Affiliate thereof to MP or any Affiliate thereof under any Patents, Know-How, or other intellectual property rights).

(b) MP shall, and MP shall ensure that its Affiliates, use Commercially Reasonable Efforts to (I) include in any agreement (other than the Harvard License) between MP or any Affiliate thereof and any Third Party concerning the (i) manufacture, use, sale, or import of any Derivative, (ii) grant of any intellectual property rights with respect to any Derivative (or the use or manufacture thereof), or (iii) enablement of the manufacture of any Derivative, a provision prohibiting any such Derivative procured from MP or any Affiliate

thereof, manufactured in the exercise of any rights granted by MP or any Affiliate thereof, or whose manufacture is otherwise enabled by MP or any Affiliate thereof to, in any case, from being used in the manufacture of the Compound and (II) ensure that Cempra is a third party beneficiary entitled to enforce such provision.

3. FINANCIAL TERMS

3.1 Initial License Fee. In consideration of the rights granted under Sections 2.2, 2.3, and 8.1, Cempra will pay MP a non-refundable, non-creditable fee (the “Initial License Fee”) in the aggregate amount of Three Hundred and Seventy Five Thousand Dollars (\$375,000), payable by wire transfer of immediately available funds, within five (5) Business Days of the Effective Date.

3.2 Facilities Fee. In consideration of the facilities, equipment, supplies and related goods and services that MP will need to purchase, acquire or provide to conduct the Evaluation Program, Cempra will pay MP a non-refundable, non-creditable fee (the “Facilities Fee”) in the aggregate amount of Three Hundred and Seventy Five Thousand Dollars (\$375,000), payable by wire transfer of immediately available funds, within five (5) Business Days of the Effective Date.

3.3 Research Funding . In consideration of the conduct by MP of the Evaluation Program, Cempra will pay MP the expected reasonable, documented, direct compensation-related costs of employees and advisors necessary to conduct MP’s portion of the Evaluation Program, mutually agreed by the parties to be an aggregate amount equal to One Million Four Hundred Ninety-Nine Thousand Nine Hundred Ninety-Nine Dollars and Ninety-Four Cents (\$1,499,999.94), which shall be paid by Cempra monthly in eighteen (18) equal consecutive non-refundable, non-creditable monthly installments of \$83,333.33 (each, a “Research Funding Payment”), payable by wire transfer of immediately available funds on or prior to each of the eighteen (18) consecutive monthly anniversaries of the Effective Date (the “Research Funding Dates”).

3.4 Initial Milestone Payments . In consideration of the rights granted under Sections 2.2, 2.3, and 8.1, Cempra shall pay MP the respective non-refundable, non-creditable amounts set forth on Schedule 3.3-1 upon the satisfaction of the respective corresponding conditions described therein (the “Initial Milestone Payments”), in each case payable by wire transfer of immediately available funds within thirty (30) Calendar Days following satisfaction of the relevant conditions for the relevant payment and written notice thereof from MP.

3.5 Second License Fee . If Cempra exercises or is deemed to have exercised its Option under Section 2.2, Cempra shall pay MP a non-refundable, non-creditable license fee in the aggregate amount of One Million Dollars (\$1,000,000) (the “Second License Fee”), payable as follows:

a. Five Hundred Thousand Dollars (\$500,000) of the Second License Fee shall be paid by Cempra within fifteen (15) Business Days of its exercise or deemed exercise of the Option; and

b. Five Hundred Thousand Dollars (\$500,000) of the Second License Fee shall be paid by Cempra in the form of “deemed royalty” payments equal to [*] percent ([*]%) of Net Sales of Products (whether or not a Compound, as incorporated as an API into such Product, is actually synthesized or Manufactured using any methods or processes Covered by a Valid Claim of an MP Patent in the country in which such Product is actually sold) sold by Cempra, its Affiliates, Sublicensees, and Product Partners following the exercise or deemed exercise of the Option (i.e., the total payment obligation under this Section 3.5.b. shall not exceed \$500,000); provided that for all purposes of this Section 3.5.b. (including the calculation of such deemed royalty payments), the provisions of this Agreement pertaining to payments due on the basis of Net Sales of Royalty Products shall apply, *mutatis mutandis*, to the Net Sales of all Products sold by Cempra, its Affiliates, Sublicensees, and Product Partners, further provided that, notwithstanding anything to the contrary, with respect to sales of Products by Sublicensees and Product Partners, the “deemed royalty” shall only be due under this Section 3.5.b. to the extent such Sublicensees and Product Partners pay a royalty to Cempra or an Affiliate thereof with respect to such sales.

3.6 Royalty Payments. Except as otherwise set forth in this Agreement, Cempra will make royalty payments based on a percentage of the applicable Annual Net Sales, on a Royalty Product-by-Royalty Product and country-by-country basis, from the date of the First Commercial Sale of each Royalty Product in each country until the expiration of the Royalty Term applicable to such Royalty Product in such country. Such royalty payments shall be calculated based on Annual Net Sales of all Royalty Products by applying the tiered royalty rate shown below:

<u>Annual Net Sales</u>	<u>Royalty</u>
Annual Net Sales up to and including \$[*]	[*]%
Annual Net Sales over \$[*]	[*]%

For example, if, during a Calendar Year, Annual Net Sales of Royalty Products were equal to \$[*], then the royalties payable would be calculated by adding (a) the royalties with respect to the first \$[*] at the first-level percentage of [*] percent ([*]%) ($[\$[*]] \times [*] = \$[*]$) and (b) the royalties with respect to the next \$[*] at the second-level percentage of [*] percent ([*]%) ($[\$[*]] \times [*] = \$[*]$), for a total royalty of \$[*].

3.7 Additional Royalty Payments Following First Commercial Sale . Cempra shall pay to MP a non-refundable, non-creditable additional royalty equal to [*] percent ([*]%) of the first (1st) \$[*] in combined, aggregate Net Sales of all Royalty Products sold by Cempra, its Affiliates, Sublicensees, and Product Partners (i.e., the total payment obligation under this Section 3.7 shall not exceed \$1,000,000).

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

3.8 Third Party Royalties. If (a) any technology Covered by any MP Patents, to the extent licensed to Cempra under this Agreement, is Covered by any Valid Claim in an Infringed Patent owned, licensed, or controlled by a Third Party in any country(ies) of the Territory, and Cempra, an Affiliate thereof, any Sublicensee, or any Product Partner, after arms'-length negotiations, is required to license such Infringed Patent, then Cempra shall be entitled to deduct [*] percent ([*]%) of the consideration paid to any such Third Party for any such rights (such consideration, "Third Party Royalties") from any payments due MP under Section 3.6, provided that such amounts payable shall not be reduced, with respect to any Calendar Quarter, below [*] percent ([*]%) of the amounts otherwise due MP with respect to such Calendar Quarter without such offset.

3.9 Compulsory Licenses . Should a compulsory license be granted, or be the subject of a possible grant, to a Third Party under the Applicable Laws of any country in the Territory under any MP Patent(s), the Party receiving notice thereof or otherwise becoming aware thereof shall promptly notify the other Party thereof, including any material information concerning such compulsory license, and the total amount payable under Section 3.6 (as adjusted by Section 3.8) with respect to sales of Royalty Products in such country will be adjusted to match any lower amount such Third Party may be allowed to pay with respect to the sales of such Royalty Products in such country, with such lower amount subject to further adjustments pursuant to Section 3.8.

3.10 Challenge of Harvard Patents.

a. In the event that Cempra, its Affiliate, or a Sublicensee (a "Challenging Party") commences, during any period of time during which such entity enjoys rights to any Harvard Patents granted hereunder, an action in which it challenges the validity, enforceability, or scope of any Harvard Patents (a "Harvard Patent Challenge"), Cempra shall reimburse Harvard for all reasonable, documented expenses incurred by Harvard (including reasonable attorneys' fees) in connection with such Harvard Patent Challenge. If the outcome of such Harvard Patent Challenge is a determination in favor of the Challenging Party, such Challenging Party will not have any right to recoup any royalties paid before or during the pendency of such Harvard Patent Challenge.

b. In the event that a Challenging Party commences a Harvard Patent Challenge with respect to any Harvard Patent to which Cempra enjoys rights under this Agreement, Cempra shall pay, directly to Harvard, a royalty of [*] percent ([*]%) of Net Sales on Licensed Products (as defined in the Harvard License) sold by Cempra, its Affiliates, and Sublicensees during the pendency of such Harvard Patent Challenge. If the outcome of such Harvard Patent Challenge is a determination against the Challenging Party and its assertions in such Harvard Patent Challenge (e.g., that the Harvard Patents subject to such Harvard Patent Challenge are not invalid or unenforceable), Cempra shall continue to pay such royalty, on a country-by-country and Licensed Product-by-Licensed Product basis, until the earlier of (i) the date on which Cempra no longer enjoys rights to the Harvard Patents subject to such Harvard Patent Challenge under this Agreement or (ii) such time as the applicable Product is no longer covered by a Valid Claim of the Harvard Patents in the country in which such Product is sold.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

c. The Parties agree that neither Section 3.10.a nor Section 3.10.b shall apply to (i) Cempra or its Affiliates with respect to a Harvard Patent Challenge regarding a Harvard Patent to which Cempra does not enjoy rights under this Agreement or (ii) any Sublicensee with respect to a Harvard Patent Challenge regarding a Harvard Patent to which such Sublicensee does not enjoy rights under any sublicense granted under this Agreement.

d. The Parties agree that neither (I) arguments and comments made by or on behalf of Cempra, its Affiliates, or any Sublicensee with respect to the prosecution, maintenance, or defense of Cempra's, its Affiliates', or any Sublicensee's owned or licensed patents or patent applications (other than Harvard Patents) in response to examiners' citations of or references to the Harvard Patents in office actions and other communications from governmental patent offices, agencies, or authorities, but only to the extent reasonably necessary to attempt to overcome the examiner's rejection of the relevant claims, nor (II) in the event an opposing party (that is not Cempra, an Affiliate thereof, any Sublicensee, or any Third Party acting on behalf, or with the knowing assistance, of any of the foregoing) uses in any legal proceeding a Harvard Patent to make a bona fide challenge to the validity, enforceability, scope, or patentability of any patents or patent applications of Cempra, any Affiliate thereof, or any Sublicensee (other than Harvard Patents), any arguments and comments made by Cempra, its Affiliate, or any Sublicensee, as appropriate, but only to the extent reasonably necessary to defend such owned or licensed patents or patent applications in such legal proceedings, shall, in either case, constitute a Harvard Patent Challenge for purposes of this Section 3.10. Harvard is not a party to this Agreement; however, Harvard shall be a third party beneficiary of the terms of this Section 3.10, and Harvard may enforce such terms directly against Cempra.

3.11 Royalty Term. Subject to any earlier termination of this Agreement, amounts due under Section 3.6 (as they may be further adjusted under this Agreement) shall only be payable on a country-by-country and Royalty Product-by-Royalty Product basis for sales occurring, as applicable, with respect to a particular Royalty Product in a particular country prior to the first (1st) date on which there are no Valid Claims of any MP Patent Covering such Royalty Product (or any Royalty Compound incorporated therein as an API) in such country (the period from the Effective Date until such date for a particular Royalty Product in a particular country, the "Royalty Term" for such Royalty Product in such country).

3.12 Payments and Payment Reports. Except as otherwise provided in this Section 3, all royalties due under Section 3.5.b., 3.6, and 3.7 shall be paid within ninety (90) Calendar Days of the end of the Calendar Quarter during which the applicable Net Sales occur. Each royalty payment shall be accompanied by a statement stating (as applicable) the number, description, and aggregate Net Sales, by country, of each Royalty Product and cumulative Annual Net Sales of all Royalty Products sold during the relevant Calendar Quarter and Calendar Year by Cempra, its Affiliates, Sublicensees, and Product Partners, with a list of Harvard case numbers for all Harvard Patents that have Valid Claims Covering the Royalty Products (to the extent such case numbers are ascertainable from Schedule 1.40 or similar information provided by MP prior to the end of the Calendar Quarter for which such report is being provided), and detailing the calculation of royalties and amounts due for such Calendar Quarter.

3.13 Payment Method. Except as set forth in Section 3.17 below, all payments due under this Agreement to MP shall be made by bank wire transfer in immediately available funds to an account designated by MP in writing. All payments hereunder shall be made in the legal currency of the United States.

3.14 Taxes. In the event any tax or similar amount is paid or required to be withheld by Cempra or any Affiliate thereof for the benefit of MP on account of any royalties or other payments payable to MP under this Agreement, the corresponding amounts payable to MP shall be reduced by the amount of taxes or similar amounts deducted and withheld, and Cempra or its Affiliates shall pay the amounts of such taxes or similar amounts to the proper Governmental Authority in a timely manner and promptly transmit to MP an official tax certificate or other evidence of such tax or other obligations together with proof of payment from the relevant Governmental Authority of all amounts deducted and withheld sufficient to enable MP to claim such payment of taxes or similar amounts. Any such withholding taxes or similar amounts required under applicable law to be paid or withheld shall be an expense of, and borne solely by, MP. Cempra will provide MP with, at MP's expense, reasonable assistance to enable MP to recover such taxes or amounts otherwise withheld as permitted by law.

3.15 Sublicenses. For avoidance of doubt, the Parties agree that in the event that Cempra grants licenses or sublicenses to Third Parties any right under MP Technology to sell Royalty Products, Cempra shall include in such licenses or sublicenses an obligation for such Sublicensee to account for and report its sales of Royalty Products on a basis reasonably sufficient to enable Cempra to pay MP the royalties due under this Agreement and satisfy Cempra's reporting obligations hereunder.

3.16 Foreign Exchange. All payments due under this Agreement will be paid in United States dollars. Conversion of amounts received or sales made in foreign currency to United States dollars will, for reporting or payment purposes hereunder, be made at the conversion rate existing in the United States, as reported in the Wall Street Journal on the last Business Day of the applicable Calendar Quarter. If The Wall Street Journal ceases to be published, then the rate of exchange to be used shall be that reported in such other business publication of national circulation in the United States on which the Parties reasonably agree.

3.17 Blocked Currency. In each country where the local currency is blocked and cannot be removed from the country, payments under this Agreement arising from activities in that country for which Cempra or an Affiliate thereof does not receive payment in United States' currency, freely useable outside of such country, shall, notwithstanding anything to the contrary, be paid to MP in the country in local currency by deposit in a local bank designated by Cempra, unless the Parties otherwise mutually agree in writing.

3.18 Interest. If Cempra fails to make any payment when due to MP under this Agreement, then interest shall accrue on the balance due on a daily basis at a rate equal to LIBOR (as published in The Wall Street Journal, New York edition), or at the maximum rate permitted by applicable law, whichever is lower, until Cempra meets the full financial obligation due under this Agreement.

3.19 Records; Audits. Cempra shall maintain, and shall cause its Affiliates, Sublicensees, and Product Partners to maintain, complete and accurate records of Royalty Products that are made, used, sold, leased or transferred under this Agreement, which records shall contain sufficient information to permit MP to confirm the accuracy of any reports or notifications delivered to it under Section 3.12 of this Agreement. Cempra shall retain, and cause its Affiliates, Sublicensees to retain, such records relating to a given Calendar Quarter for at least five (5) years after the conclusion of that Calendar Quarter, during which time MP and Harvard will, subject to the terms of this Section 3.19, have the right, at their expense, to cause an independent, certified public accountant (or, in the event of a non-financial audit, other appropriate independent, neutral auditor) to inspect such records during normal business hours for the purposes of verifying the accuracy of any reports and payments delivered under this Agreement and Cempra's compliance with the terms hereof. Such accountant or other auditor, as applicable, shall be bound by obligations of confidentiality and non-use with respect to information disclosed by Cempra and shall not disclose to MP or Harvard any information other than information relating to the accuracy of reports and payments delivered under this Agreement. MP shall promptly provide Cempra a copy of the results of any audit or inspection under this Section 3.19, and the Parties shall reconcile any underpayment or overpayment within thirty (30) days after the accountant delivers the results of the audit, provided that any overpayment by Cempra of royalties or any other amount paid to MP revealed by an inspection or audit shall, in Cempra's sole discretion, (i) be fully-creditable against future payments under this Agreement or (ii) refunded to Cempra within thirty (30) Calendar Days of its request. If any audit performed under this Section 3.19 reveals an underpayment in excess of five percent (5%) in any Calendar Year, Cempra shall reimburse MP for all reasonable, documented amounts incurred in connection with such audit. MP and Harvard may collectively exercise their rights under this Section 3.19 only once every Calendar Year per audited entity and only with reasonable prior notice to Cempra.

4. TECHNOLOGY TRANSFER ; DILIGENCE ; COMPLIANCE

4.1 Technology Transfer . Upon Cempra's exercise or deemed exercise of the Option and, additionally, as reasonably requested at any time prior to the date ninety (90) days following such exercise or deemed exercise, MP shall transfer to Cempra, at no additional cost, all MP Know-How (including copies of any tangible embodiments thereof), that is necessary to the practice of the license granted under Section 2.3.b. MP shall use Commercially Reasonable Efforts to effect the purposes of the foregoing as promptly as practicable, which shall include but not be limited to taking reasonable actions necessary to enable Cempra, any Affiliate thereof, or any designated contractor of Cempra or any Affiliate thereof to undertake the manufacture and/or synthesis of the Compound and/or Products using the technology, methods, or processes described, embodied, or claimed in the MP Technology. Such actions shall include providing Cempra with (i) the data, files and results of any chemistry, manufacturing, or control-related activities relating to the Compound or a Product (and, if necessary to manufacture the Compound, a Derivative), and (ii) all other information known to or possessed by MP or any of its Affiliates that is necessary or reasonably useful to the Manufacturing and/or synthesis of the Compound and/or Products (and, if necessary to manufacture the Compound or such Products, any Derivative). The Parties agree that the costs and expenses of MP in performing its obligations under this Section 4.1 shall be borne by MP and that MP shall not be required to provide more than [*] person-hours of assistance in using Commercially Reasonable Efforts in fulfilling its obligations under this Section 4.1. at its expense

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

4.2 Additional Assistance. In the event Cempra desires any additional assistance from MP with respect to the understanding, utilization, or application of the MP Technology necessary or reasonably useful to the Manufacturing and/or synthesis of the Compound and/or Products (and, if necessary to manufacture the Compound or such Products, any Derivative) , beyond the assistance to be provided in Section 4.1, Cempra shall provide written notice thereof to MP, and the parties shall enter into good faith discussions concerning the financial and other terms upon which such assistance may be provided by MP, provided that MP shall not have any obligation to provide such assistance unless and until the Parties have executed a mutually agreeable definitive written agreement governing the provision of such assistance on Commercially Reasonable terms. MP shall permit any of its or its Affiliates' employees, officers, or directors to enter into one or more consulting or service agreement(s) with Cempra concerning the Compound and/or Products (and, if necessary to manufacture the Compound or such Products, any Derivative) (or the Commercialization or Manufacture thereof) to the extent to the extent so requested by Cempra, consistent with Cempra's rights under this Agreement, and acceptable to such employee, officer, or director.

4.3 Diligence; Reporting.

a. If Cempra exercises its Option, Cempra shall thereafter use Commercially Reasonable Efforts to pursue the Development and Commercialization of Products. The Parties agree that the efforts of Cempra's Affiliates, Sublicensees, and contractors or consultants of Cempra, its Affiliates, or Sublicensees shall constitute the efforts of Cempra for purposes of satisfying Cempra's obligations under this Section 4.3.a.

b. Within sixty (60) days after the end of each Calendar Year, Cempra shall furnish MP with a written report summarizing Cempra's, its Affiliates' and Sublicensees' efforts during the prior Calendar Year to Develop and Commercialize Royalty Products, including: (a) research and development activities; (b) Commercialization efforts; and (c) marketing efforts. Each report must contain a reasonably sufficient level of detail for MP to assess whether Cempra is in compliance with its obligations under Section 4.3.a. and a discussion of intended efforts for the then current Calendar Year. All reports delivered pursuant to this Section 4.3.b. shall be deemed Confidential Information of Cempra pursuant to this Agreement. All reports delivered pursuant to this Section 4.3.b. shall be deemed Confidential Information of Cempra pursuant to this Agreement.

4.4 Compliance . Cempra shall comply, and shall use Commercially Reasonable Efforts to ensure that its Affiliates and any Sublicensees comply, with all Applicable Laws in the exercise of the rights granted under this Agreement. Without limiting the foregoing, Cempra represents and warrants, on behalf of itself and its Affiliates, that it shall, and it will contractually obligate Sublicensees to comply with all United States laws and regulations controlling the export of certain commodities and technical data, including without limitation all Export Administration Regulations of the United States Department of Commerce. Cempra hereby gives written assurance that it will comply with, and will cause its Affiliates to comply with (and will contractually obligate its Sublicensees to comply with), all United States export control laws and regulations, that it bears sole responsibility for any violation of such laws and regulations by itself or its Affiliates or Sublicensees, and that it will indemnify, defend, and hold each of MP (in accordance with Section 11.2) and Harvard (in accordance with Section 11.4) harmless for the consequences of any such violation.

4.5 Preference for US Industry . During the period of exclusivity of the licenses granted hereunder with respect to Harvard Patents in the United States (but no longer than the expiration of the last Valid Claim thereof), Cempra shall comply, and shall use Commercially Reasonable Efforts to ensure that its Affiliates and Sublicensees comply, with 37 CFR 401.14(i) or any successor rule or regulation.

5. PATENT PROSECUTION AND MAINTENANCE .

5.1 Prosecution and Maintenance by MP . Prior to exercise of the Option by Cempra, MP shall have sole responsibility for, and use Commercially Reasonable Efforts to pursue, the filing, prosecution, and maintenance of the MP Patents. From and after exercise of the Option, except as provided in Sections 5.2 and 5.3, MP shall have primary responsibility for, and use Commercially Reasonable Efforts to pursue, the filing, prosecution, and maintenance of the MP Patents and, subject to Sections 5.2 and 5.3 below, MP will be responsible for all reasonable costs and expenses it incurs with respect such filing, prosecution, and maintenance. MP will, to the extent reasonably practicable, provide Cempra a reasonable opportunity to review and comment on any material patent filings or correspondence with patent authorities pertaining to the MP Patents and the Manufacture of the Compound, provided that all decisions with respect to the filing, prosecution, and maintenance of MP Patents under this Section 5.1 shall be made by MP in its reasonable discretion. Schedule 1.40 shall be updated periodically by MP to reflect the further prosecution and maintenance of such Patents and the addition of any such MP Patents coming under the Control of MP or any Affiliate thereof after the Effective Date, and any such update shall indicate whether or not any MP Patents subject to such update are Harvard Patents (and include the Harvard case number therefor). MP shall not abandon (or permit any Affiliate thereof or, in the case of Harvard Patents, Harvard to abandon) prosecution, maintenance, or financial support of any such MP Patent without first notifying Cempra in a reasonably timely manner of MP's intention and/or reason therefor, and providing Cempra with a reasonable opportunity to assume responsibility for prosecution, maintenance, and/or financial support of such MP Patent or, in the case of any Harvard Patents that MP may wish to abandon or permit Harvard to abandon, using Commercially Reasonable Efforts to cause Harvard to continue the filing, prosecution, and maintenance of such Harvard Patents or provide Cempra an opportunity to discuss such issue with Harvard.

5.2 Prosecution and Maintenance by Cempra of Compound-Specific Patents . Upon Cempra’s exercise of its Option, and subject to Section 5.3 below, Cempra shall assume and have primary responsibility for, and use Commercially Reasonable Efforts to pursue, the filing, prosecution, and maintenance of all MP Patents licensed to Cempra and its Affiliates under Section 2.3.b. that (i) are owned by MP or an Affiliate thereof, (ii) solely contain claims Covering the Compound (and not any other compounds), and (iii) are not Harvard Patents (such MP Patents, “Compound Patents.”), using patent counsel of Cempra’s choosing and, subject to Section 5.3 below, Cempra will be responsible for all costs and expenses it incurs with respect its filing, prosecution, and maintenance of Compound Patents. Cempra will, to the extent reasonably practicable, provide MP a reasonable opportunity to review and comment on any material patent filings or correspondence with patent authorities pertaining to Compound Patents, provided that all decisions with respect to the filing, prosecution, and maintenance of Compound Patents under this Section 5.2 shall be made by Cempra in its reasonable discretion. Schedule 1.40 shall be updated periodically by Cempra to reflect its further prosecution of Compound Patents, and MP shall provide notice to Cempra of, and update Schedule 1.40 to reflect the addition thereto of, the Compound Patents coming under the Control of MP or an Affiliate thereof after the Effective Date. Cempra shall not abandon prosecution or maintenance of a Compound Patent without first notifying MP in a reasonably timely manner of Cempra’s intention and reason therefor, and providing MP with reasonable opportunity to assume responsibility for prosecution and maintenance of such Compound Patent, at MP’s cost and expense, as set forth in Section 5.3.

5.3 Abandonment by a Party; Prosecution and Maintenance by the other Party. If a Party responsible for filing, prosecution, and maintenance of any MP Patents, other than Harvard Patents (to which this Section 5.3 shall not apply), pursuant to Section 5.1 or 5.2 (such Party, the “Patent Party”) provides the other Party (the “Non-Patent Party”) with written notification that the Patent Party will no longer support or pursue the filing, prosecution, or maintenance of a specified MP Patent in a particular country, then (A) the Patent Party’s responsibility for such filing, prosecution, or maintenance of such MP Patent in such country, and the fees and costs related thereto, will terminate on the earlier of (x) the date sixty (60) Calendar Days after the Non-Patent Party’s receipt of such written notice from the Patent Party or (y) the Non-Patent Party’s assumption of the filing, prosecution and maintenance of such MP Patent in such country and (B) the Non-Patent Party shall have the right, upon written notice to the Patent Party given during such sixty (60) Calendar Day period, to assume control of, and responsibility for, the filing, prosecution, or maintenance of such MP Patent in such country, at the Non-Patent Party’s expense. In the event of such an assumption by a Non-Patent Party with respect to such MP Patent in such country, the Non-Patent Party will thereafter advise the Patent Party in writing of the status of such MP Patent (including any related hearings or other proceedings) on a reasonably regular basis and, at the Patent Party’s request, will provide the Patent Party with copies of all documentation concerning such MP Patent in such country, including all correspondence to and from any patent authority with respect thereto. The Non-Patent Party assuming filing, prosecution, or maintenance of a particular MP Patent under this Section 5.3 shall consult with the Patent Party prior to abandoning any such MP Patent or any claim contained therein, and will solicit the Patent Party’s advice and review of such MP Patent (or any correspondence related thereto) and important prosecution or maintenance matters related thereto in reasonably sufficient time prior to any filing, submission, or communication thereof or with respect thereto, and will take into account the Patent Party’s reasonable

comments related to any of the foregoing. For purposes of clarification, but not limitation, any MP Patent subject to this Section 5.3 shall in any event remain an MP Patent, and remain included in the rights granted to Cempra, its Affiliates, and Sublicensees, under this Agreement, until such time as such MP Patent no longer has any Valid Claims.

5.4 Patent Term Extensions . Cempra shall promptly notify MP of the issuance of each Regulatory Approval and, to the extent reasonably and legally possible and reasonably useful or materially valuable in the Commercialization of Products Covered by a Valid Claim of any MP Patent to which Cempra and its Affiliates have rights hereunder, use Commercially Reasonable Efforts to apply (or cause its Affiliates or Sublicensee(s) to apply) for a patent term extension, adjustment or restoration, supplementary protection certificate, or other form of market exclusivity conferred by Applicable Laws with respect to any MP Patents (collectively, “Patent Term Extensions.”) in the relevant country(ies) of the Territory. MP shall, if and as requested by Cempra, (i) use Commercially Reasonable Efforts to obtain, and assist Cempra, its Affiliates, and Sublicensees in obtaining, all available Patent Term Extensions and (ii) take all actions necessary to obtain all Patent Term Extensions. The Parties shall reasonably cooperate with each other in obtaining Patent Term Extensions wherever and whenever applicable.

5.5 Small Entity Designation. If Cempra, any of its Affiliates, any Sublicensee, or any holder of an option to become a Sublicensee, at any point prior to the first date on which there are no Valid Claims of any Harvard Patents in the United States that are licensed to Cempra under this Agreement, ceases to qualify as an entity entitled to pay lesser patent-related fees as provided by the United States Patent and Trademark Office (i.e., a “small entity”), Cempra shall so notify MP as soon as reasonably possible, in order to enable MP and Harvard to comply with USPTO regulations regarding payment of fees with respect to the Harvard Patents.

5.6 Patent Marking. Cempra shall mark, shall cause its Affiliates to mark, and shall use Commercially Reasonable Efforts to cause its Sublicensees to, mark all Products Covered by a Valid Claim of any MP Patent(s) sold or otherwise disposed of in such a manner as to conform with the patent laws and practice of the country to which such products are shipped or in which such products are sold for purposes of ensuring maximum enforceability of MP Patents in such country.

6. INFRINGEMENT AND DEFENSE .

6.1 Notice. If either Party becomes aware of any actual, potential, or alleged infringement of any of the rights to MP Patents granted under this Agreement, such Party shall give to the other Party prompt and reasonably detailed written notice of such actual, potential, or alleged infringement.

6.2 Infringement of MP Patents.

a. **Prior to Option Exercise.** Notwithstanding anything to the contrary, this Section 6.2.a. shall only apply with respect to rights to MP Patents that have not been granted under Section 2.3.b.; upon the grant of any rights to MP Patents under Section 2.3.b., Section 6.2.b. shall apply with respect to such rights under the MP Patents in lieu of this Section

6.2.a., except with respect to any patent infringement litigation initiated in accordance with this Section 6.2.a. prior to the grant of such rights to Cempra under Section 2.3.b. MP shall have the sole right, but not the obligation, to, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect to any actual, potential, or alleged infringement of any MP Patents, provided that MP shall not (and shall ensure that its Affiliates do not) initiate or undertake any of the foregoing actions or activities, or otherwise communicate with any Third Party concerning any actual, potential, or alleged infringement of, or need for a license to, any MP Patents within the scope of Cempra's actual or potential rights under this Agreement without providing Cempra thirty (30) days advance written notice thereof and an opportunity to discuss in detail the circumstances concerning such actual, potential, or alleged infringement of, or need for a license to, any MP Patents within the scope of such actual or potential rights and, if Cempra exercises its Option during such thirty (30) day period, or otherwise prior to the initiation or undertaking of any such activities, Section 6.2.b. shall apply with respect to the rights under the MP Patents that are the subject of the exercise of the Option.

b. Following Option Exercise.

(i) **Compound Patents.** Notwithstanding anything to the contrary, this Section 6.2.b(i) shall apply with respect to rights to Compound Patents within the MP Patents for which Cempra has exercised the Option. With respect to any actual, potential, or alleged infringement of the rights to Compound Patents within the MP Patents granted under Section 2.3.b., Cempra shall have the first and primary right (which may be further granted to Affiliates of Cempra, but not to Sublicensees), but not the obligation, to, initiate, prosecute, and control any action or legal proceedings, and/or enter into a settlement, including any declaratory judgment action, with respect to such actual, potential, or alleged infringement, provided that, notwithstanding the foregoing, (i) Cempra shall keep MP reasonably informed of the progress of any such action and shall give MP a reasonable opportunity in advance to consult with Cempra and offer its views about major decisions affecting the litigation, (ii) Cempra shall give careful consideration to those views, but shall have the right to control the action in its discretion, and (ii) if Cempra (or its Affiliate controlling such litigation as permitted hereby) fails to defend in good faith the validity and/or enforceability of any Harvard Patent(s) or MP Patents in the action or, or if the license granted hereunder to any MP Patent(s) in the suit terminates, MP may elect to take control of the action pursuant to the second paragraph of this Section 6.2.b. with respect to such Harvard Patent(s) or MP Patent(s). In any such litigation brought by Cempra (and/or any Affiliate thereof), Cempra (and/or any Affiliate thereof) shall have the right to use and sue in MP's or any MP's Affiliate's name, and join MP or any Affiliate thereof as a party to such litigation, and MP shall cooperate (and cause its Affiliates to cooperate) reasonably, as requested by Cempra and at Cempra's expense (which expense shall be reasonable and documented). If, within one hundred eighty (180) Calendar Days of the notice in Section 6.1, Cempra and/or its Affiliates (i) shall have been unsuccessful in persuading the actual, potential, or alleged infringer to desist, (ii) shall not have brought and shall not be diligently prosecuting an infringement action with respect to such actual, potential, or alleged infringement, and (iii) have not entered into settlement discussions with respect to such actual, potential, or alleged infringement, or if Cempra notifies MP that it has decided not to undertake any of the foregoing against any such alleged, potential, or actual infringer, then MP shall have the right to bring suit to enforce such rights under the MP Patents against such actual, alleged, or potential infringer at its own expense. In any such litigation brought by MP, Cempra shall cooperate reasonably, as requested by MP and at MP's expense (which expense shall be reasonable).

(ii) **MP Patents Other than Compound Patents.** Notwithstanding anything to the contrary, this Section 6.2.b(ii) shall apply with respect to rights to MP Patents, other than Compound Patents, for which Cempra has exercised the Option (“MP-Controlled Patents”). If Cempra becomes aware of any possible, alleged, or actual infringement of any MP-Controlled Patents with respect to (1) the Compound or any Product or (2) any use or manufacture of the Compound or any Product in, in the case of (1) or (2), the Field in the Territory (“Cempra Infringement”), Cempra will notify MP of such Cempra Infringement. MP shall, as between the Parties, have the right to take action in the prosecution, prevention, or termination of any Cempra Infringement, provided that, notwithstanding anything to the contrary, (i) MP shall not have any right to grant any licenses under any of the rights to MP-Controlled Patents granted to Cempra under this Agreement as part of any settlement, voluntary disposition, or other resolution of any Cempra Infringement, (ii) any recovery or damages received by Harvard, MP, or any Affiliate of MP with respect to any Cempra Infringement, or in settlement or voluntary disposition of any matter with respect thereto, shall be used (A) first, to reimburse Cempra, its Affiliates, and Sublicensees for unreimbursed reasonable, documented expenses incurred in connection with any cooperation thereof rendered to Harvard, MP, or any Affiliate thereof, at their request, with respect to such action, settlement, or voluntary disposition, then (B) second to reimburse Harvard, MP, and its Affiliates with respect to their unreimbursed reasonable, documented expenses incurred in connection with such action, settlement, or voluntary disposition, and (C) third, Cempra shall be paid seventy-five percent (75%) of any remaining portion of any such recovery or damages, with the remaining twenty-five percent (25%) of such remainder to be retained by MP (or, with respect to any Cempra Infringement concerning any Harvard Patents, split between Harvard and MP pursuant to the applicable percentage set forth in the Harvard License), and (iii) Cempra, its Affiliates, and Sublicensees shall, at their expense, have the right to be represented by counsel of their choice in any proceeding governed by this Section 6.2.b(ii). If Cempra desires to take action in the prosecution, prevention, or termination of any Cempra Infringement, and neither MP nor, with respect to any Harvard Patents, Harvard are so enforcing the MP-Controlled Patents, Cempra may petition MP (and, with respect to any Harvard Patents, Harvard) in writing to pursue such enforcement action. If MP (and, with respect to any Harvard Patents, Harvard) consents in writing to such action, in its sole discretion, Cempra may commence such action with respect to such Cempra Infringement, and compromise, settle, or enter into voluntary dispositions of such litigation, provided that (i) any settlement, consent judgment or other voluntary disposition of such actions which limits the scope, validity, or enforceability of, or otherwise may adversely affect, any MP-Controlled Patents shall not be entered into, consented to, approved, or agreed upon by Cempra, an Affiliate thereof, or any Sublicensee without MP’s (and, with respect to any Harvard Patents, Harvard’s) prior written approval, (ii) nothing in this Section 6.2.b(ii) shall be construed as prohibiting or limiting Cempra’s, its Affiliates’, or Sublicensees’ rights under this Agreement to grant sublicenses or any other rights under any MP Patents to any party, whether with respect to any Cempra Infringement or otherwise, and (iii) if (x) MP (and, with respect to any Harvard Patents, Harvard) does not take any material action in the prosecution, prevention, or termination of any Cempra Infringement, (y) Cempra petitions MP (and, with respect to any Harvard Patents, Harvard) to pursue an enforcement action with respect thereto,

and (z) MP (and, with respect to any Harvard Patents, Harvard) does not consent in writing to such action, Cempra's royalty and payment obligations under Section 3 with respect to any Products covered (or whose manufacture, use, or sale is covered) by the MP-Controlled Patents subject to such Cempra Infringement shall terminate, upon the ninetieth (90th) day following such written petition by Cempra, with respect to all countries in which Cempra's, its Affiliates', or any Sublicensee's commercialization of the Compound or Products is adversely affected by such Cempra Infringement (whether or not such Cempra Infringement actually exists in such country). Notwithstanding anything to the contrary, the Parties agree that, solely for purposes of clause (iii) of the preceding sentence, a Cempra Infringement shall, without limitation of the definition thereof established above, also include an infringement of the MP-Controlled Patents with respect to the manufacture, use, sale, import, or export of any Derivative solely for purposes of making or having made the Compound or a Product, and Cempra shall be entitled to the economic benefit set forth in such clause (iii) in the event any such Cempra Infringement satisfies the applicable conditions set forth therein.

6.3 Infringement of Third Party Rights. In the event that a claim of infringement of a Third Party's Patent(s) is made or brought against either Party or any Affiliate thereof with respect to the Manufacture, use, sale, or importation of the Compound or a Product that is the subject of any of the rights granted under this Agreement, the Party receiving such claim (or whose Affiliate receives such claim) shall promptly inform the other Party in writing, and, to the extent such claim relates to any rights granted hereunder or the practice thereof, the Parties shall consult with each other in order to develop a strategy for addressing the alleged infringement. Each Party shall reasonably cooperate with the other in any investigations undertaken to determine any such potential infringement. As between the Parties, Cempra (and/or its Affiliates and/or Sublicensees) shall have the first and primary right, but not the obligation, at its own expense to defend, control the defense of, and/or settle any such claim against Cempra, its Affiliates, Sublicensees, or Product Partners using counsel of its own choice.

6.4 Third Party Challenge .

a. Without limitation of any Party's (or, in the case of Cempra, its Affiliates' or Sublicensees') rights under Section 6.2 or 6.3, and subject to Section 6.4.b., in the event that a declaratory judgment action is brought against MP, any Affiliate thereof, Cempra, any Affiliate thereof, or any Sublicensee by a Third Party alleging invalidity, unpatentability, unenforceability, or non-infringement of a Compound Patent to which Cempra and its Affiliates have rights under Section 2.3.b. hereof, Cempra shall, at its option, have the first right (which it may grant to any Affiliate or Sublicensee), within ninety (90) days after commencement of such action, to take over the sole defense of the action at its own expense. If Cempra, an Affiliate thereof, or a Sublicensee exercises such right, Cempra (and/or such Affiliate thereof or Sublicensee) shall have the right to use and defend in MP's or MP's Affiliate's name and join MP or any Affiliate thereof as a party to such litigation, and MP shall cooperate (and cause its Affiliates to cooperate) reasonably, as requested by Cempra and at Cempra's expense (which expense shall be reasonable and documented). If neither Cempra, an Affiliate thereof, nor any Sublicensee exercises this right within such time period, MP shall have the right to assume such defense, subject to Section 6.5.

b. Notwithstanding anything to the contrary, if a declaratory judgment action is brought naming Cempra, any Affiliate thereof, or any Sublicensee as a defendant and alleging invalidity or unenforceability of any claims within the Harvard Patents, Cempra shall promptly notify Harvard in writing and Harvard may elect, upon written notice to Cempra within thirty (30) days after Harvard receives notice of the commencement of such action, to take over the sole defense of the invalidity and/or unenforceability aspect of the action at its own expense.

6.5 Litigation Control. Except as otherwise set forth in, and subject to, Section 6.2.b(ii), the Party pursuing or controlling any action or defense under Section 6.2, 6.3, or 6.4 (the “Controlling Party”) shall be free to enter into a settlement, consent judgment, or other voluntary disposition of any such action or defense, provided, however, that (i) the Controlling Party shall, to the extent reasonably practicable, consult with the other Party (the “Secondary Party”) prior to entering into any settlement or voluntary disposition thereof, (ii) any settlement, consent judgment or other voluntary disposition of such actions which (1) subjects the Secondary Party to any non-indemnified liability or obligation or (2) admits fault or wrongdoing on the part of Secondary Party must, in each case, be approved in advance and in writing by the Secondary Party, (iii) any settlement, consent judgment or other voluntary disposition of such actions which materially limits the scope, validity, or enforceability of, or otherwise may materially adversely affect, any MP Patents shall not be entered into, consented to, approved, or agreed upon without the Secondary Party’s prior written approval, such approval not to be unreasonably withheld, and (iv) any settlement, consent judgment or other voluntary disposition of such actions that would reasonably be expected to materially adversely affect any Patents owned, controlled or licensed by Cempra, any Affiliate thereof, any Sublicensee, or any Product Partner, or the ability of Cempra, any Affiliate thereof, any Sublicensee, or any Product Partner to Manufacture, Develop or Commercialize the Compound or any Products shall not be entered into, consented to, approved, or agreed upon by MP or any Affiliate thereof without Cempra’s prior written consent, provided that the foregoing shall not be construed to prevent Harvard from entering into any settlement, consent judgment, or other voluntary disposition of any matter concerning any infringement of the Harvard Patents. Except as otherwise set forth in, and subject to, Section 6.2.b(ii), any recovery or damages received by the Controlling Party with respect to the infringement of the rights to MP Patents granted under this Agreement, or in settlement of any matter subject to Section 6.2, 6.3, or 6.4, shall be used first to reimburse the Parties for unreimbursed reasonable, documented expenses incurred in connection with such action or settlement, and the remainder shall be split [*] percent ([*]%) to the Controlling Party and [*] percent ([*]%) to the Secondary Party. Notwithstanding the foregoing, the Secondary Party, at its expense, shall have the right to be represented by counsel of its choice in any proceeding governed by this Section 6.5.

6.6 Reimbursement. Each Party shall invoice the other Party for any reasonable, documented costs incurred that are to be borne by the other Party pursuant to this Section 6. Each Party shall pay the other Party such amounts within thirty (30) Calendar Days of its receipt of any such invoice, except to the extent such amounts are the subject of a good faith dispute, in which the amounts subject to such dispute shall be due within thirty (30) Calendar Days of the resolution of such dispute.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

6.7 Litigation Credit. To the extent there is no recovery of damages, or amounts received in settlement, by Cempra or its Affiliates with respect to any matter contemplated by Section 6.2, 6.3, or 6.4 above, or all such amounts received with respect to a particular matter are insufficient to fully reimburse Cempra or its Affiliates for any amounts incurred with respect to such matter (including but not limited to attorneys' fees, out-of-pocket costs, and all amounts paid as judgments, damages, or in settlement) (such amounts, "Infringement Costs"), Cempra shall be entitled to credit all Infringement Costs against royalties or other fees thereafter payable to MP under this Agreement. If the total Infringement Costs incurred in any particular Calendar Quarter exceed more than [*] percent ([*]%) of amounts payable to MP under this Agreement with respect to such Calendar Quarter, then the amount of such Infringement Costs in excess of [*] percent ([*]%) of the amounts payable to MP under this Agreement with respect to such Calendar Quarter shall be carried over and remain creditable against payments due MP in future Calendar Quarters, subject to such [*] percent ([*]%) limitation (and continued rollover) in each case.

6.8 Trademarks. Cempra, its Affiliates, Sublicensees, and/or Product Partners may, in their sole discretion, select trademarks for Products ("Product Marks") and shall own all such trademarks. To the extent Cempra, its Affiliates, Sublicensees, and/or Product Partners pursue trademarks for Products, as between the parties, Cempra, its Affiliates, Sublicensees, and/or Product Partners shall have the sole responsibility for the filing, prosecution and maintenance of registrations of trademarks for Products, as determined in their sole discretion, at their sole expense.

7. C ONFIDENTIALITY

7.1 Confidentiality Obligations. The Parties agree that, for the term of this Agreement and for seven (7) years thereafter, each Party will keep completely confidential and will not publish, submit for publication or otherwise disclose, and will not use for any purpose except for the purposes contemplated by this Agreement, any Confidential Information of the other Party.

7.2 Authorized Disclosure . Each Party may disclose Confidential Information of the other Party to the extent that such disclosure is:

(a) made in response to a valid order of a court of competent jurisdiction; provided, however, that in each case such disclosing Party will, to the extent reasonably practicable, (i) first have given written notice to the other Party and given such other Party a reasonable opportunity to take appropriate action and (ii) cooperate with such other Party as necessary to obtain an appropriate protective order or other protective remedy or treatment; provided, further, that in each case, the Confidential Information disclosed in response to such court or governmental order will be limited to that information which is legally required to be disclosed in response to such court or governmental order, as determined in good faith by counsel to the Party that is obligated to disclose Confidential Information pursuant to such order;

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(b) otherwise required to be disclosed by Applicable Law or the requirements of any stock exchange to which a Party is subject; provided, however, that the Party that is so required will provide such other Party with written notice of such disclosure reasonably in advance thereof to the extent reasonably practicable and reasonable measures will be taken to assure confidential treatment of such information, including such measures as may be reasonably requested by the disclosing Party with respect to such Confidential Information;

(c) made by such Party, in connection with the performance of, or exercise of rights under, this Agreement, to such Party's Affiliates, licensors, licensees or sublicensees, directors, officers, employees, consultants, representatives or agents, or to other Third Parties, in each case on a need-to-know basis and solely to use such information for business purposes relevant to and permitted by this Agreement, and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations no less than substantially as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations;

(d) made by such Party to existing or potential acquirers, acquisition targets, collaborators, investment bankers, accountants, attorneys, investors, merger candidates, partners, venture capital firms or other financial institutions or investors for use of such information for business purposes relevant to this Agreement or for due diligence in connection with the financing, licensing or acquisition of such Party (or such Party's acquisition of, or merger with, a Third Party), and provided that (i) each individual and entity to whom such Confidential Information is disclosed is bound in writing to non-use and non-disclosure obligations (or in the case of attorneys or accountants, an equivalent professional duty of confidentiality) at least as restrictive as those set forth in this Agreement and (ii) the Party making such disclosure shall be liable for such Third Parties' compliance with such obligations; or

(e) authorized in writing by the disclosing Party.

7.3 Publicity. Press releases or other similar public communication by either Party not required by Applicable Law or the requirements of any stock exchange to which a Party is subject and disclosing the existence or terms of this Agreement will require the advance written approval of the other Party, which approval will not be unreasonably withheld, conditioned or delayed. The foregoing notwithstanding, communications required by Applicable Law or the requirements of any stock exchange to which a Party is subject, and disclosures of information for which consent has previously been obtained, will not require advance approval, but will be provided to the other Party as soon as practicable after the release or communication thereof, provided that, with respect to any such communications required by Applicable Law or the requirements of any stock exchange to which a Party is subject, the Party required to make such disclosure shall, to the extent reasonably practicable and to the extent such disclosure does not include information for which consent has previously been obtained, provide the other Party a reasonable opportunity to review and comment on such communications.

8. INTELLECTUAL PROPERTY

8.1 Compound Data . Cempra shall be entitled to sole ownership of all data, results, information, analyses and reports directly related to the Compound or a Product (or the use or manufacture thereof) generated by or on behalf of either Party, any Affiliate thereof, or any director, officer, employee, contractor, agent, or representative of any of the foregoing, solely or jointly with the other Party, any Affiliate thereof, or any director, officer, employee, contractor, agent, or representative of any of the foregoing resulting from the conduct of the Evaluation Program, MP's or its Affiliates' access to or knowledge, use, or manufacture of the Compound or a Product, or Cempra's Confidential Information, or Cempra's exercise of rights under this Agreement (such data, results, information, analyses and reports, "Compound Data"). MP shall promptly report all Compound Data to Cempra in writing. MP will assign and hereby assigns, and will cause its Affiliates to assign, all right, title, and interest in Compound Data, and intellectual property rights therein, to Cempra, free and clear of all liens, claims, and encumbrances. MP shall take all actions, and shall cause its Affiliates and any officers, employees, contractors, agents or representatives of MP or any Affiliate thereof, to take all actions, including but not limited to the execution of documents, reasonably requested by Cempra to effect the purposes of the foregoing. Notwithstanding the foregoing, MP shall have the right to use any Compound Data generated by or on behalf of MP, or by Cempra or any Affiliate thereof as part of the Evaluation Program, on an anonymized basis: (i) to prosecute and file applications for MP Patents or MP Improvement Patents that are prosecuted or filed in accordance with the provisions of this Agreement; (ii) to disclose to potential investors in MP for bona fide fundraising purposes; (iii) for MP's internal research purposes; and (iv) to file applications for regulatory approval for human pharmaceutical products containing or comprised of a Macrolide other than (q) the Compound or (r) other compound covered, in the case of this clause (r), by any claims of any Patents owned, licensed, or controlled by Cempra or any Affiliate thereof, provided that, with respect to clause (i), (ii), (iii), or (iv), (X) the foregoing rights shall not limit MP's or its Affiliates' obligations under the last paragraph of Section 2.2 or Section 2.6, (Y) MP shall maintain the confidentiality of Compound Data pursuant to its obligations under Section 7, and (Z) MP shall, in exercising the foregoing rights, not identify the Compound except to the extent reasonably necessary to exercise such rights. Following exercise of the Option, Cempra shall, reasonably in advance of any public disclosure of any Compound Data, provide a copy of such Compound Data to MP (*provided*, that MP shall maintain such Compound Data in strict confidence, and shall not use such Compound Data for any purpose or disclose the same to any Third Party, unless and until Cempra publicly discloses such Compound Data).

8.2 MP Improvements . MP shall be entitled to sole ownership of all inventions, discoveries, or improvements that are (i) (a) conceived, invented, or otherwise discovered by MP, any Affiliate thereof, or any director, officer, employee, contractor, agent, or representative of any of the foregoing following the Effective Date and prior to the Improvements Date, solely or jointly with Cempra, any Affiliate thereof, any of its or their officers, employees, contractors, agents or other representatives, or any Third Party(ies), as a result of the Parties' interactions or performance under this Agreement or MP's or its Affiliates' access to or knowledge or use or manufacture of the Compound, any Product, or Cempra's Confidential Information or (b) conceived, invented, or otherwise discovered by Cempra, any Affiliate thereof, or any employee, agent, or representative of any of the foregoing, solely or

jointly with MP, any Affiliate thereof, or any employee, agent, or representative of any of the foregoing, following the Effective Date and prior to the Improvements Date as a direct result of Cempra's or its Affiliates' exercise of rights under this Agreement to manufacture the Compound through the practice of MP Technology or Cempra's or its Affiliates' access to, or use or knowledge of, MP Technology or MP's Confidential Information, (ii) directly related to the synthesis or manufacture of one or more Macrolides, and (iii) (X) an improvement to or enhancement or modification of any MP Technology existing as of the Effective Date or (Y) Covered by a Valid Claim of any Initial MP Patent at the time of such conception, invention, or discovery (all such inventions, discoveries, or improvements, and all intellectual property rights with respect thereto, collectively, "MP Improvements"). Cempra shall promptly disclose to MP in writing and in reasonable detail any MP Improvement of which it has knowledge as soon as reasonably possible upon the conception, invention, or other generation of such MP Improvement. MP shall promptly disclose to Cempra any MP Improvement of which it or any Affiliate thereof has knowledge and which pertains to the research, Development, Manufacture, or Commercialization of the Compound or any Product as soon as reasonably possible upon the conception, invention, or discovery of such MP Improvement and, if Cempra provides written notice to MP within thirty (30) days following such disclosure indicating that Cempra wishes to include in the licenses granted to Cempra and its Affiliates under this Agreement the Patents Covering such MP Improvement ("MP Improvement Patents") and/or Know-How Controlled by MP or its Affiliates with respect to such MP Improvement, then such MP Improvement Patent and/or such Know-How, respectively, shall automatically be included in the MP Patents and/or MP Know-How, respectively, for purposes of this Agreement. Cempra will assign and hereby assigns, and will cause its Affiliates to assign, all right, title, and interest in any MP Improvements to MP, free and clear of all liens, claims, and encumbrances (except for such rights thereto granted under this Agreement). Cempra shall take all actions, and shall cause its Affiliates and any officers, employees, contractors, agents or representatives of Cempra or any Affiliate thereof, to take all actions, including but not limited to the execution of patent assignments or other documents, reasonably requested by MP to effect the purposes of the foregoing. Notwithstanding anything to the contrary however, (i) MP's obligations, and Cempra's rights, to the inclusion of MP Improvements in MP Know-How under this Section 8.2 and Section 1.38 shall be subject to Harvard's ownership under the Harvard License of an undivided half interest in any MP Improvement conceived and/or reduced to practice by Dr. Andrew G. Myers ("Myers") (for so long as he is employed by Harvard) in his performance of consulting or other advisory services for MP related to Macrolides for the treatment of disease, (ii) Cempra shall have the right, upon written notice to MP, to terminate the rights granted by license under this Agreement to any MP Improvement Patent(s), and (iii) MP agrees not to disclose any of Cempra's Confidential Information to Myers or, except to the extent required to enable MP to comply with its obligations to Harvard under the Harvard License, Harvard without Cempra's prior written consent.

8.3 Cempra Improvements . Cempra shall be entitled to sole ownership of all inventions, discoveries, or improvements, other than MP Improvements, that (i) are conceived, invented, or discovered by MP, any Affiliate thereof, or any director, officer, employee, contractor, agent, or representative of any of the foregoing following the Effective Date and prior to the Improvements Date, solely or jointly with Cempra, any Affiliate thereof, any of its or their officers, employees, contractors, agents or other representatives, or any Third Party(ies), (ii) result from the Parties' interactions, performance, or exercise of rights under this Agreement

or MP's, its Affiliates', or MP's or its Affiliates' officers', employees', contractors', agents' or representatives' knowledge or use or manufacture of, or access to, Cempra's Confidential Information, the Compound or any Product, and (iii) relate directly and solely to the Compound, a Product, or use of either of the foregoing, and not to the synthesis or manufacture of the Compound or Product (such inventions, discoveries, or improvements, and all intellectual property rights with respect thereto, collectively, the "Cempra Improvements"). MP will promptly notify Cempra in writing and in reasonable detail of any Cempra Improvements. MP will assign and hereby assigns, and will cause its Affiliates and any officers, employees, contractors, agents or representatives of MP or any Affiliate thereof to assign, all right, title, and interest in any Cempra Improvements to Cempra, free and clear of all liens, claims, and encumbrances. MP shall take all actions, and shall cause its Affiliates and any officers, employees, contractors, agents, or representatives of MP or any Affiliate thereof to take all actions, including but not limited to the execution of patent assignments or other documents, reasonably requested by Cempra to effect the purposes of the foregoing. Notwithstanding anything to the contrary however, (x) MP's obligations and Cempra's rights under this Section 8.3 shall be subject to Harvard's ownership under the Harvard License of an undivided half interest in any Cempra Improvement conceived and/or reduced to practice by Myers (for so long as he is employed by Harvard) in his performance of consulting or other advisory services for MP related to Macrolides for the treatment of disease, (y) Cempra shall have the right, upon written notice to MP, to terminate the rights granted by license under this Agreement to any Harvard Patent(s) Covering any Cempra Improvement(s), and (z) MP agrees not to disclose any of Cempra's Confidential Information to Myers or, except to the extent required to enable MP to comply with its obligations to Harvard under the Harvard License, Harvard without Cempra's prior written consent.

8.4 Harvard Improvements . MP shall notify Cempra in writing and in reasonable detail of each Improvement Invention (as defined in the Harvard License) which directly pertains to the Compound or any Product (or any Derivative, to the extent necessary to the manufacture or synthesis of the Compound or a Product), or the use or manufacture of any of the foregoing, as soon as MP receives notice thereof or otherwise becomes aware of such Improvement Invention, with such notice to be provided as soon as reasonably possible following such notice or knowledge thereof, and in any event within fifteen (15) business days thereof. If Cempra provides written notice to MP, within the thirty (30) day period set forth in the Harvard License, indicating that Cempra wishes MP to exercise its option under Section 2.4 of the Harvard License to amend the Harvard License to include Patents Covering such Improvement Invention in the Harvard Patents, MP shall (i) immediately provide notice to Harvard exercising such right and, during the ninety (90) days thereafter and (ii) negotiate in good faith with Harvard and Cempra regarding the upfront fee and development plan necessary to include such Patents in the Harvard Patents, as contemplated by Section 2.4 of the Harvard License, on terms reasonably acceptable to Cempra.

9. TERM AND TERMINATION

9.1 Term. This Agreement shall become effective on the Effective Date and shall continue on a country-by-country and Product-by-Product (and Compound-by-Compound) basis, until the date on which there are no Valid Claims in the MP Patents Covering a particular Product (or Compound) in a particular country, subject to any earlier termination of this

Agreement (the period from the Effective Date until such expiration or termination, the “Term”), provided that, except to the extent Cempra has exercised the Option prior to the end of the Option Period and, therefore, Cempra and its Affiliates have been granted rights under Section 2.3.b., this Agreement shall automatically expire with respect to the Option and the rights granted under Section 2.3.a. as of the end of the Option Period. If Cempra has exercised the Option prior to the end of the Option Period, then, (i) upon expiration (but not termination) of this Agreement as set forth above with respect to a particular Product (and/or Compound) and country or (ii) with respect to any country in which there never were any Valid Claims of any MP Patents covering a particular Product (and Compound), Cempra and its Affiliates shall have a perpetual, irrevocable, fully-paid, royalty-free, exclusive right (transferable in accordance with Section 12.2), with rights of sublicense, under MP Technology to make, have made, use, sell, offer for sale, and import such Product (and Compound) in the Field in such country.

9.2 Termination for Payment Default or Material Breach .

a. If Cempra defaults in the making of any payment as and when due hereunder (including without limitation the payment the Initial License Fee, any Research Funding Payment, any Initial Milestone Payment, Second License Fee or Royalty Payment) MP shall have the right to terminate this Agreement by written notice to Cempra if such non-payment is not cured within thirty (30) Business Days of written notice given by MP to Cempra specifying such non-payment.

b. If either Party materially breaches any other provision of this Agreement at any time, the non-breaching Party shall have the right to terminate this Agreement by written notice to the breaching Party, if (a) such material breach is not cured within sixty (60) Calendar Days of written notice given by the non-breaching Party to the breaching Party specifying such material breach and (b) the non-breaching Party provides notice confirming such termination within sixty (60) Calendar Days following the expiration of such sixty (60) Calendar Day cure period without later cure of such material breach, provided that, notwithstanding anything to the contrary, if such material breach is cured or remedied or shown, in a manner satisfactory to MP in its reasonable discretion, to be non-existent or not material within the aforesaid sixty (60) Calendar Day period or, if later, prior to notice of termination from the non-breaching Party, the non-breaching party’s notice(s) hereunder shall be automatically withdrawn and of no effect.

9.3 Termination for Convenience by Cempra . This Agreement may be terminated by Cempra in its entirety or in part with respect to any particular country(ies) in the Territory, in Cempra's sole discretion, upon sixty (60) Calendar Days' written notice to MP; provided that (i) termination of this Agreement in whole or in part under this Section 9.3 following Cempra's exercise of its Option shall not become effective unless and until (i) Cempra shall have irrevocably paid to MP the amount (if any) by which \$[*] exceeds the total combined sum of the payments made under Section 3.5.b. prior to such termination (and upon such payment, Cempra shall have no further payment obligations to MP under Section 3.5.b), with any amount paid under this clause (i) being fully creditable against amounts due, payable, or owing under Section 3.5, and, if and only if Cempra, an Affiliate thereof, a Sublicensee, or a Product Partner has obtained Regulatory Approval with respect to a Royalty Product and Net Sales have occurred with respect to such Royalty Product prior to termination of this Agreement under this Section 9.3, (ii) Cempra shall have irrevocably paid to MP the amount (if any) by which \$[*] exceeds the total combined sum of the payments made under Section 3.7 prior to such termination (and upon such payment, Cempra shall have no further payment obligations to MP under Section 3.7). Notwithstanding anything to the contrary, (a) Cempra shall not be required to make any payment under clause (ii) above as a condition to termination if either (x) Regulatory Approval with respect to a Royalty Product has not been obtained or (y) no Net Sales of Royalty Products have occurred prior to the effective date of termination and (b) the total aggregate amount payable to MP under Sections 3.5.b., 3.7, and this Section 9.3 shall not in any event exceed \$[*].

9.4 Termination for Bankruptcy. MP may terminate this Agreement upon written notice to Cempra if (i) Cempra becomes insolvent, is adjudged bankrupt, applies for judicial or extra-judicial settlement with its creditors, makes an assignment for the benefit of its creditors, voluntarily files for bankruptcy or has a receiver or trustee (or the like) in bankruptcy appointed by reason of its insolvency, (ii) an involuntary bankruptcy action is filed against Cempra and not dismissed within ninety (90) days, or (iii) Cempra becomes the subject of liquidation or dissolution proceedings or otherwise discontinues business.

9.5 Effects of Termination.

a. Upon any termination in whole or in part of this Agreement occurring following Cempra's exercise of its Option, other than the expiration of this Agreement or a termination of this Agreement by Cempra pursuant to Section 9.3, Cempra, its Affiliates, Sublicensees, and Product Partners shall have the privilege, subject to the payment of royalties as required under Section 3.6 (as they may be adjusted under this Agreement), of (i) completing the Manufacture of Compound or Products that are in the process of Manufacture as of the effective date of such termination (the "Termination Date"), (ii) selling such Compound or Products and all other such Compound or Products in Cempra's, its Affiliates', or Sublicensees', or Product Partners' possession or control as of such termination for a period of one year following such termination upon commercially reasonable conditions, and (iii) completing performance of all contracts entered into with third parties prior to such termination (1) for the marketing, sale, or Manufacture of Compound or Products or (2) requiring the practice of the rights to MP Technology, or the use of Compound or Products, for a period of one year following such termination.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

b. Notwithstanding any provision herein to the contrary, in the event (A) Cempra or an Affiliate thereof has entered into any sublicense agreement granting any Third Party rights to Manufacture, Develop and/or Commercialize Products as permitted by this Agreement, (B) this Agreement is terminated by MP with respect to any such sublicensed rights, and (C) such sublicense is in effect as of such termination, such sublicense granted hereunder and such Sublicensee's rights under such sublicense will, to the extent concerning rights that are subject to such termination and provided in such sublicense, survive such termination, with MP as the Sublicensee's direct licensor, provided that:

(i) such Sublicensee's payment obligations with respect to its exercise of its surviving rights to the rights to MP Technology that are the subject of such termination (but not with respect to its exercise or enjoyment of any other rights or assets) shall not exceed the corresponding payment obligations set forth in this Agreement with respect to the Compound, any Product(s), fields of use, and/or territory(ies) that are the subject of such surviving rights;

(ii) such Sublicensee's collective, aggregate payment obligations with respect to the MP Technology and any other rights granted or transferred by Cempra or MP to such Sublicensee with respect thereto shall not exceed the amounts payable under its agreement with Cempra (or any Affiliate thereof) with respect to all of the foregoing as such agreement was in effect immediately prior to the applicable termination of this Agreement; and

(iii) such Sublicensee delivers to MP within ninety (90) Calendar Days after termination of this Agreement a license agreement, executed by such Sublicensee and proposed thereby for execution by MP, that (a) is consistent with the terms and conditions set forth in this Agreement with respect to the rights to MP Technology subject to such termination under this Agreement, as reasonably modified to be no greater in scope than the scope of the sublicense granted to Sublicensee thereunder with respect to territory, duration/term of sublicense grant, Products, fields of use, etc. (e.g. if the Sublicensee's sublicense to rights subject to termination under this Agreement, as in effect immediately prior to such termination, included rights and obligations only with respect to a particular Product, country, field of use, and/or indication, such license agreement shall only include rights and obligations with respect to such a particular Product, country, field of use, and/or indication) (such a license agreement, a "New License Agreement"), provided that (a) such New License Agreement shall not be required to impose any obligations on such Sublicensee in excess of those obligations of Cempra under this Agreement corresponding to such Sublicensee's rights to MP Technology, and MP shall not be entitled to impose any additional obligations on such Sublicensee as a condition to MP's execution of a New License Agreement therewith; (b) MP shall have no liability to such Sublicensee for any actual or alleged breach of the sublicense agreement under which such Sublicensee was granted rights to MP Technology by the entity (Cempra, an Affiliate thereof, or Sublicensee) that granted such Sublicensee such sublicense; and (c) MP shall not have any obligations to such Sublicensee in excess of those obligations corresponding to, and consistent with, those of MP set forth in this Agreement with respect to the applicable rights of such Sublicensee to MP Technology; and

(iv) MP shall promptly execute any New License Agreement, provided that all of the conditions thereto for the benefit of MP in subclauses (i)-(iii) above have

been materially satisfied, and MP shall not require, as a condition to its exercise of any New License Agreement, that any Sublicensee assume any obligations or liabilities in connection with the rights to MP Technology that are greater than the corresponding obligations and liabilities of Cempra under this Agreement.

The provisions of this Section 9.5.b. must be included, referenced, or otherwise reasonably accounted for in a sublicense agreement with a Sublicensee concerning MP Technology in order for the applicable Sublicensee's rights to survive any termination of this Agreement as set forth above.

9.6 Survival of Rights Upon Harvard License Termination . MP shall provide notice to Cempra immediately upon (i) any termination of the Harvard License, (ii) any receipt of notice from Harvard regarding any actual or threatened termination of the Harvard License or breach of the Harvard License, (iii) MP becoming aware of any other circumstance that may enable Harvard to terminate the Harvard License, and (iv) any notice from Harvard claiming any breach of the Harvard License on the basis of any action, omission, or breach of this Agreement or any sublicense granted hereunder by Cempra, any Affiliate thereof, or any Sublicensee. In the event of any termination of the Harvard License, other than a termination thereof pursuant to the Cempra Breach Proviso (as defined in the Harvard License), if Cempra is not in material breach of this Agreement, (i) the rights granted to Cempra and its Affiliates under the Harvard Patents pursuant to this Agreement (including Cempra's option under Section 2.2) shall automatically survive and continue thereafter as, and pursuant to the terms therefor, set forth in the Harvard Waiver and (ii) Sections 3.5, 3.6, 3.7, 3.10, and 3.12 of this Agreement, all payment and reporting obligations thereunder, and any payment obligations under this Agreement with respect to any Harvard Patents, any products Covered by any Valid Claims thereof, or any infringements thereof shall terminate, and the remaining rights and licenses granted to MP Technology other than Harvard Patents under this Agreement shall become royalty-free and fully-paid, upon termination of the Harvard License (except to the extent any such payments to MP accrued thereunder prior to such termination); for clarity, the foregoing clause (ii) is not intended to reduce Cempra's payment obligations to Harvard under any Post-Termination License (as defined in the Harvard License), but to ensure that Cempra's payment obligations thereunder replace, and are not additive to, the payment obligations to MP referenced above upon termination of the Harvard License.

9.7 Remedies. Any rights or remedies set forth in this Section 9 are not exclusive, and shall not limit any other legal or equitable remedies that are available to the Parties with respect to any breach or other matter under this Agreement.

9.8 Survival. Termination or expiration of this Agreement for any reason will be without prejudice to any rights that will have accrued to the benefit of any Party prior to such termination or expiration, and any termination or expiration of this Agreement shall not relieve either Party of any obligation which has accrued prior to the effective date of such termination or expiration, which obligations shall remain in full force and effect. The following provisions shall survive any expiration or termination of this Agreement: Sections 1, 2.5, 3.14, 3.16, 3.17, 3.18, 6.2.b (with respect to infringement occurring prior to termination or expiration), 6.3, 6.5, 6.6, 6.7, 6.8, 7, 8.1, 8.2, 8.3, 9.1, 9.5, 9.6, 9.7, 9.8, 10.4, 10.5, 11.1, 11.2, 11.3, 11.4, 11.5, 11.6 (to the extent set forth therein), and 12, together with any Sections referenced in such surviving provisions or necessary to give them effect.

10. REPRESENTATIONS, WARRANTIES, AND COVENANTS

10.1 Representations and Warranties of MP. MP represents and warrants to Cempra as of the Effective Date as follows:

- a. MP is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.
- b. MP has full power and authority to execute, deliver and perform this Agreement. There are no liens or other encumbrances on the MP Technology or any portion thereof which would interfere with the rights granted to Cempra hereunder. This Agreement constitutes the legally binding and valid obligation of MP, enforceable in accordance with its terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.
- c. The execution, delivery and performance by MP of this Agreement and the consummation of the transactions contemplated hereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement to which MP or any Affiliate thereof is a party.
- d. There is no action, suit, proceeding or investigation pending or, to MP's and its Affiliates' knowledge, currently threatened in writing against or affecting MP that questions the validity of this Agreement or the right of MP to enter into this Agreement or consummate the transactions contemplated hereby.
- e. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority, or any Third Party, on the part of MP or any Affiliate thereof is required in connection with the execution, delivery and performance of this Agreement.
- f. MP has disclosed in writing to Cempra all Patents Controlled by MP or its Affiliates as of the Effective Date which, to MP's and its Affiliates' knowledge, Cover the Compound or any Product (or any Derivative, to the extent necessary to the manufacture or synthesis of the Compound or any Product), or which are necessary or appropriate to Develop, Manufacture and Commercialize Products, and all such Patents are set forth on Schedule 1.40 attached hereto.
- g. To the best of MP's and its Affiliates' knowledge, there are no inventors of any Initial MP Patents other than those listed as inventors on the Initial MP Patents as they exist as of the Effective Date and, to MP's and its Affiliates' knowledge, there are no pending or threatened disputes over inventorship with respect to any Initial MP Patents.
- h. Except with respect to the Harvard Patents, no research or Development of any MP Technology, or research or other activities, leading to the inventions Covered by the MP Patents was supported in whole or part by funding or grants by any governmental agency or philanthropic or charitable organization.

i. Except with respect to the Harvard Patents, which have been exclusively licensed to MP pursuant to the Harvard License, the MP Technology existing as of the Effective Date is wholly owned by MP, free and clear of all mortgages, pledges, charges, liens, equities, security interests, or other encumbrances or similar agreements (including with respect to any “proceeds”) (including any liens or claims on or to rights to sue for past, present and future infringements thereof, any licenses, claims, damages and proceeds of suit arising therefore, or any payments or rights to payments arising out of the sale, lease, license assignment, or other disposition thereof).

j. Except with respect to the Harvard Patents, which have been exclusively licensed to MP pursuant to the Harvard License, (i) no Third Party or Affiliate of MP has, to MP’s or any Affiliates’ knowledge, any rights or ownership interest in any MP Technology, except for certain limited rights expressly reserved in the Harvard License for the benefit of Harvard and the United States Government, and (ii) neither MP nor any Affiliate thereof has obtained rights to any of the MP Technology by license or any similar contract or agreement with any Third Party. Neither MP nor any Affiliate thereof has granted any Third Party any rights with respect to the MP Technology.

k. Neither MP nor any Affiliate thereof is aware of any Third Party intellectual property rights (including any Patent(s)) that were (prior to the Effective Date) or would be (following the Effective Date) infringed, misappropriated, or otherwise violated by the practice of the technology or inventions described, claimed, or embodied by any MP Technology.

l. No written communication has been received by MP or any Affiliate thereof, and no investigation, regulatory enforcement action (including seizure, injunction, civil penalty or criminal action) or any related Governmental Authority or Regulatory Authority review is or, to the knowledge of the MP or any Affiliate thereof, was at any time pending or is threatened by any Governmental Authority or Regulatory Authority with respect to (i) any alleged or actual violation by MP, any Affiliate thereof, or any contractor of either of the foregoing, of any permit, Applicable Law or other requirement of any Governmental Authority or Regulatory Authority relating to the operations conducted by or on behalf of MP or any Affiliate thereof with respect to any MP Technology or (ii) any alleged or actual failure to have or maintain in effect all permits required in connection with the operations conducted by or on behalf of MP or any Affiliate thereof with respect to any MP Technology.

m. To the knowledge of MP and its Affiliates, MP and its Affiliates have taken all reasonable actions necessary or appropriate to preserve the confidentiality of all trade secrets, proprietary and other confidential information material to the MP Technology.

n. Neither MP nor any Affiliate thereof is aware of any Third Party activities that would constitute misappropriation or infringement of any MP Technology.

o. Neither MP nor any Affiliate thereof owns, controls or has licensed any right, title, and interest to any Regulatory Filings or Regulatory Approvals concerning the Compound or a Product. No Compound or Product Manufactured by or on behalf of MP or any Affiliate thereof has been administered to any human or animal subjects, and no animal or clinical study of the Compound or a Product has been sponsored or performed by or on behalf of MP or any Affiliate thereof.

p. All information provided to Cempra, its Affiliates, and their employees, officers, directors, agents, and other representatives by or on behalf of MP or any Affiliate thereof with respect to the MP Technology has, to the best of MP's and its Affiliates' knowledge, been accurate.

q. There is no pending or, to the knowledge of MP, threatened claim, interference, opposition or demand of any Third Party challenging the ownership, validity or scope of any MP Technology in existence as of the Effective Date, and MP is not aware of any facts from which it could reasonably conclude that any of the MP Patents is invalid or that the exercise thereof would infringe any Patent(s) of Third Parties.

r. To MP's and its Affiliates' knowledge, each item included in the MP Patents that is registered, filed or issued under the authority of an appropriate governmental authority is and at all times has been in compliance with all legal requirements applicable thereto, and all filings, payments, and other actions required to be made or taken to maintain such item of the MP Patents in full force and effect have been made by the applicable deadline, including complying with the required duty of candor and good faith in dealing with the U.S. Patent and Trademark Office, including the duty to disclose as defined in 37 C.F.R. § 1.56 with respect to all U.S. Patents, and any equivalent disclosure requirement in any other country. Furthermore, (1) no patent application or patent included in the MP Patents has been abandoned or allowed to lapse and (2) no provisional patent application included therein has expired without the filing of a nonprovisional patent application that claims the benefit of such provisional patent application.

s. MP and its Affiliates have at all times complied with, and are currently in compliance, in all material respects, with all terms and conditions of the Harvard License. All milestones established under the Harvard License that were required to be achieved by a date prior to the Effective Date have been achieved by the date required therefor.

t. This Agreement, to the extent that it constitutes a sublicense under the Harvard License of MP's rights to the Harvard Patents, constitutes a valid such sublicense granted in accordance with the terms of the Harvard License.

u. MP has, prior to the Effective Date, provided Cempra with a complete, full, and accurate copy of the Harvard License (including but not limited to all amendments thereto and any side letters, waivers, consents, or other arrangements between MP or any Affiliate thereof and Harvard or any Affiliate thereof with respect to the subject matter thereof).

10.2 Covenants of MP. MP will not, and will ensure that none of its Affiliates, grant any rights to any Third Party that would conflict with Cempra's rights under this Agreement.

MP will not grant, and will ensure that none of its Affiliates' grant, any lien or make any assignment of amounts hereunder that would reasonably be expected to adversely affect in any respect any rights or obligations of either Party (or any Affiliate thereof) under this Agreement. MP shall at all times comply with the Harvard License and any other agreement by which MP previously acquired or later acquires Control of any MP Technology.

10.3 Representations and Warranties of Cempra. Cempra represents and warrants to MP as follows as of the Effective Date:

a. Cempra is a corporation, duly incorporated, validly existing and in good standing under the laws of its jurisdiction of incorporation, with full corporate power and authority to operate its properties and to carry on its business as presently conducted.

b. Cempra has full power and authority to execute, deliver and perform this Agreement. This Agreement constitutes the legally binding and valid obligations of Cempra, enforceable in accordance with their terms, except as such enforcement may be limited by applicable bankruptcy, moratorium and other laws affecting creditors' rights generally.

c. The execution, delivery and performance by Cempra of this Agreement and the consummation of the transactions contemplated thereby will not result in any violation of, conflict with, result in a breach of or constitute a default under any contract or agreement material to Cempra, its business or its assets.

d. No consent, approval, order or authorization of, or registration, qualification, designation, declaration or filing with, any federal, state or local governmental authority on the part of Cempra is required in connection with the execution, delivery and performance of this Agreement.

e. There is no action, suit, proceeding or investigation pending or, to Cempra's knowledge, currently threatened in writing against or affecting Cempra that questions the validity of this Agreement or the right of Cempra to enter into this Agreement or consummate the transactions contemplated hereby.

f. There is no action, suit, proceeding or investigation pending or, to Cempra's knowledge, currently threatened against or affecting Cempra or that questions the validity of this Agreement, or the right of Cempra to enter into this Agreement or consummate the transactions contemplated hereby and, to Cempra's knowledge, there is no reasonable basis for the foregoing.

10.4 Cempra Covenant. To the extent this Agreement constitutes a sublicense under the Harvard License, Cempra shall not be entitled to enter into any agreement under which Cempra grants to or otherwise creates in any Third Party a security interest in this Agreement or any of the rights granted to Cempra herein, provided that, notwithstanding the foregoing, Cempra, its Affiliates, and Sublicensees shall be entitled to grant or create a security interest in this Agreement and/or any sublicenses granted under either of the foregoing in connection with a blanket lien (subject to customary and reasonable exclusions) granted to institutional lenders to secure debt instruments held by such lenders.

10.5 Disclaimer. EXCEPT FOR THE EXPRESS WARRANTIES SET FORTH IN THIS AGREEMENT, INCLUDING SECTIONS 12.1 AND 12.3, AS APPLICABLE, THE PARTIES MAKE NO REPRESENTATIONS AND GRANT NO WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND THE PARTIES EACH SPECIFICALLY DISCLAIM ANY OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE, OR AS TO THE SUCCESS OR LIKELIHOOD OF SUCCESS OF THE RESEARCH, DEVELOPMENT, MANUFACTURE OR COMMERCIALIZATION OF THE COMPOUND OR ANY PRODUCT UNDER THIS AGREEMENT.

11. INDEMNITIES ; LIMITS ON LIABILITY

11.1 Indemnification by MP. Subject to Section 11.3, MP hereby agrees to defend, indemnify and hold harmless Cemptra and its Affiliates, and each of their directors, officers and employees (“Cemptra Indemnitees”), from and against all suits, claims, proceedings or causes of action brought by Third Parties (“Claims”), and all associated damages, liabilities, expenses and/or loss, including reasonable legal expenses and reasonable attorneys’ fees (“Losses”), to the extent arising out of MP’s, its Affiliates’, or MP’s or its Affiliates’ officers’, directors’, employees’, contractors’, agents’, or other representatives’ (i) negligence or willful misconduct with respect to this Agreement or the subject matter hereof, (ii) breach of this Agreement, or (iii) failure to comply with any Applicable Law with respect to this Agreement or the subject matter hereof, or (iv) practice or use of any MP Technology, except to the extent such Losses result from the negligence or willful misconduct, breach of this Agreement, or failure to comply with Applicable Laws on the part of, in each case, any Cemptra Indemnitee.

11.2 Indemnification by Cemptra. Subject to Section 11.3, Cemptra hereby agrees to indemnify, defend and hold harmless MP and its Affiliates, and each of their officers, directors and employees (collectively, “MP Indemnitees”) from and against any Claims and all associated Losses to the extent arising out of Cemptra’s, its Affiliates’, or Cemptra’s or its Affiliates’ officers’, directors’, employees’, agents’, or other representatives’ (i) negligence or willful misconduct with respect to this Agreement or the subject matter hereof, (ii) breach of this Agreement, or (iii) failure to comply with Applicable Laws with respect to this Agreement or the subject matter hereof, except to the extent such Losses result from the negligence or willful misconduct, breach of this Agreement, or failure to comply with Applicable Laws on the part of, in each case, any MP Indemnitee.

11.3 Indemnification Procedures . Each Party’s agreement to indemnify, defend, and hold harmless under Section 11.1 or 11.2, as applicable, is conditioned upon the indemnified party (a) providing written notice to the indemnifying Party of any claim, demand or action arising out of the indemnified matter as soon as reasonably possible, and in any event no later than within thirty (30) Calendar Days after the indemnified Party has actual knowledge of such claim, demand or action, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any such claim, demand or action, (c) assisting the indemnifying Party, at the indemnifying Party’s reasonable expense, in the investigation, preparation, defense, and settlement or

voluntary disposition of any such claim, demand or action, and (d) not compromising, settling, or entering into any voluntary disposition of any such claim, demand or action without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld; provided, however, that, if the party entitled to indemnification fails to promptly notify the indemnifying Party pursuant to the foregoing clause (a), the indemnifying Party will only be relieved of its indemnification obligation to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any claim, demand or action in any manner that admits material fault or wrongdoing on the part of the indemnified party or incurs non-indemnified liability on the part of the indemnified party without the prior written consent of the indemnified party, and in no event may the indemnifying Party settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which may adversely affect any portion of the MP Technology, any Patents owned, controlled, or licensed by Cempra, or Cempra's, its Affiliates', Sublicensees', or Product Partners' ability to Manufacture or Commercialize Products, without Cempra's prior written consent.

11.4 Harvard Indemnity . Cempra shall indemnify, defend and hold harmless Harvard and its current and former directors, governing board members, trustees, officers, faculty, medical and professional staff, employees, students, and agents and their respective successors, heirs and assigns (collectively, the "Harvard Indemnitees") from and against any claim, liability, cost, expense, damage, deficiency, loss or obligation of any kind or nature (including reasonable attorneys' fees and other costs and expenses of litigation), due to any third party claim based upon, or arising out of the practice by or on behalf of Cempra, any of its Affiliates, or Sublicensees of license rights granted under this Agreement, including any cause of action relating to product liability concerning any product, process, or service made, used, sold or performed pursuant to any right or license granted by MP under this Agreement (collectively, "Harvard Claims"). The previous sentence will not apply to the extent that any Harvard Claim is determined with finality by a court of competent jurisdiction to result from the gross negligence or willful misconduct of a Harvard Indemnitee or from any breach by Harvard of a representation made under Section 8.1 of the Harvard License. MP will notify Cempra of any Harvard Claim hereunder as soon as reasonably practicable after it receives notice or otherwise becomes aware of a Harvard Claim, provided that Harvard's or MP's failure to notify of a Harvard Claim will relieve Cempra from liability for indemnification only if and to the extent Cempra did not otherwise promptly learn of such Harvard Claim and such failure results in additional costs, expenses or liability of Cempra this Section 11.4. MP and Harvard shall permit Cempra to assume direction and control of the defense of the Harvard Claim (including the right to settle the Harvard Claim, solely at Cempra's expense); provided, however, that Cempra shall not settle any Harvard Claim without the prior written consent of Harvard where such settlement (a) would include any admission of liability on the part of any Harvard Indemnitee, (b) would impose any restriction on any Harvard Indemnitee's conduct of any of its activities, or (c) would not include an unconditional release of all Harvard Indemnitees from all liability for claims that are the subject matter of the settled Harvard Claim. MP and Harvard shall (i) cooperate as reasonably requested (at the expense of Cempra) in the investigation and defense of any Harvard Claim and (ii) not settle a Harvard Claim (or, in the case of MP, permit Harvard to settle a Harvard Claim) without the express written consent of Cempra. Cempra agrees that the Harvard Indemnitees are intended third-party beneficiaries of this Agreement solely for purposes of enforcing Cempra's obligations under this Section 11.4.

11.5 Limitation of Liability . IN NO EVENT SHALL EITHER PARTY OR ITS AFFILIATES BE LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, SPECIAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES, WHETHER BASED UPON A CLAIM OR ACTION OF CONTRACT, WARRANTY, NEGLIGENCE, STRICT LIABILITY OR OTHER TORT, OR OTHERWISE, ARISING OUT OF THIS AGREEMENT, PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 11.1, 11.2, OR 11.4 ABOVE OR EITHER PARTY’S LIABILITY FOR PATENT INFRINGEMENT OR BREACH OF SECTION 7.

11.6 Insurance.

a. General. Each Party shall carry and maintain insurance of the types and in amounts that are reasonable and customary in the pharmaceutical industry for companies of comparable size and activities. Such insurance will insure against all liability, including but not limited to, bodily injury or property damage arising out of the Manufacture, sale, distribution, marketing, Development or Commercialization of Products. Such insurance shall include commercial general liability insurance, including product liability insurance, which coverage shall have limits of liability that are commercially reasonable for the pharmaceutical industry. Such coverage shall be maintained by each party for not less than three (3) Calendar Years following expiration or termination of this Agreement or if such coverage is of the “claims made” type, for five (5) Calendar Years following expiration or termination of this Agreement. Upon written request from a Party, the other Party shall promptly provide written evidence (e.g., certificates) of such insurance that is reasonably satisfactory to the requesting Party. Notwithstanding the foregoing, commencing at the time any Product is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Cempra, an Affiliate thereof, a Sublicensee or a Product Partner or an agent of Cempra, Cempra shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$[*] per incident and \$[*] annual aggregate and naming MP as an additional insured. During clinical trials of any such Product, Cempra shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable amounts, naming MP as an additional insured. Such commercial general liability insurance shall provide: (a) product liability coverage and (b) broad form contractual liability coverage for Cempra’s indemnification obligations under Section 11.2.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

b. Harvard Obligation. For so long as the Harvard License is in effect and the rights to MP Patents granted hereunder include rights to any Harvard Patents (and any longer period as set forth below):

i. Beginning at the time any Harvard Product is being commercially distributed or sold (other than for the purpose of obtaining regulatory approvals) by Cempra, an Affiliate thereof, a Sublicensee, or an agent of Cempra, Cempra shall, at its sole cost and expense, procure and maintain commercial general liability insurance in amounts not less than \$[*] per incident and \$[*] annual aggregate and naming the Harvard Indemnitees as additional insureds. During clinical trials of any such Harvard Product, Cempra shall, at its sole cost and expense, procure and maintain commercial general liability insurance in commercially reasonable amounts, naming the Harvard Indemnitees as additional insureds. Such commercial general liability insurance shall provide: (a) product liability coverage and (b) broad form contractual liability coverage for Cempra's indemnification obligations under Section 11.4.

ii. If Cempra elects to self-insure all or part of the limits described above in this Section 11.6.b. (including deductibles or retentions that are in excess of \$[*] annual aggregate) such self-insurance program must be acceptable to Harvard and CRICO/RMF (Harvard's insurer) in their sole discretion. The minimum amounts of insurance coverage required shall not be construed to create a limit of Cempra's liability with respect to its indemnification obligations under Section 11.4.

iii. Cempra shall provide Harvard with written evidence of such insurance upon request of Harvard or MP within ten (10) days after such request. Cempra shall provide Harvard and MP with written notice at least fifteen (15) days prior to the cancellation, non-renewal or material change in such insurance that would result in non-compliance with clause i. or ii. of this Section 11.6.b. and shall obtain replacement insurance providing comparable coverage within such fifteen (15) day period.

iv. Cempra shall maintain such commercial general liability insurance beyond the expiration or termination of this Agreement during: (a) the period that any Harvard Product is being commercially distributed or sold by Cempra, an Affiliate thereof, a Sublicensee, or an agent of Cempra and (b) a reasonable period after the period referred to in (a) above which in no event shall be less than ten (10) years.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

12. MISCELLANEOUS

12.1 Force Majeure . 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, which may include, but shall not be limited to, fire, floods, embargoes, power shortage or failure, acts of war (whether war be declared or not), insurrections, riots, terrorism, civil commotions, strikes, lockouts or other labor disturbances, acts of God or any acts, omissions or delays in acting by any Governmental Authority or the other Party, provided that, notwithstanding the foregoing, the payment of amounts due under this Agreement may not be delayed due to a force majeure affecting the Party required to make such payment.

12.2 Assignment . Neither Party may assign this Agreement, or any of its rights or obligations hereunder without the other Party's prior written consent, which consent shall not be unreasonably withheld, and Cempra may not assign this Agreement without Harvard's prior written consent, provided that, notwithstanding the foregoing, (a) either Party shall be entitled, without the other Party's prior written consent (and, in the case of an assignment by Cempra, without Harvard's prior written consent), to assign or transfer this Agreement: (i) in connection with the transfer or sale of all or substantially all of its assets or business (or that portion thereof related to the subject matter of this Agreement), (ii) in the event of such Party's merger, consolidation, reorganization, change of control or similar transaction, or (iii) to an Affiliate of such Party and (b) any assignee of this Agreement agrees in writing to be bound by the terms of this Agreement and to assume all obligations of its assignor arising under this Agreement following such assignment. Any purported assignment by a Party of this Agreement or any of such Party's rights or obligations hereunder in violation of this Section 12.2 shall be void. Any permitted assignee of either Party shall, as a condition to such assignment, assume all obligations of its assignor arising under this Agreement following such assignment. Any purported assignment by a Party of this Agreement or any of such Party's rights or obligations hereunder in violation of this Section 12.2 shall be void.

12.3 Severability . If one or more provisions of this Agreement is held to be invalid, illegal or unenforceable, the Parties shall substitute, by mutual consent, valid provisions for such invalid, illegal or unenforceable provisions which valid provisions are, in their economic effect, 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 the event that such provisions cannot be agreed upon, the invalidity, illegality or unenforceability of one or more provisions of the Agreement shall not affect the validity of this Agreement as a whole.

12.4 Notices . Any notice, consent or report required or permitted to be given or made under this Agreement by one Party to the other Party shall be in English and in writing, delivered personally or by U.S. first class mail or express courier providing evidence of receipt, postage prepaid (where applicable), at the following address for a Party (or such other address for a Party as may be specified by like notice):

To Cempra:

Cempra Pharmaceuticals, Inc.
6320 Quadrangle Dr. #360
Chapel Hill, NC 27517
Attn: Chief Executive Officer or President

With a copy (which shall not constitute notice) to:

Wyrick Robbins Yates & Ponton LLP
4101 Lake Boone Trail, Suite 300
Raleigh, NC 27607
Attn: Jason S. Wood

To MP:

Macrolide Pharmaceuticals, Inc.
480 Arsenal St., Suite 130
Watertown, MA 02472
Attn: President and Chief Executive Officer

With a copy (which shall not constitute notice) to:

Mintz Levin Cohn Ferris Glovsky and Popeo, P.C.
One Financial Center
Boston, MA 02111
Attention: Lewis J. Geffen

All such notices, consents or reports shall be effective upon receipt.

12.5 Applicable Law; Jurisdiction . This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of Delaware, excluding that body of law known as choice of law, and shall be binding upon the Parties hereto in the United States and worldwide. All disputes with respect to this Agreement shall be brought and heard either in the Delaware state courts located in New Castle County, Delaware or the federal district court for the State of Delaware located in Wilmington, Delaware. The Parties each consent to the *in personam* jurisdiction and venue of such courts. The Parties agree that service of process upon them in any such action may be made if delivered in person, by courier service, by telegram, by telefacsimile or by first class mail, and shall be deemed effectively given upon receipt. The United Nations Convention on Contracts for the International Sale of Goods is expressly disclaimed by the Parties with respect to this Agreement and the transactions contemplated hereby.

12.6 Entire Agreement . This Agreement (including any Schedules or Exhibits attached hereto) contains the entire agreement by the Parties with respect to the subject matter hereof and supersedes any prior express or implied agreements, understandings and representations, either oral or written, which may have related to the subject matter hereof in any way.

12.7 Interpretation . The captions to the several Sections of this Agreement are not a part of this Agreement, but are included for convenience of reference and shall not affect its meaning or interpretation. In this Agreement: (a) the word "including" shall be deemed to be

followed by the phrase “without limitation”, “including but not limited to”, or like expression; (b) the singular shall include the plural and *vice versa* ; and (c) masculine, feminine and neuter pronouns and expressions shall be interchangeable.

12.8 Independent Contractors . It is expressly agreed that Cempra and MP shall be independent contractors and that the relationship between the two Parties shall not constitute a partnership, joint venture or agency or other fiduciary relationship. Neither Cempra nor MP 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.

12.9 Waiver; Amendment . Except as otherwise expressly provided in this Agreement, any term of this Agreement may be waived only by a written instrument executed by a duly authorized representative of the Party waiving compliance. The delay or failure of any Party at any time to require performance of any provision of this Agreement shall in no manner affect such Party’s rights at a later time to enforce the same. This Agreement may be amended, and any term of this Agreement may be modified, only by a written instrument executed by a duly authorized representative of each Party.

12.10 Binding Effect . This Agreement shall be binding upon and inure to the benefit of the Parties and their respective legal representatives, successors and permitted assigns.

12.11 Counterparts . This Agreement may be executed in two (2) or more counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument. Facsimile and other electronically scanned signatures shall have the same effect as their originals.

12.12 United States Dollars . References in this Agreement to “Dollars”, “dollars”, or “\$” shall mean the legal tender of the United States of America.

12.13 No Strict Construction . This Agreement has been prepared jointly and shall not be strictly construed against either Party.

12.14 Responsibility for Affiliates. The Parties recognize that each Party may perform some or all of its obligations, or exercise its rights, 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. Any breach of any provision of this Agreement by any Affiliate of a Party shall be deemed a breach hereof by such Party, with such Party being liable hereunder with respect to such breach as if such Party itself had breached this Agreement.

12.15 Use of Name . Except as explicitly permitted or contemplated by this Agreement, Cempra shall not, and shall ensure that its Affiliates and Sublicensees do not, use or register Harvard’s name (alone or as part of another name) or any logos, seals, insignia or other words, names, symbols or devices that identify Harvard or any Harvard school, unit, division or affiliate (“Harvard Names”) for any purpose except with the prior written approval of, and in accordance with restrictions required by, Harvard. Without limiting the foregoing, Cempra shall cease, and shall ensure that its Affiliates and Sublicensees cease, all use of the Harvard

Names, on the termination or expiration of the earlier of the Harvard Agreement or this Agreement, except as otherwise approved by Harvard. The restrictions of this Section 12.15 shall not apply to any information required by law, regulation, or the rules of any securities exchange to be disclosed.

[S IGNATURE PAGE TO FOLLOW .]

I N W ITNESS W HEREOF , the Parties have executed this Agreement by their proper officers as of the date and year first above written.

MACROLIDE PHARMACEUTICALS, INC.

B Y : / S / L AWRENCE M ILLER

N A M E L AWRENCE M ILLER

:

T I T L E : P R E S I D E N T

CEMPRA PHARMACEUTICALS, INC.

B Y : / S / P RABHAVATHI F ERNANDES

N A M E P RABHAVATHI F ERNANDES , P H .D.

:

T I T L E : P R E S I D E N T A N D C H I E F E X E C U T I V E O F F I C E R

EVALUATION PROGRAM

[*]

[*] **Confidential treatment requested; certain information omitted from two pages and filed separately with the SEC.**

SCHEDULE 1.40

MP PATENTS

Harvard Patents

<u>Docket # 4712</u> <u>Country</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Status</u>
Australia	2014248014	April 4, 2014	Pending
Brazil	BR112015025159-5	April 4, 2014	Pending
Canada	2908575	April 4, 2014	Pending
China	201480031522.6	April 4, 2014	Pending
Europe	14779590.0	April 4, 2014	Pending
Israel	241878	April 4, 2014	Pending
India	9189/DELNP/2015	April 4, 2014	Pending
Japan		April 4, 2014	Pending
Korea	10-2015-7031656	April 4, 2014	Pending
Mexico	MX/A/2015/014026	April 4, 2014	Pending
PCT	PCT/US2014/033025	April 4, 2014	National Phase
United States	61/808,441	April 4, 2013	Expired
Unites States	61/832,639	June 7, 2013	Expired
United States	61/946,604	Feb. 28, 2014	Expired
United States	14/781,719	Oct. 1, 2015	Pending
United States	62/061,571	Oct. 8, 2014	Expired
PCT	PCT/US2015/054700	Oct. 8, 2015	Pending

<u>Docket # 5716</u> <u>Country</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Status</u>
United States	62/138,198	March 25, 2015	Pending

<u>Docket # 5629</u> <u>Country</u>	<u>Application No.</u>	<u>Filing Date</u>	<u>Status</u>
United States	62/138,168	March 25, 2015	Pending

MP Patents Other Than Harvard Patents

None as of the Effective Date.

SCHEDULE 3.3-1

EVALUATION LICENSE PAYMENTS

<u>Initial Milestone Payment Trigger</u>	<u>Expected Delivery Date</u>	<u>Initial Milestone Payment</u>
[*]	Approximately [*] after the Effective Date	\$[*]
[*]	Approximately [*] after the Effective Date	\$[*]
[*]	Approximately [*] after the Effective Date	\$[*]

[*] Confidential treatment requested; certain information omitted from one page and filed separately with the SEC.

SCHEDULE 3.3-2A

EVALUATION LICENSE PAYMENT #1 - MP MATERIALS SPECIFICATIONS

[*]

[*] **Confidential treatment requested; certain information omitted from one page and filed separately with the SEC.**

SCHEDULE 3.3-2B

EVALUATION LICENSE PAYMENTS #2 AND #3 - MP MATERIALS SPECIFICATIONS

[*]

[*] **Confidential treatment requested; certain information omitted from one page and filed separately with the SEC.**

SCHEDULE 3.3-2C
RELATED SUBSTANCES

[*]

[*] Confidential treatment requested; certain information omitted from four pages and filed separately with the SEC.

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

API MANUFACTURING AND SUPPLY AGREEMENT

T HIS API M ANUFACTURING AND S UPPLY A GREEMENT (the “ **Agreement** ”) is entered into as of _____, 2015 (the “ **Effective Date** ”) by and between **Cempra Pharmaceuticals, Inc.** , a company organized under the laws of Delaware, USA with a place of business at 6340 Quadrangle Drive, Suite 100, Chapel Hill, NC 27517, USA (“ **Cempra** ”), and **FUJIFILM F INECHEMICALS C O., L TD.** , a company organized under the laws of Japan with a place of business at 2-3, Higashiyawata 5-chome, Hiratsuka, Kanagawa 254-0016, Japan (“ **FFFC** ”). Cempra and FFFC may be referred to herein individually as a “ **Party** ”, and collectively as the “ **Parties** ”.

R ECITALS

A. Cempra and FFFC’s Affiliate, Toyama Chemical Co., Ltd. (“ **Toyama** ”), are parties to an Exclusive License and Development Agreement dated May 8, 2013 (the “ **Toyama License Agreement** ”) and a Supply Agreement dated May 8, 2013 (the “ **Toyama Supply Agreement** ”), under which Toyama obtained a license from Cempra to develop and commercialize certain products incorporating the API (as defined below) in Japan and Cempra agreed to supply Toyama with API for development and commercial purposes.

B. Cempra desires to engage FFFC to manufacture and supply to Cempra quantities of API for use in manufacturing solithromycin-based drug products.

C. FFFC possesses or plans to build the necessary facilities, equipment, manufacturing technology, professional expertise, personnel, and capacity to manufacture and supply such API, and desires to undertake such API manufacturing and supply for Cempra under the terms of this Agreement.

D. The Parties intend to conduct certain activities as part of preparing for the commercial manufacture and supply of API, which may include construction of a manufacturing plant, technology transfer, manufacture of registration lots, process development, process validation, stability studies and other pre-approval activities with respect to the manufacture of API under the terms of this Agreement.

N OW, T HEREF ORE , the Parties hereby agree as follows:

1. D EFINITIONS

The following capitalized words and phrases when used in this Agreement shall have the meaning provided in this **Section 1** .

1.1 “Acceptance Tests” means the specific tests to be used to determine whether API manufactured by FFFC conforms to the API Specifications, which tests shall be established (and amended from time to time if required) in writing by Cempra in consultation with FFFC.

1.2 “Affiliate” means, with respect to a particular Party, any corporation, organization, or other business entity that, directly or indirectly, controls, is controlled by, or is under common control with such Party. The term “control” (including, with correlative meaning, the terms “controlled by” and “under common control with”), as used in this **Section 1.2**, means the possession of the power to direct, or cause the direction of, the management and business of the applicable corporation, organization, or other business entity, whether through the ownership or control of voting securities (or their voting power) or by contract, or court order, or otherwise.

1.3 “API” means the active pharmaceutical ingredient known as solithromycin as further described in *Exhibit A* of this Agreement (“**Solithromycin**”).

1.4 “API Improvements” means inventions, discoveries know-how or improvements specifically related to API or API Manufacturing Procedures (including analytical methods, manufacturing processes and packaging) that FFFC invents, develops, creates, discovers, conceives, or reduces to practice, in connection with or arising from its activities under this Agreement.

1.5 “API Manufacturing Procedures” means the specific methods, techniques, processes and standard operating procedures (including Quality Control Procedures) that are to be used by FFFC (or any of its Affiliates or subcontractors) in manufacturing the API under this Agreement in accordance with the API Specifications.

1.6 “API Specifications” mean the specifications, characteristics, qualities and labeling and packaging requirements established by Cempra in writing for API, with which API must conform (including release criteria and associated analytical methods), as such may be amended from time to time under the terms of this Agreement. The API Specifications shall be attached to this Agreement as *Exhibit B*.

1.7 “Applicable Laws” means collectively all laws, regulations, ordinances, decrees, judicial and administrative orders, policies and other requirements of any applicable Regulatory Authority that cover or apply to the manufacture, supply, or distribution of API for use in human pharmaceuticals, including the FD&C Act and the regulations administered by the FDA (including 21 C.F.R. Parts 11, 210 and 211), any equivalent laws, rules, and regulations in the Territory, and the following to the extent not in conflict with any laws or regulations that are issued or enforced by the FDA, MHLW, and other Regulatory Authorities as in effect during the provision of and applicable to API Manufacturing and other services provided by FFFC hereunder: (a) USP/NF/EP and other applicable compendia standards; (b) guidance documents (including Guidelines, Points to Consider, Inspection Technical Guides, International Conference on Harmonization “Step 4 and 5” documents); and (c) cGMP.

1.8 “Batch” means the total amount of Intermediate or API manufactured in one particular production run conducted by FFFC (or any of its Affiliates or subcontractors) for manufacturing API.

1.9 “Batch Record” means, with respect to a particular production run conducted by FFFC for manufacturing one Batch of Intermediate or API, the completed manufacturing records, in the form of an executed Master Batch Record, for such production run containing all the relevant manufacturing details and information for the run, including quality control information and any deviations, and reviewed and approved by Quality Assurance.

1.10 “Cempra Licensed Patents” means those Patents in the Territory listed on *Exhibit C* attached hereto and any Patents in the Territory claiming priority to such Patents that are Controlled by Cempra.

1.11 “Certificate of Analysis” means a written document, for example in the form set forth in *Exhibit D* of this Agreement, which confirms that the quantity of the API manufactured and delivered by FFFC has been tested in accordance with the applicable Acceptance Tests and meets the API Specifications. The Certificate of Analysis will include the results of all Acceptance Tests performed by FFFC or, to the extent permitted by this Agreement, on behalf of FFFC by qualified Third Party subcontractors on the particular Batch of API.

1.12 “Certificate of Compliance” means a document, in a form acceptable to Cempra, from FFFC that approves the release of API to Cempra and certifies that the manufacturing and supply of the API has been performed in compliance with all Applicable Laws, including cGMP requirements.

1.13 “CMC ” means the Chemistry, Manufacturing and Controls sections of any Regulatory Submission (including an IND, DMF, NDA, or equivalent of any of the foregoing in the Territory), as defined by Applicable Laws.

1.14 “ Confidential Information ” means all information and know-how and any tangible or intangible embodiments thereof provided by or on behalf of one Party (the “ **Disclosing Party** ”) to the other Party (the “ **Receiving Party** ”) from time to time either in connection with the discussions and negotiations, whether in written or oral form, pertaining to this Agreement, or in the course of performing under or acting in relation to this Agreement, which may include data, knowledge, practices, processes, ideas, research plans, formulation or manufacturing processes and techniques, scientific, manufacturing, marketing and business plans, and financial and personnel matters relating to the Disclosing Party or to its present or future products, sales, suppliers, customers, employees, investors or business; provided, that, information or know-how of a Party will not be deemed Confidential Information of such Party for purposes of this Agreement if such information or know-how: (a) was already known to the Receiving Party, other than under an obligation of confidentiality or non-use, at the time of disclosure to such Receiving Party, as can be shown by written records; (b) was generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or was otherwise part of the public domain, at the time of its disclosure to such Receiving Party; (c) became generally available or known to parties reasonably skilled in the field to which such information or know-how pertains, or otherwise became part of the public domain, after its disclosure to such

Receiving Party through no fault of the Receiving Party; (d) was disclosed to such Receiving Party, other than under an obligation of confidentiality or non-use, by a Third Party who had no obligation to the Disclosing Party not to disclose such information or know-how to others, as can be shown by written records; or (e) was independently discovered or developed by such Receiving Party, as can be shown by its written records, without the use or benefit of, or reliance on, Confidential Information of the Disclosing Party. Notwithstanding anything to the contrary, (i) all information provided to Cempra, any Affiliate thereof, or any of Cempra's or its Affiliates' licensees by or on behalf of FFFC concerning API and (ii) the terms of this Agreement shall each be deemed the Confidential Information of both Parties.

1.15 "Control" means, with respect to any intellectual property or right therein, the possession by Cempra of the ability to enable FFFC to practice under such rights in its manufacture of API hereunder as provided for herein without violating the terms of any arrangement or agreements between Cempra (or any Affiliate thereof) and any Third Party

1.16 "Cover" means that the use, manufacture, sale, offer for sale, development, commercialization or importation of the subject matter in question by an unlicensed entity would infringe a Valid Claim of a Patent.

1.17 "Current Good Manufacturing Practices" or "cGMP" means the then-current standards for the manufacture of pharmaceutical products, pursuant to (a) the FD&C Act; (b) relevant United States regulations in Title 21 of the United States Code of Federal Regulations (including Parts 11, 210, and 211); (c) EC Directive 2003/94 EC of October 8, 2003; (d) the EC Guide to Good Manufacturing Practice for Medicinal Intermediate Products; (e) International Conference on Harmonization ("ICH") ICH Q7A Good Manufacturing Practice Guidance for Active Pharmaceutical Ingredients; (f) MHLW Ministerial Ordinance No. 179, 2004, MHW Ministerial Ordinance No. 2, 1961, and GMP Guideline for Drugs and Quasi-Drugs (Drug Products) 2005 and (g) all additional Regulatory Authority documents or regulations that replace, amend, modify, supplant or complement any of the foregoing.

1.18 "DMF" means a Drug Master File, as provided for in Article 80-6 of Japan's Pharmaceutical Products and Medical Equipment Law or similar submission to or file maintained with the MHLW or other Regulatory Authority that may be used to provide confidential detailed information about facilities, processes, or articles used in the manufacturing, processing, packaging, and storing of one or more human drugs or APIs.

1.19 "Drug Product" means a finished dosage form of human pharmaceutical product containing API as an active pharmaceutical ingredient, alone or in combination with one or more other active pharmaceutical ingredients.

1.20 "Facility" means the specific premises of FFFC (or its Affiliates or its subcontractors) where the API is Manufactured, as identified in *Exhibit E* of this Agreement.

1.21 "FDA" means the United States Food and Drug Administration or any successor thereto.

1.22 "FD&C Act" means the United States Food, Drug and Cosmetic Act (21 U.S.C. 321 et seq.), as amended from time to time.

1.23 “FFFC Quality System” means the procedures and control documentation that FFFC has in place at its Facility during the Term that are necessary to evidence compliance with cGMP and all ICH guidelines, as well as any other requirements necessary to Manufacture the API in compliance with all Applicable Laws (including cGMP requirements) and the API Specifications.

1.24 “IND” means an investigational new drug application filed with the MHLW, in order to commence human clinical testing of a drug.

1.25 “Intermediates” means any of the compounds produced in the intermediate Manufacturing steps beginning with the initial modification of the relevant Raw Material and prior to the completion of final manufacturing steps to produce the API.

1.26 “Losses” means any and all judgments, liabilities, losses, costs, damages and expenses (including, without limitation, reasonable attorneys’ fees and legal and court costs) together with any related interest, fines and penalties, resulting from any Claim (as defined below).

1.27 “Lot” means one (1) discrete quantity of API as that term is defined under Title 21 of the United States Code of Federal Regulations §210(b)(10), specifically a batch, or a specific identified portion of a batch, having uniform character and quality within specified limits; or, in the case of a drug product produced by continuous process, it is a specific identified amount produced in a unit of time or quantity in a manner that assures its having uniform character and quality within specified limits.

1.28 “Manufacture” or **“Manufacturing”** means the steps and activities conducted to produce the API from Raw Material and/or Intermediate in accordance with the API Manufacturing Procedures and the Master Batch Records, including obtaining all other needed raw materials and reagents, manufacturing steps and processing, packing, labeling, holding, testing, and quality control of the API and/or Intermediates, and actions taken to comply with Applicable Laws with respect to such manufacturing activities (*e.g.*, equipment, methods and operations).

1.29 “Marketing Approval” means an approval by MHLW to commence commercial marketing and distribution of the Drug Product for human therapeutic, prophylactic, or palliative use, or comparable approvals or registrations in countries or jurisdictions outside the Territory, including amendments and supplements to such approvals.

1.30 “Master Batch Record” means a controlled document specifying the procedures to Manufacture the API or an Intermediate as established by the Parties under **Section 2.2** , including all applicable API Manufacturing Procedures, the in-process testing and release testing which are to be used in the Manufacture by FFFC hereunder of API.

1.31 “MHLW” means Japanese Ministry of Health, Labor and Welfare, or any successor thereto, including the Pharmaceuticals and Medical Devices Agency.

1.32 “NDA” means a New Drug Application for Marketing Approval filed in the United States.

1.33 “Non-Conforming API” means API delivered by FFFC that does not comply with the API Specifications, that is otherwise defective, or that otherwise does not comply with the warranties set forth in **Sections 7.4 and 7.5** .

1.34 “ Out of Specification ” or “ **OOS** ” means failure of API to meet the API Specifications.

1.35 “ Patents ” means any granted patents and pending patent applications, together with all additions, divisionals, continuations, continuations-in-part, substitutions, reissues, re-examinations, extensions, registrations, patent term extensions, revalidations, supplementary protection certificates, and renewals of any of the foregoing, and all foreign applications and patents corresponding to or claiming priority from any of the foregoing.

1.36 “ Project Manager” means the individuals designated by FFFC and Cempra, respectively, to act as managers for the manufacturing project under this Agreement as provided in **Section 3.1** .

1.37 “ Quality Agreement ” means the document mutually agreed upon by the Parties, a copy of which shall be attached hereto as **Exhibit F** , which contains the policies, procedures, and standards by which the Parties will coordinate and implement the operational and quality assurance activities needed to efficiently achieve regulatory compliance objectives, and as such agreement may be amended from time to time by the Parties in writing.

1.38 “ Product Failure ” means (a) as indicated in writing by Cempra to FFFC, no Drug Product will be marketed or further developed by or on behalf of Cempra, any Affiliate thereof, or any of its or their licensees in the Territory or (b) Drug Product is taken off the market or no longer able to be marketed in the Territory by or on behalf of Cempra, any Affiliate thereof, or any of its or their licensees in the Territory for the following reasons: (i) any non-approvable or rejection letter or withdrawal of a Marketing Approval application in the Territory or any order from Regulatory Authority withdrawing Drug Product from the market or otherwise suspending use of Drug Product in the Territory, (ii) any serious safety problem with respect to the Drug Product, or (iii) any infringement of Patents or infringement or misappropriation of other intellectual property right arising from the manufacture, development, use, or commercialization of Drug Product or manufacture of API hereunder, which the terminating Party in reasonably determines in good faith cannot be reasonably and promptly resolved after consultation with the other Party regarding whether the infringement or misappropriation could be cured or remedied via a license or other settlement without material adverse affect on either Party, provided, that in the case of the circumstances described in clauses (i) and (ii), the terminating Party must reasonably determine in good faith that the Drug Product cannot be approved, commercially sold for human therapeutic use, re-launched, or marketed in the Territory, as applicable, within six (6) months of the occurrence of the circumstances originally constituting such Product Failure.

1.39 “ Raw Material ” means the chemicals, compounds, water, solvents, reagents and other materials and supplies, including disposable manufacturing materials and labeling and packaging materials, used in Manufacturing.

1.40 “Records” means all documents, reports, data, data listings, charts, process control/monitoring commands and data summaries, logs, notes, standard operating procedures, Master Batch Records, lot Batch Records, analyses, correspondences, notes, memoranda, (including, without limitation, production and quality assurance and quality control documentation) and other items containing information or data related to Manufacturing API from the Raw Material and/or Intermediate, whether in paper or electronic form, including originals and copies, and including any other items that would be considered manufacturing “records” under any Applicable Laws.

1.41 “Regulatory Approval” means any and all approvals, licenses, registrations, clearances, or authorizations of any national, supra-national, regional, state or local regulatory agency, department, bureau, commission, council or other governmental entity, that are necessary for the commercial manufacture, distribution, use, and sale of a Licensed Product for human therapeutic, prophylactic, or palliative use in a particular jurisdiction, provided that Regulatory Approvals shall exclude pricing and reimbursement approvals

1.42 “Regulatory Authority” means any multinational, federal, regional, state and/or local government authority (including public, quasi-public and private bodies contracted, certified or authorized by such governmental bodies) in a country or other jurisdiction with authority to regulate, approve, license, inspect, review or otherwise control or supervise the manufacture, sale, labeling, use, marketing, distribution, import, export, price or reimbursement for API or final Drug Product, including but not limited to the FDA, MHLW, and their counterparts in the European Union and other countries outside the Territory.

1.43 “Regulatory Submission” means any document, correspondence, data, article, certifications, or physical samples that are, or that are required to be, delivered or made available for inspection or review by any Regulatory Authority in connection with the activities carried out by either Party relating to this Agreement, including applications, dossiers or reports supporting the manufacture, use, sale, or marketing of the API or Drug Product for investigational or commercial use, and including but not limited to any INDs, NDAs, applications for Marketing Authorizations, field reports, annual reports, adverse event and corrective action reports, and export approvals, change being effected reports, communication (e.g., meeting packages, teleconference, written correspondence) with any Regulatory Authorities and any amendments, supplements, corrections, and updates to any of the foregoing.

1.44 “Territory” means Japan.

1.45 “Third Party” means any party other than FFFC, Cempra, or an Affiliate of either of the foregoing.

1.46 “Transfer Price” means the price charged by FFFC for the quantities of API delivered to Cempra to fill a Purchase Order submitted by Cempra, as provided in **Section 4.1** .

1.47 “Valid Claim” means a claim of any pending patent application or any issued, unexpired or granted 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 to be invalid or unenforceable or of a scope not covering a particular product or service through reissue, disclaimer or otherwise.

1.48 “Waste” means all hazardous waste, as defined by Applicable Laws, and all non-hazardous waste to the extent, in each case, arising out of Manufacturing and other activities performed by FFFC under this Agreement, including without limitation, rejected or unusable Raw Materials, Intermediates, or API, disposable manufacturing equipment, and materials (including solvents and other consumables).

1.49 Miscellaneous Interpretation Aids .

(a) Each use in this Agreement of the term “including,” “comprising,” or “containing” (or a variant form thereof) shall be understood to have an open, non-limiting meaning. Thus, e.g., “including” shall be interpreted as meaning “including without limitation” or “including but not limited to,” regardless of whether the words “without limitation” or “but not limited to” actually follow the term “including.” Similarly, the terms “such as,” “for example,” and “e.g.” shall be understood as referring to non-limiting illustrations or examples.

(b) “Herein,” “hereby,” “hereunder,” “hereof,” and other equivalent words shall be understood as referring to this Agreement in its entirety, and not solely to the particular provision or portion of this Agreement in which any such word is used.

(c) Wherever used herein, any pronoun or pronouns shall be understood to cover all genders.

(d) All references to days, months, quarters, or years shall be understood to refer, respectively, to calendar days, calendar months, calendar quarters, or calendar years, unless otherwise indicated.

(e) Any reference to a supranational, national, federal, state, local, or foreign statute or law shall be understood to refer to the applicable version of the law or statute then in force (as it may have been amended or superseded) as well as all rules and regulations promulgated thereunder, unless the context requires otherwise.

(f) All references to “dollars,” “Dollars,” “US\$,” or “\$” shall mean United States dollars.

2. MANUFACTURE AND SUPPLY OF API

2.1 Obligation to Supply and Purchase. Pursuant to the terms of this Agreement, FFFC shall supply Cempra with, and Cempra shall purchase, the API, for use as the active pharmaceutical ingredient in human drug product to be used or sold in the Territory, in such quantities as Cempra may order pursuant to the provisions in of **Section 2.6** . FFFC shall deliver API in the quantity specified in each Purchase Order by Cempra as set forth in **Section 5.4(b)** and on the delivery date as specified by Cempra on such Purchase Order, or store such API as may be requested by Cempra for later delivery in accordance with **Section 5.4(b)(ii)** . All manufacturing and storage of API under this Agreement shall be performed at the Facility, unless otherwise agreed to in writing by Cempra.

2.2 Master Batch Records. The API Manufacturing Procedures contained in the Master Batch Records shall, except to the extent based on or reflecting methods, techniques, processes and standard operating procedures covered by Cempra Licensed Patents or Cempra's know-how related thereto provided by Cempra to FFFC, be based upon applicable FFFC technology, and any applicable API Improvements. The Master Batch Records shall contain such items and requirements as typical and customary in the industry for manufacturing processes applicable to similar bulk pharmaceutical manufacturing, and shall be set forth in a written document. The API will be Manufactured to the then-current API Specifications at the time of manufacturing. If appropriate during the Term (such as, to include new API Improvements that are useful to Manufacturing the API), the Parties will agree on appropriate amendments or modifications to the API Specifications and/or the Master Batch Record. The details of the procedure for amending the API Specifications and/or the Master Batch Records shall be as specified in the Quality Agreement. FFFC will, at its cost, provide all documents required under the Quality Agreement or this Agreement to be provided to Cempra, in English. FFFC shall not have any obligations to disclose any information maintained in the DMF as confidential to Cempra or any Third Parties, provided that, if (i) either Party or any Affiliate is required by Applicable Law or to satisfy any obligation thereunder, (ii) either Party or any Affiliate thereof is requested by a Regulatory Authority, or (iii) it is reasonably necessary to satisfy any requests of any Regulatory Authority, in the case of (i), (ii) or (iii), to disclose any information maintained in the DMF as confidential, (X) Cempra and FFFC shall promptly use reasonable efforts to, as quickly as possible, determine the reasonable plan for satisfying such requests by mutual good-faith and reasonable consultation based on the careful study of confidentiality of such information maintained in the DMF and (Y) FFFC shall in any event be required to disclose such information if and as reasonably necessary to satisfy, or enable Cempra, any Affiliate thereof, or any licensee or sublicensee of either of the foregoing with respect to Drug Product in the Territory to satisfy, any such requests or requirements. For clarity, in this case, such information maintained in the DMF which is disclosed hereunder shall be used and disclosed only to the extent necessary for any such requests or requirements, and shall not be used or disclosed to any other party exceeding the scope necessary for any such requests or requirements.

2.3 Registration Batches. Upon Cempra's request, FFFC shall prepare registration Batches of API as needed for Cempra (or its Affiliate or its or its Affiliates' licensee) to seek Regulatory Approval in the Territory, in accordance with a plan therefor (and related payment provisions) to be reasonably negotiated in good faith and agreed upon in writing by the Parties (which plan, upon such agreement in writing by the Parties, will be set forth in **Exhibit G**), and coordinate with Cempra on any request from any Regulatory Authority. Upon successful delivery of the registration Batches in accordance with such plan (*i.e.*, such Batches meet the API Specifications and are manufactured in a way that they meet the criteria for registration Batches), Cempra shall pay FFFC for the delivery of such Batches in accordance with the payment provisions to be set forth in **Exhibit G**. FFFC shall work in good faith to establish, in consultation and cooperation with Cempra, and subject to Cempra's written agreement, reasonably appropriate success criteria for the registration Batches for API. If a particular registration Batch supplied by FFFC pursuant to this Section fails to meet such criteria, appropriate representatives from each Party shall meet and discuss and seek to determine the causes of such Batch having failed to meet such criteria and shall cooperate diligently to try to find a solution to such causes, and FFFC shall use best efforts to rectify any such problems as soon as practicable. FFFC will replace any such failed Batches at its cost (including paying for needed Raw Materials and the internal costs of

conducting the manufacturing and supply). FFFC shall recommence manufacture and supply of the required registration Batches for API as soon as possible, and shall continue until such time as FFFC has successfully delivered to Cempra the number of consecutive Batches of API that meet the criteria that shall be set forth in **Exhibit G**, once agreed upon by the Parties as set forth above. Each such registration Batch supplied by FFFC shall meet the API Specifications and shall be suitable for use to support registration stability studies.

2.4 Manufacturing Process Validation. Promptly after the Parties have completed the Master Batch Records, and at Cempra's request, FFFC will commence and conduct certain validation studies (the "**Validation Studies**") to validate the API Manufacturing Procedures pursuant to a mutually agreeable validation plan, in preparation for commercialization, to be reasonably negotiated in good faith and agreed upon in writing by the Parties (which plan, upon such agreement in writing by the Parties, will be set forth in **Exhibit H**). The actual detailed protocols for such Validation Studies shall be established by the FFFC, in consultation with, and subject to the written agreement of, Cempra, with FFFC preparing the initial proposed protocols for review and comment by Cempra and written approval by Cempra. FFFC shall disclose to Cempra in written reports all results of such Validation Studies and all other deliverables as required under the mutually-agreed upon plan for such Validation Studies. Notwithstanding the foregoing, unless otherwise agreed by FFFC, such protocols for the Validation Studies and such reports shall not contain any information of FFFC included as confidential in the DMF maintained by FFFC under this Agreement. Cempra shall pay FFFC as provided in the form of **Exhibit H** to be agreed upon for FFFC's conduct of the Validation Studies. In the event that the Validation Studies are not successfully completed (i.e., they do not satisfy the predefined acceptance criteria in the validation protocol and related site SOPs), FFFC shall work cooperatively with Cempra using commercially diligent efforts to determine the cause of the failure, and shall work diligently and, as soon as possible, implement such changes in the Facility or as otherwise needed to assure that the Validation Studies are successfully completed. Each such validation Batch supplied by FFFC shall meet the API Specifications and shall be suitable for human clinical trial use and/or commercial use in humans, as applicable. FFFC shall use reasonable efforts to work in good faith with Cempra to obtain appropriate Marketing Approvals as needed.

2.5 Stability Studies and Report. To the extent requested by Cempra in writing, FFFC shall conduct stability studies on the API manufactured by FFFC hereunder, in accordance with stability study protocols customary, reasonable, and typical for pharmaceutical manufacturing (e.g., ICH) to be negotiated in good faith and agreed upon by the Parties as soon as reasonably possible following the Effective Date, and which, upon mutual written agreement thereon by the Parties, shall be set forth on **Exhibit I** hereto. FFFC shall prepare and deliver to Cempra written reports setting forth the results of the studies, such reports to be in the form and at the time points described in such agreed protocols.

2.6 Forecasts; Purchase Orders; Minimum Purchase Requirement.

(a) No later than the eighth (8th) day of each calendar month following the Effective Date, Cempra shall provide to FFFC a rolling forecast (each, a “**Forecast**”) of its anticipated orders for API to be placed during each of the [*] through (and including) the [*] calendar month (or, if earlier, the final calendar month of the Term) following the calendar month in which such forecast is provided. In each Forecast submitted by Cempra, the forecast for the first [*] months covered by the Forecast shall be binding on the Parties (pursuant to Purchase Orders placed under subsection (b) below), and the forecast for the last [*] months covered by each Forecast shall be non-binding on both Parties, not subject to any forecasting restrictions, provided that the quantity of API specified for any month in the nonbinding portion of any revised Forecast shall not (i) exceed [*] percent ([*]%), or be less than [*] percent ([*]%), of the quantity of API provided for such month in the initial Forecast including a forecast quantity of API for such month nor (ii) exceed [*] percent ([*]%), or be less than [*] percent ([*]%), of that quantity of API provided for such month in the most recent previous Forecast. FFFC shall notify Cempra in writing within three (3) business days of FFFC’s receipt of any Forecast if the quantities of API indicated in the non-binding portion thereof exceed FFFC’s production capacity therefor. Should Cempra wish to increase order quantities at any time in excess of the volumes permitted under this Section 2.6(a) or Section 2.6(b), Cempra may contact FFFC to request and FFFC shall use commercially reasonable efforts to supply any such increase in volumes.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(b) Cempra shall have the right to place binding written purchase orders (each a “**Purchase Order**”) from time to time under and subject to the conditions regarding a Forecast set forth in Section 2.6(a), provided that, with respect to the first [*] Purchase Orders placed hereunder, Cempra may, at its option, place its Purchase Orders for API no less than [*] months in advance of the desired delivery date(s) (or, as contemplated by Section 5.4(b)(ii), storage date) therefor. Except as described above with respect to the first [*] Purchase Orders placed hereunder, Cempra shall issue each Purchase Order to FFFC no later than [*] calendar month preceding the date on which Cempra has requested FFFC to first deliver (or make available for storage pursuant to Section 5.4(b)(ii)) API pursuant to each such Purchase Order. Each Purchase Order shall specify the API to be supplied during the period from the [*] business day of the following calendar month to the end of the [*] calendar month of the period for which the Purchase Order is placed (corresponding to the binding portion of each Forecast). Such Purchase Order shall specify order quantity(ies), delivery (and/or storage) date(s), and other necessary matters. FFFC shall be obligated to supply to Cempra the amount of API as Cempra orders hereunder, which shall not be less than [*] ([*]%), nor more than [*] percent ([*]%), of the forecasted quantity for the applicable forecast period in the most recent Forecast, and will use commercially reasonable efforts to supply any additional quantities ordered by Cempra. Not later than five (5) days after receipt of a binding Purchase Order, FFFC will confirm in writing its receipt of the Purchase Order (“**Order Acceptance**”), and FFFC shall fulfill each Purchase Order. If there is any conflict between the Purchase Order or an Order Acceptance and the terms of this Agreement, this Agreement prevails and such conflicting terms are rejected and of no effect, unless the Parties mutually agree otherwise in writing. From time to time, due to significant unforeseen circumstances, Cempra may deliver to FFFC a Purchase Order for volumes of API in excess of those specified in the binding portion of any Forecast and, upon Cempra’s written request, FFFC shall use commercially reasonable efforts to provide Cempra with such excess API volumes; provided, however, that if FFFC is required to spend an additional unforeseen material expense, in excess of its typical expenses to supply API hereunder, in order to provide Cempra with such excess API volumes, (i) FFFC shall notify Cempra as soon as possible of the amount of such additional expense, (ii) Cempra shall have ten (10) business days following such notice within which to accept such additional expense in writing, and (iii) if Cempra does accept such additional expense in writing within such ten (10) business day period, Cempra shall be obligated to bear such expense upon and FFFC shall be obligated to supply such excess API volumes triggering such expense. If Cempra rejects such additional expense in writing, or otherwise does not accept such additional expense, within such ten (10) business day period, Cempra shall have no obligation to bear any such additional expense with respect to any excess API volume and FFFC shall not have any obligation to supply any such excess API volume.

(c) FFFC, on at least a quarterly basis, shall provide Cempra with a written schedule of all then-outstanding accepted Purchase Orders for API, including the status of manufacturing work in progress and expected delivery date(s).

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(d) Cempra agrees that, for each of the first [*] Month Periods (as defined below) during the Term, Cempra shall be obligated to place Purchase Orders for the purchase of not less than [*] kilograms ([*] kg) of API in total per Month Period (i.e., such minimum purchase obligation shall apply during each of the first [*] Month Periods, and so Cempra's minimum purchase obligation of this Agreement shall be its purchase of not less than [*] kilograms ([*] kg) of API in total during such first [*] Month Periods), provided that, notwithstanding the foregoing:

(i) such obligation shall not apply to the Month Period during which this Agreement terminates or expires unless such termination or expiration occurs on the last day of such Month Period; and

(ii) the requirement above shall not apply to a Month Period during which a Supply Failure occurs or the Month Period following such Supply Failure.

For purposes of clarity, the minimum purchase requirement set forth in this **Section 2.6(d)** shall, subject to clause (i) and (ii) above, only apply for up to the first (1st) [*] Month Periods as described above, and Cempra's breach of such minimum purchase requirement shall be construed as a material breach enabling termination of this Agreement by FFFC as set forth in **Section 10.2 (b)**. "Month Period" means (y) the twelve (12) consecutive complete calendar month period, following (a) successful completion of the Validation Studies pursuant to Section 2.4 and (b) written notice from FFFC that the Facility is completed and capable of Manufacturing [*] kg in the course of a twelve (12) consecutive month period, beginning with (and including) the first calendar month during which API is delivered, in accordance with a Purchase Order placed pursuant to Section 2.6(b), for use in the manufacture of Drug Product for commercial sale for human therapeutic use in Japan following Regulatory Approval of such Drug Product in Japan and (z) each subsequent twelve (12) consecutive calendar month period following the initial Month Period. Except to the extent otherwise agreed to in a separate written agreement between the Parties that shall not affect the terms of this Agreement, the Parties agree that FFFC shall not deliver any such API, pursuant to any Purchase Order placed by Cempra, prior to such initial delivery contemplated in clause (y) of the preceding sentence (i.e., prior to the first month of the first Month Period).

2.7 Use of Affiliates or Subcontractors. FFFC shall have the right to fulfill its supply obligations hereunder through the engagement of any of its Affiliates or subcontractors, provided that the engagement of any such Affiliates or subcontractor shall be subject to the prior written approval of Cempra (such approval shall not be unreasonably withheld by Cempra). FFFC shall ensure that any Affiliate or subcontractor performing any obligations of FFFC hereunder agrees to be bound by the terms and conditions of this Agreement pertaining to the manufacture and supply of the API as if it is a party to this Agreement. FFFC shall remain fully responsible for its obligations under this Agreement, and the acts and omissions of its Affiliates and subcontractors with respect to this Agreement (as if such acts and omissions were those of FFFC hereunder), regardless of whether such obligations are performed by FFFC itself or through such Affiliate or subcontractor.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

2.8 Raw Materials and Equipment. FFFC shall procure, at its own cost, all Raw Materials needed for Manufacturing the API ordered under this Agreement, provided that, if and as requested by Cempra, FFFC shall use reasonable efforts to consult in good faith with Cempra regarding the manner in which, and the Third Parties from which, any critical Raw Materials (e.g., clarithromycin) may be procured. FFFC shall conduct further audits of such Third Party vendors as needed or as reasonably requested by Cempra. FFFC shall be responsible for ensuring that the Raw Materials procured by FFFC in accordance with this **Section 2.8** meet the quality requirements as set forth in the Quality Agreement. FFFC shall be responsible for procuring at its cost all equipment, personnel and other resources needed for Manufacturing and/or storing, as applicable, API ordered under this Agreement. FFFC shall be responsible for allocating appropriate space in the Facility, and for obtaining, installing and maintaining in such Facility all capital equipment, as needed to manufacture and/or store, as applicable, the amounts of API as ordered by Cempra in compliance with the terms of this Agreement. FFFC shall allocate sufficient time, effort, equipment and facilities to the program for manufacturing API, and shall dedicate and use personnel with sufficient skills and experience as are required to accomplish the manufacturing tasks, so as to manufacture and deliver API on a timely basis and in accordance with the terms of this Agreement. FFFC shall conduct its Manufacturing efforts and perform all of its other obligations under this Agreement in compliance with all Applicable Laws.

2.9 Labeling and Packaging. FFFC shall label and package API to be supplied in accordance with the API Manufacturing Procedures, API Specifications (or other labeling and packaging specifications provided by Cempra), the Quality Agreement, and Applicable Laws, in each case that are applicable to active pharmaceutical ingredients for human use for shipment in bulk to Cempra or to one or more locations (e.g., manufacturing sites, distribution centers) designated by Cempra.

2.10 Title to API. Title to all API shall remain with FFFC until it is delivered pursuant to **Section 5.4** or stored on behalf of Cempra pursuant to **Section 5.4(b)(ii)**. FFFC shall keep all Raw Material, Intermediates, and API stored in accordance with the API Specifications and Applicable Laws. FFFC shall bear the risk of loss, contamination or damage to the Raw Material, Intermediates, and API in its possession (including during such time as FFFC may be storing API on behalf of Cempra pursuant to **Section 5.4(b)(ii)**), until the finished API is actually delivered to Cempra or its designee pursuant to **Section 5.4**, and FFFC will pay the actual costs of replacing any Raw Material that is lost or damaged while in FFFC's possession due storage or handling problems or losses or failures in Manufacturing or storage; provided, however, that in case that FFFC delivers API pursuant to **Section 5.4** and enable Cempra to receive the same but Cempra fails to pickup, the risk of loss, contamination or damage to the Raw Material, Intermediates, and API shall pass to Cempra at the time of such delivery, except to the extent otherwise set forth in this Agreement, including but not limited to **Section 5.4** hereof.

2.11 Limitation on Use; Supply for Outside the Territory . Cempra shall use reasonable efforts to ensure that API supplied hereunder is only used for the manufacture of Drug Product for use or sale in the Territory (or purposes related thereto). If Cempra desires FFFC to supply Cempra with API for use in manufacturing Drug Product for use or sale outside the Territory (within FFFC's reasonable production capacity), the Parties shall, upon written notice from Cempra to FFFC, use reasonable efforts to negotiate in good faith an agreement, or amendment to this Agreement, providing for such supply on commercially reasonable terms.

3. PROJECT MANAGEMENT

3.1 Project Managers. Each Party shall designate a representative (the “ **Project Manager** ” of such Party) with proper experience and authority as to technical matters to serve as the primary contact with the other Party regarding the Parties' manufacturing and supply relationship for API under this Agreement. Each Project Manager shall be responsible for obtaining cooperation and input from other individuals within such Project Manager's organization whose expertise and ability may be required from time to time to maximize the potential for successful relationship under this Agreement. The Project Managers shall develop procedures to optimize communication and collaboration between the Parties. The Project Managers will communicate regularly during the Term at mutually agreeable times, and, when necessary, hold meetings at mutually agreeable places, to review project management and status. The Project Managers shall use good faith, reasonable efforts to facilitate communication and collaboration between the Parties, but neither Project Manager shall have the ability or authority to modify the terms of this Agreement, to bind either Party, or to waive any rights or obligations of a Party.

3.2 Monthly Progress & Budget Reports. Each calendar month (or on such other regular period as agreed by the Parties), FFFC shall provide Cempra with a status report on completion of outstanding obligations (*e.g.*, production runs, process development, validation, stability data, Regulatory Submissions, and pending corrective actions). The status report shall indicate FFFC's progress toward task or delivery milestones relative to planned completion schedules.

3.3 Adverse Issues & Corrective Actions . FFFC shall inform Cempra promptly in writing of any events that might materially affect the ability of FFFC to timely and fully perform and/or deliver API ordered by Cempra under this Agreement, or otherwise affect the established schedule, including any unexpected adverse final or interim results or data from validation, stability or other studies. The status report also shall fully describe all Out of Specification (“ **OOS** ”) and out of trend events, failure investigations, process deviations, Batch failures and similar matters, as well as the corrective or other actions to be taken by FFFC. FFFC shall conduct periodic review of production records, on at least an annual basis, including trend analysis of Batch production records and other process data, and prepare a report for submission to Cempra summarizing FFFC's findings, conclusions and recommendations. FFFC shall be responsible for ensuring that the adverse issues and corrective actions undertaken with respect thereto by FFFC in accordance with this Section 3.3 meet the quality requirements as set forth in the Quality Agreement.

4. TRANSFER PRICES, INVOICING & PAYMENT

4.1 Transfer Prices. The Transfer Price for a particular shipment of API that is manufactured and supplied to Cempra by FFFC under this Agreement shall be equal to the total number of kilograms in such shipment, multiplied by the per-kilogram Transfer Price as set forth in the transfer price schedule and further otherwise determined as set forth on *Exhibit J*. Without any delay after the end of each Month Period, FFFC shall send Cempra a written report stating the Forecast-Based Price for such Month Period (or, if adjusted by mutual agreement of the Parties as contemplated by Exhibit J, the applicable Forecast-Based Prices for such Month Period and the volumes of API to which such Forecast-Based Prices applied) and the Final Price for such Month Period, and including a detailed calculation thereof. If the total amount that would have been owed or paid to FFFC for all API delivered during a particular Month Period meeting the API Specifications and accepted by Cempra in accordance with this Agreement (such Month Period's " **Accepted API** ") had the Final Price been applicable thereto exceeds the total amount owed or paid to FFFC for all of such Month Period's Accepted API based on the applicable Forecast-Based Price(s) therefor, then FFFC shall send Cempra an invoice for the amount of such excess and, within [*] days following Cempra's receipt of such invoice, Cempra shall pay FFFC an amount equal to such excess. If the total amount owed or paid to FFFC for all of a particular Month Period's Accepted API based on the applicable Forecast-Based Price(s) therefor exceeds the total amount that would have been owed or paid to FFFC for all of such Month Period's Accepted API had the Final Price been applicable thereto, then FFFC shall pay Cempra an amount, or credit Cempra an amount against outstanding invoices or future amounts due under this Agreement, as elected in writing by Cempra in its sole discretion (with such payment to be made within [*] days, and such credit to become immediately effective, following such election by Cempra), equal to, in either case, such excess.

4.2 Payments. Subject to any additional payments required of, or credits granted to Cempra under, **Section 4.1**, FFFC shall be paid for API meeting the API Specifications delivered and accepted in accordance with this Agreement within [*] days of receipt by Cempra of the applicable invoice setting forth the total Transfer Price applicable to such delivered API, as provided in **Section 4.1**. Subject to **Section 5.5**, payment of all undisputed invoices shall be delivered by wire transfer in US Dollars to the account provided in *Exhibit J*. Payment shall be considered received once funds become available to FFFC, or FFFC's agent, at its bank account. In the case one invoice is in dispute, its payment shall not affect settlement of other outstanding and due invoices.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

4.3 Access to Funds Received for Cempra's Sale of API. Cempra and FFFC shall use reasonable efforts to work in good faith to establish, on commercially reasonable and customary terms of a separate agreement to be negotiated by the Parties and an internationally-recognized bank reasonably acceptable to both parties, a bank account in Cempra's name and owned by Cempra into which Cempra will deposit payments received by Cempra from Toyama or other licensees or distributors of Cempra who commercialize Drug Products in the Territory, if any, for Toyama's or such licensee's or distributor's purchases of API, acquired by Cempra from FFFC under this Agreement, sold to Toyama or such licensee or distributor by Cempra, and from which FFFC shall be entitled to withdraw the amount due FFFC for such API under this Agreement, and for which Toyama or such licensee or distributor has already paid Cempra, upon presentment to Cempra and the applicable bank of invoices therefor properly sent in accordance with this Agreement; provided, however, that Cempra shall use reasonable efforts to maintain and keep up the level of the amount of deposit in such bank account reasonably sufficient for the payments to FFFC of undisputed amounts due under Section 4.2 of this Agreement.

4.4 No Liens. FFFC shall ensure that all API ordered by Cempra is delivered free of any liens, claims, or encumbrances, with good and marketable title.

5. QUALITY CONTROL, DELIVERY AND ACCEPTANCE

5.1 Quality Control. FFFC shall maintain and follow a quality control and quality assurance testing program consistent with the API Specifications, cGMP, the Quality Agreement, and all other requirements of Applicable Laws and consistent with industry standards (the "**Quality Control Procedures**"), which shall include performing the applicable Acceptance Tests on each Batch of API. FFFC shall ensure that all API supplied to Cempra hereunder shall be manufactured in accordance with the API Manufacturing Procedures, cGMP, the Quality Agreement, and all other Applicable Laws, and all other applicable requirements of Regulatory Authorities, (collectively, "**Regulatory Standards**") and shall comply with the API Specifications. FFFC shall promptly notify Cempra of any deviation from API Manufacturing Procedures or the Regulatory Standards that occurs during any Batch process or Manufacturing or any Batch failure, including the details and causes thereof, to meet the quality requirements as set forth in the Quality Agreement.

5.2 Certificates. FFFC shall provide to Cempra, accompanying each delivery of API: (a) the Batch number and Purchase Order number of the delivered API, (b) a completed and accurate Certificate of Analysis as to such Batch, and, upon Cempra's request, copies of the analytical data used to generate such Certificate of Analysis, and (c) copies of all other documentation required for API release. Cempra or its Affiliate or designee may, but shall not be obligated to, test each amount of API delivered to confirm that it meets the API Specifications, that the assigned expiry/retest aligns with agreed upon period, and that the API otherwise complies with the terms of this Agreement.

5.3 Quality Audits. FFFC shall maintain all quality control documentation and Acceptance Test results for each Batch of API for a period and in a manner consistent with Regulatory Standards, the Quality Agreement, and pharmaceutical industry standards. Cempra, its Affiliates, and any designees or licensees of Cempra or any Affiliate thereof may, from time-to-time, and at any time, periodically review, upon reasonable prior notice, such

documentation and results, and shall have the right, from time-to-time, and at any time, to audit, survey, verify the adherence of FFFC to the Quality Control Procedures and Regulatory Standards. In addition to the above and to Cempra representatives provided for in **Section 8.13**, and upon reasonable prior written notice to FFFC, Cempra, its Affiliates, and any designees or licensees of Cempra or any Affiliate thereof shall have the right, from time-to-time, and at any time, to have its representatives visit the Facility to audit or inspect the aspects of the Facility related to Manufacturing (including testing) of API and to discuss quality issues and any related issues with FFFC's manufacturing and management personnel as relating to Manufacture of API. Except to the extent otherwise set forth in this Agreement, such audits or inspections shall not be limited in number or frequency, occur during regular business hours, and meet the quality requirements as set forth in the Quality Agreement. Audit report responses shall be provided as agreed upon by the Parties, and the Parties shall each use reasonable efforts in good faith to ensure completion of the action items. Follow up visits may, as reasonably determined by Cempra, be needed to confirm completion of action items and, in such cases, FFFC shall permit such visits and reasonable times upon reasonable notice. For critical observations, Cempra shall be permitted to assess impact to any product or filing documentation.

5.4 Delivery of API.

(a) Release Testing. FFFC shall be responsible for analyzing each API lot for compliance with the API Specifications and for conducting all testing required prior to the release of any API for shipment as provided in this **Section 5.4**. FFFC shall send to Cempra a Certificate of Analysis and a Certificate of Compliance prior to or concurrent with each shipment of API. FFFC shall retain all Records necessary to fulfill the requirements established by cGMP and all other Applicable Laws. Prior to changing its testing methods, FFFC shall inform Cempra of such changes in writing and obtain Cempra's written approval, including as set forth in the Quality Agreement.

(b) Shipment, Storage, and Delivery.

(i) Each amount of API to be delivered to Cempra shall be delivered by FFFC EXW (Incoterms 2010) at the Facility to Cempra's designated carrier or shipper for shipping to Cempra's, its Affiliate's, or its or its Affiliates' licensee's designated manufacturing or storage facility, or to such other location as specified by Cempra. Cempra shall arrange for such shipping. FFFC shall be responsible for delivering the properly-packaged API to Cempra's designated carrier or shipper. Deliveries of API under this Agreement (including the date on which API, initially being stored on behalf of Cempra pursuant to **Section 5.4(b)(ii)** following manufacture, shall be made available for shipment, as requested by Cempra) shall not vary by more than five (5) calendar days from the specified delivery date set forth in the applicable Purchase Order (or such later date as may be requested by Cempra for pick-up following storage of API on behalf of Cempra pursuant to subsection (ii) below) (i.e., may be between five (5) calendar days before the specified delivery date and five (5) calendar days after the specified delivery date). Such variance in actual date of delivery shall not constitute a breach of contract by FFFC. All risks of loss and all normal transport costs that occur after proper delivery by FFFC to the carrier or shipper shall be borne by Cempra. API shall be shipped in accordance with the shipping conditions and procedures established by this Agreement and written agreement of the Parties. Each lot of API shall be accompanied by all required shipping documentation including the Certificates of Analysis and Certificate of Compliance.

(ii) Notwithstanding anything to the contrary, if Cempra notifies FFFC in writing, in conjunction with, as part of, or following the placement of, a particular Purchase Order that Cempra's designated carrier will not be picking up all API ordered under such Purchase Order on the initial date on which the relevant API will be ready for delivery and requests storage thereof by FFFC, FFFC shall, with respect to such portion of any Purchase Order, store such API at the Facility in accordance with Applicable Laws, the API Specifications, and cGMP, until such date as Cempra requests that such API be delivered EXW (Incoterms 2010) at the Facility to Cempra's designated carrier or shipper for shipping pursuant to **Section 5.4(b)(i)**. The reasonable, documented, direct cost incurred in connection with FFFC's storing of such API under this **Section 5.4(b)(ii)** shall be borne by FFFC for the first month's storage of each delivery of API following the initial delivery date thereof, and by Cempra for all periods thereafter; provided, however, that, notwithstanding the foregoing, such reasonable, documented, direct cost incurred in connection with FFFC's storing of such API for all periods prior to the end of the second (2nd) Month Period shall in any event be borne by FFFC. In the event of such a notice and/or request by Cempra, Cempra shall be required to pay for such API as if it had been so delivered on the original intended delivery date therefor, and title to such API shall pass to Cempra upon such date, and risk of loss with respect to such API (and the obligation to insure against such loss) shall also pass to Cempra on such date, except to the extent that such loss of such API occurring during such period when FFFC stores such API at a Facility hereunder results from FFFC's negligence, intentional misconduct, breach of this Agreement, or failure to comply with Applicable Laws, the applicable standards (which shall in any event include, but not be limited to, cGMP), or the applicable storage conditions for such API, which risks of loss shall be borne by FFFC. The Parties agree that any API that is stored in accordance with the foregoing pursuant to Cempra's request or notice shall be included in determining the applicable Transfer Price.

5.5 Acceptance/Rejection. Cempra (or its authorized representative or designee (which may include any of its Affiliates or its or its Affiliates' licensees)) will inspect all deliveries of API (which, for API stored on Cempra's behalf under **Section 5.4(b)(ii)**, shall mean delivery following such storage, not at the time of storage) and Cempra will report to FFFC any Non-Conforming API that is reasonably discoverable by reasonable visible inspection within forty-five (45) days of receipt by Cempra, its Affiliate, its or its Affiliate's licensee, or any of the foregoing's designated manufacturer of Drug Product. If any API is found to be Non-Conforming API, then FFFC shall, at Cempra's request and solely at its option (to be exercised by Cempra promptly), either: (a) replace said Non-Conforming API as soon as practically possible at no charge to Cempra and pay all round-trip shipping charges to and from the destination of the original shipment, (b) refund to Cempra the purchase price paid to FFFC for the Non-Conforming API, or (c) credit Cempra's account in an amount equal to the purchase price paid for said Non-Conforming API. FFFC shall reimburse Cempra for the reasonable costs incurred by Cempra in properly disposing of any such Non-Conforming API. Any notice given hereunder shall specify the reason why such API was found to be Non-Conforming API. If Cempra does not report any defect or non-conformity of any API within forty-five (45) days of receipt by Cempra, then Cempra shall be deemed to have accepted such API, provided that, notwithstanding anything to the contrary, (a) Cempra shall have the right to rely on the data provided by FFFC in the Certificate of Analysis and the Certificate of Compliance for such inspection, and shall have the right to reject

such shipment at a later time for any inaccuracy in the Certificate of Analysis or Certificate of Compliance, and (b) if there is any latent defect that is not reasonably discoverable upon reasonable visual inspection in accordance with customary and reasonable procedures that causes such API to be Non-Conforming API, then Cempra may reject such Non-Conforming API within ten (10) business days of Cempra becoming aware of such latent defect.

5.6 Dispute Regarding Rejection. If the Parties disagree as to whether a particular delivery of API contains Non-Conforming API, an independent and mutually acceptable independent, neutral Third Party arbitrator will be appointed to (a) review data that are in question and/or (b) to oversee the evaluation and testing of a sample of such purportedly Non-Conforming API at an independent, neutral referee laboratory. Such referee laboratory will conduct testing in accordance with the methods established for testing as set forth in the API Specifications. The costs of the referee testing will be charged to the Party whose position in the dispute was not supported by the referee's findings. FFFC, if at fault, shall be solely responsible for the prompt replacement of all amounts of Non-Conforming API, or at Cempra's election, FFFC shall refund the amounts paid or incurred by Cempra on account of the delivery of such Non-Conforming API (if previously paid for).

6. SUPPLY ASSURANCES

6.1 Production Site and Commercial Capacity Assurance. All Manufacturing of API (including all testing, filing and packaging activities) shall occur at the Facility, except as otherwise approved by Cempra in writing. No Manufacturing work shall be subcontracted to or performed by any Affiliate of FFFC or Third Party except with Cempra's prior written approval (however, such approval shall not be unreasonably withheld by Cempra). If Cempra approves of any subcontracted Manufacturing or Manufacturing by an Affiliate of FFFC, FFFC shall be and remain fully responsible for the work of the subcontractor or Affiliate as if it was performed by FFFC directly.

6.2 Change Control. Without Cempra's prior written consent, FFFC shall make no change to any part of the API manufacturing process, including: (i) the API Manufacturing Procedures; (ii) any validated analytical methods used to test critical Raw Materials, Intermediates, or the API; (iii) any Regulatory Submission (including but not limited to any DMF) made by FFFC for the API product; (iv) the Master Batch Records; and (v) Batch records or other process documentation. In the event a change is requested and approved by Cempra in writing, FFFC will continue to Manufacture the API in accordance with the previously-applicable process changes pending the completion of process changes that require such changes. The implementation of changes shall be subject to Cempra's prior written authorization. Where changes are implemented that reduce costs in the manufacturing process, the Parties will reduce the Transfer Price in an amount proportional to Cempra's contributions to such changes. The API Specifications shall not be modified or revised except by the procedures are set forth below.

(a) Notice. A Party proposing a change to the API Specifications or the API Manufacturing Procedures shall provide reasonable advance written notice to the other Party, including as necessary to enable, in the case of Cempra in furtherance of its obligations under the any supply agreement between Cempra and any purchaser from Cempra (including Toyama) regarding Drug Products, Cempra to notify such purchaser thereof and, thereby, enable such

purchaser to notify and, if necessary, obtain approval of the relevant Regulatory Authority(ies) in the Territory. If the proposed change is required by a Regulatory Authority, then such notice shall include complete and full disclosure of the Regulatory Authority's request and relevant correspondence, if any. Cempra, its Affiliates, its or their licensees, and any designees of any of the foregoing shall have the opportunity to directly participate in any dialogue FFFC has with the Regulatory Authority regarding the proposed change. If and as requested in writing by Cempra, FFFC will participate in any dialogue Cempra, any Affiliate thereof, or any licensee of Cempra or any Affiliate thereof has with the Regulatory Authority regarding the proposed change. If the change is proposed by Cempra or is required by a Regulatory Authority, then within thirty (30) days of such notice, FFFC shall notify Cempra in writing whether and the extent to which FFFC's direct cost of Manufacturing and, therefore the Transfer Price, will increase or decrease if the proposed revision is implemented. Any proposed increase or decrease in FFFC's Transfer Prices shall be supported by documentation, in a form and content satisfactory to, and subject to verification by, Cempra. If Cempra rejects any proposed price increase, the Parties agree to negotiate in good faith a mutually acceptable increase or decrease to the Transfer Prices based on the proposed change and its impact on Manufacturing Costs. If Cempra adopts the proposed API Specifications or API Manufacturing Procedures revision, the Transfer Prices for the API will be adjusted as per such agreement, upon the implementation of such revisions or as otherwise agreed by the Parties. Notwithstanding anything to the contrary, any changes API Specifications mandated by a Regulatory Authority shall be implemented (and **Exhibit B** correspondingly amended) by FFFC as soon as reasonably possible upon, and in accordance with, Cempra's written request, subject only to Cempra's written agreement to any price increases demanded by FFFC in amounts equal to the extent of any increase in FFFC's Manufacturing Costs directly caused by such changes to API Specifications.

(b) Feasibility Determination. If Cempra, in consultation with FFFC, determines that FFFC cannot implement the proposed revision to the API Specifications or API Manufacturing Procedures in a cost-effective manner, it may withdraw the proposed revision. If the revision is required by a Regulatory Authority, however, then the Parties shall discuss in good faith to implement such revisions in a cost-effective manner upon mutual agreement of the Parties with respect thereto.

(c) Implementation Plan. Before implementing any agreed revision to the API Specifications or API Manufacturing Procedures, the Project Managers shall, if needed, develop and agree on a reasonable and appropriate implementation plan, which sets forth the specific procedures to be used in preparing for and implementing such change to the API Specifications and/or API Manufacturing Procedures.

(d) Regulatory Submissions. Cempra (or its Affiliate or its or its Affiliate's licensee) will, except to the extent FFFC has filed and is maintaining a DMF in the Territory with respect to the API Manufactured by or on behalf of it hereunder, be responsible for any Regulatory Submission with the MHLW and other Regulatory Authorities in the Territory pertaining to the changes to the API Specifications and/or API Manufacturing Procedures. The Parties shall advise each other of the MHLW's or other Regulatory Authorities' approval and the effective date of any such changes to such API Specifications and/or API Manufacturing Procedures. FFFC's responsibility shall be limited to the documents it prepares in connection with any Regulatory Submissions, and FFFC shall provide Cempra with all documentations to support such Regulatory

Submissions at the request of Cempra, including without limitation the right for Cempra, its Affiliates, or its or their licensees or other designees to reference FFFC's DMF or the like pertaining to the API.

6.3 Supply Failure and Right of Reference.

(a) Supply Failure. A "Supply Failure" shall be deemed to have taken place if (i) FFFC fails to supply (by making available to Cempra or storing at Cempra's request, pursuant to **Section 5.4(b)(ii)**) at least[*] percent ([*]%) of the quantity of API ordered in any Purchase Order under this Agreement by the date(s) specified by such Purchase Order or (ii) FFFC fails to supply (by making available to Cempra or storing at Cempra's request, pursuant to **Section 5.4(b)(ii)**), in the aggregate, [*] percent ([*]%) of the total quantity of API ordered by Cempra in any three (3) consecutive Purchase Orders. In the event of a Supply Failure, Cempra shall be entitled to, if and as elected by Cempra, (i) provide FFFC with a revised Forecast for the purchase of API which shall replace the then-existing Forecast (including any binding portion thereof) or (ii) terminate this Agreement under **Section 10.2(d)**.

(b) Right of Reference. FFFC hereby grants Cempra and its Affiliates a sublicensable right of reference, transferable in accordance with **Section 15.6**, to the DMF owned or maintained by or on behalf of FFFC for the API and the information contained therein only for the purposes of Cempra's, Cempra's Affiliates', and Cempra's and its Affiliates' licensees' Regulatory Submissions or other development, manufacture or commercialization of Drug Product.

6.4 Exclusivity. During the Term and until the later of (a) five (5) years after termination or expiration of this Agreement or (b) the date on which there are no remaining Valid Claims in the Patents set forth on **Exhibit K** or any other Patent claiming priority thereto in the Territory, FFFC will not manufacture, supply, sell or otherwise transfer API or any other form of Solithromycin to any Third Party or Affiliate of FFFC for any purpose or enable (by technology transfer, grant of rights, or otherwise) any Affiliate of FFFC or Third Party to manufacture (or assist in the manufacture by any of the foregoing of) API or any other form of Solithromycin, provided that these contractual limitations shall not apply following any termination of this Agreement by FFFC pursuant to **Section 10.2(b)** or **10.2(c)** or by FFFC or Cempra pursuant to **Section 10.2(e)** as a result of a Product Failure directly and primarily resulting from Cempra's gross negligence or intentional misconduct. Cempra shall have the right to at all times maintain and/or utilize one or more alternative or additional manufacturer(s) for the API or itself manufacture API.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

7. **REPRESENTATIONS, WARRANTIES, AND COVENANTS.**

7.1 Legal Authority; No Conflict. Each Party represents and warrants to the other Party that: (a) it has the legal power, authority and right to enter into this Agreement and to perform all of its respective obligations; (b) it is in good standing under the law of the jurisdiction in which it is incorporated or in which it is engaged in business activities; (c) it has no knowledge of any legal or other restriction, limitation, adverse financial or other conditions affecting its ability to fully perform under this Agreement; (d) that it shall not commit any act or fail to take any action that, in any significant way, would be in conflict with its material obligations under this Agreement; and (e) that it shall comply in all material respects with Applicable Laws, and in particular those related to API Manufacturing, and with all requirements under this Agreement. The execution and delivery of this Agreement and the performance of such Party's obligations hereunder (i) do not conflict with or violate any requirement of applicable laws or regulations and (ii) do not conflict with, or constitute a default or require any consent under, any contractual obligation of such Party.

7.2 Non-Infringement; Cempra Licensed Patents. FFFC represents and warrants to Cempra that, to FFFC's best knowledge as of the Effective Date and thereafter during the Term, based on reasonable due diligence and investigation through the use of patent counsel, there are no Patents owned or controlled by Third Parties Covering the Manufacture of the API in accordance with the API Manufacturing Procedures or provision of any other services to be provided by FFFC under this Agreement, other than any Cempra Licensed Patents that may Cover the Manufacture of API or provision of other services under this Agreement. FFFC hereby agrees and covenants that neither it, any of its Affiliates, nor any of its or its Affiliates contractors will, in the course of Manufacturing API or performing any other activities under this Agreement, (i) practice any rights, or otherwise engage in any activity, perform or use any process, method, or procedure, or use any material that is, Covered by any Patents owned or controlled by any Third Party in Manufacturing API or otherwise performing its obligations under this Agreement, other than the Cempra Licensed Patents or Patents to which FFFC has directly obtained, independently of Cempra, sufficient rights to enable FFFC, its Affiliates, and its and its Affiliates' contractors to Manufacture API and perform its obligations hereunder without infringing such Patents or causing Cempra, its Affiliates, or its or its Affiliates' licensees to infringe such Patents or (ii) engage in any other misappropriation or violation of any Third Party's intellectual property rights (including but not limited to trade secrets). FFFC acknowledges that Cempra and/or its Affiliates may have certain royalty, payment, and/or other obligations to Third Parties with respect to the Cempra Licensed Patents, and FFFC agrees that, for each amount of API supplied hereunder, it shall, prior to or simultaneously with its invoice for such API, confirm to Cempra in writing that the manufacturing methods, processes, and synthetic pathways followed or performed in the manufacture of such API were those specified by Cempra therefor or, solely to the extent not constituting or requiring the practice of, any Third Party's intellectual property or rights thereto, those improved by FFFC and protected as confidential in the DMF, and FFFC further agrees and covenants that it will only utilize the methods, processes, and synthetic pathways specified by Cempra for the manufacture of API or, solely to the extent not constituting or requiring the practice of any Third Party's intellectual property or rights thereto, those improved by FFFC and protected as confidential in the DMF in performing FFFC's obligations hereunder.

7.3 Ability and Capacity. FFFC represents and warrants that: (a) it has all permits, approvals, personnel, professional experience, equipment, facilities, funds, and capacity to fully perform its obligations under this Agreement; and (b) that it will not use in any manner, employ, engage or utilize the services of any person who has been or is threatened with debarment under the United States' Generic Drug Enforcement Act of 1992 or any equivalent law, rule, or regulation outside of the United States, or subject to any other comparable administrative, institutional or other sanction for misconduct.

7.4 Warranty of Title. FFFC represents and warrants that all API, when title therefor is to be transferred to Cempra pursuant to **Section 5.4**, shall be free and clear of any and all encumbrances, liens, or other claims, and FFFC can and does grant good and marketable title thereto.

7.5 API Warranty. FFFC represents and warrants that all API, when delivered to Cempra under this Agreement, (a) will be manufactured, tested, packaged, handled, and stored in strict accordance with the API Manufacturing Procedures, the Quality Agreement, cGMP and all other Applicable Laws; (b) will meet the API Specifications; (c) will not be adulterated or misbranded within the meaning of the FD&C Act or any similar laws, regulations, or guidelines, or any applicable directives of applicable Regulatory Authorities; and (d) will not be articles that, under the provisions of the FD&C Act or any similar laws, regulations, or guidelines, or any applicable directives of applicable Regulatory Authorities, may not be introduced into interstate commerce. In the case of breach of the foregoing warranty, FFFC shall promptly replace the Non-Conforming API at no additional cost to Cempra, or refund the purchase price therefor, at Cempra's election, and provided that the foregoing shall not limit FFFC's recall obligations under **Section 9** and indemnification obligation under **Section 12.1**.

7.6 Compliance with Laws. Each Party covenants that it will comply with all Applicable Laws in its performance of this Agreement. Each Party certifies that it shall cooperate with the other Party as required to comply with Applicable Laws, including providing assistance with any disclosures required by Applicable Laws. Manufacturer represents and warrants that, as of the Effective Date, neither it, any Affiliate thereof, nor any facility of Manufacturer or any Affiliate thereof is the subject of any inquiries, notifications, inspection activity, suspensions, or holds by any Regulatory Authority with respect to the manufacture of any active pharmaceutical ingredients or finished pharmaceutical products (including but not limited to, any FDA Form 483 Establishment Inspection Reports, warning letters, or similar items).

7.7 Disclaimer . EXCEPT AS EXPLICITLY SET FORTH IN THIS AGREEMENT, NEITHER PARTY MAKES ANY REPRESENTATIONS OR GRANTS ANY WARRANTIES, EXPRESS OR IMPLIED, EITHER IN FACT OR BY OPERATION OF LAW, BY STATUTE OR OTHERWISE, AND, EXCEPT TO THE EXTENT SET FORTH IN THIS AGREEMENT, EACH PARTY SPECIFICALLY DISCLAIMS ANY AND ALL WARRANTIES, WHETHER WRITTEN OR ORAL, OR EXPRESS OR IMPLIED, INCLUDING ANY WARRANTY OF QUALITY, MERCHANTABILITY OR FITNESS FOR A PARTICULAR USE OR PURPOSE.

8. PROCESS QUALITY AND REGULATORY MANAGEMENT

8.1 Compliance with API Specifications and Other Requirements. FFFC shall Manufacture all API, and carry out all other obligations under this Agreement, in compliance with the API Specifications, the Quality Agreement, cGMP and all other Applicable Laws, and the other requirements under this Agreement.

8.2 Licenses and Permits. FFFC shall obtain and maintain at its expense all permits, licenses and approvals (including facilities licenses) needed for FFFC to be able to manufacture and supply API in compliance with cGMP and Applicable Law (the “**Facilities Licenses**”), in a timely manner such that FFFC is able to meet its Manufacturing and supply obligations under this Agreement. FFFC shall keep Cempra regularly and fully informed about status of all such Facilities Licenses and shall provide Cempra copies thereof upon request. FFFC shall ensure that the Facility complies with cGMP and all other Applicable Laws with regards to its Manufacturing and supply of API. FFFC shall use best efforts to resolve as soon as possible any issues that arise in its seeking or maintaining Facilities Licenses, including completely addressing and rectifying any deviations or other issues raised in any regulatory compliance action or any similar warning or objection by any Regulatory Authority.

8.3 Quality Agreement . The parties shall use reasonable efforts to work in good faith to negotiate and execute a customary form of quality agreement that is consistent with Applicable Law and industry standards (a “**Quality Agreement**”) as soon as reasonably possible following the Effective Date, but in any event no later than within six months of signing this Agreement; upon execution of the Quality Agreement, a copy thereof will be attached as **Exhibit F** of this Agreement. Such agreement may be amended by mutual agreement from time to time by the Parties. To the extent that the terms or conditions of the Quality Agreement, or any procedure, specification or requirement referenced by it, conflicts or is materially inconsistent with the terms of this Agreement, the terms of this Agreement shall prevail.

8.4 Information for Regulatory Applications. FFFC shall prepare and maintain a DMF in the Territory for the API manufactured hereunder, and update such DMF as required by Applicable Law, with such DMF to contain reasonably appropriate information concerning Master Batch Records (and API Manufacturing Procedures) as necessary and appropriate for all Regulatory Submissions in the Territory and for the development, manufacture, commercialization, and use of Drug Product in the Territory. Except as may be agreed in writing by the Parties in any agreement for the supply of Drug Product for use or sale outside the Territory pursuant to any agreement negotiated in accordance with **Section 2.11** , FFFC shall not file any DMF for the API or any other form of Solithromycin outside of the Territory, nor enable or permit any Affiliate of FFFC or any Third Party to file a DMF concerning the API or any other form of Solithromycin or reference any such DMF filed or maintained by or on behalf of FFFC (provided that the foregoing shall not limit Cempra’s rights, including its rights to sublicense, under **Section 6.3(b)**), and FFFC shall ensure that no Affiliate of FFFC files any DMF for API or any other form of Solithromycin except to the extent otherwise agreed to in writing by Cempra. Upon Cempra’s written request, FFFC shall provide to Cempra, in English, the complete Master Batch Records, Batch Records, and any other API production records, and specific API Manufacturing Procedures and updates, and copies of the relevant documents containing any other FFFC technology used in manufacturing API, to the extent such technology and API Manufacturing Procedures are not

maintained as confidential in the DMF maintained by FFFC. Cempra has the right to review and copy the executed, completed Batch Records for each Batch, as needed for Cempra, its Affiliates, and its or its Affiliate's licensees to prepare the CMC sections for any particular Regulatory Submissions that Cempra (or its Affiliate or its or its Affiliate's licensee) intends to file or for any other appropriate regulatory purpose relating to API or any Drug Product to the extent such technology and API Manufacturing Procedures are not maintained as confidential in the DMF maintained by FFFC. FFFC shall prepare and maintain the Batch Records for each Batch of API manufactured hereunder, and shall provide Cempra, its Affiliates, and its and its Affiliates' licensees access to such Batch Records for review and inspection, and shall provide copies thereof to Cempra upon request to the extent such technology and API Manufacturing Procedures are not maintained as confidential in the DMF maintained by FFFC.

8.5 Regulatory Submissions. Cempra, its Affiliates, and its or its Affiliates' licensees shall have the exclusive right to prepare and submit any and all Regulatory Submissions, other than the DMF to be filed by FFFC in the Territory as contemplated hereby, regarding API or Drug Products, and including filing any amendments or supplements thereto and pursuing such applications and filings to approval or registration. All Regulatory Submissions related to the API and/or the Drug Product, other than the DMF to be filed by FFFC in the Territory as contemplated hereby, shall be made, owned, and controlled by Cempra (or its Affiliates or its or its Affiliates' licensees, as applicable) in its (or their) sole discretion. To the extent required or appropriate under Applicable Laws, any such Regulatory Submissions regarding API and/or Drug Product shall list FFFC as the manufacturer of any API supplied under this Agreement. FFFC shall have no rights in or to any such Regulatory Submissions. FFFC, in consultation with Cempra, shall prepare at its expense the description of the Manufacturing operations and related information (*e.g.*, methods validation package, stability, representative data and Batch records) as required for inclusion in the Regulatory Submissions to the FDA, MHLW, and other Regulatory Authorities, which will contain all of the information relating to API Manufacturing Procedures as required in such Regulatory Submissions. FFFC will assist Cempra in the preparation of annual updates and other required or requested Regulatory Submissions, and in promptly responding to any questions from Regulatory Authorities. If and as requested by Cempra, FFFC shall provide qualified technical representatives to attend meetings and/or teleconferences with the FDA, MHLW, and other Regulatory Authorities as needed.

8.6 Regulatory Assistance. Without limiting Section 8.5 , with respect to any application or filings reasonably needed by Cempra (or its Affiliate or its or its Affiliate's licensee) to obtain or maintain Regulatory Approvals for any Drug Product, and any record-keeping, audits, inspections and audits required by Regulatory Authorities relating to the manufacture and/or supply of all API by FFFC hereunder, FFFC shall reasonably cooperate with and assist Cempra in all such matters, including providing any additional information in FFFC's control needed for such applications, filings or activities and any additional support relating to API as reasonably requested by Cempra, and Cempra shall reimburse FFFC for any actual out-of-pocket costs of providing such information and assistance, in amounts to be agreed prior to the services.

8.7 FFFC Pre-Review of Regulatory Submission. FFFC accepts responsibility for the accuracy, integrity and completeness of all documentation prepared by or on behalf of FFFC that is filed with Regulatory Authorities, including but not limited to the DMF to be filed by FFFC as contemplated by this Agreement (collectively, the “ **FFFC Regulatory Documents** ”).

8.8 OOS and Other Events. FFFC shall immediately inform Cempra in writing of all OOS and out-of-trend events (provided such trend constitutes a deviation) within two (2) business days, failure investigations, process deviations, Batch failures and similar matters (including any unexpected adverse final or interim results or data from stability or other studies) and provide Cempra with the applicable investigation report and corrective action plans prior to release of the in-process or finished Lots that are subject to the OOS event. All OOS and other investigations, and all corrective actions, shall be performed in accordance with Regulatory Standards and a written procedure acceptable to the Parties.

8.9 Pre-Approval Inspections and Other Inspections. FFFC shall use its best efforts to successfully pass MHLW inspections, and all other regulatory inspections by the Regulatory Authorities and audits performed by or on behalf of Cempra, its Affiliates, or its or its Affiliates' licensees, without material objection. Should FFFC fail MHLW inspection or review of Regulatory Submissions results in materially adverse actions by any Regulatory Authority (e.g., delay of Marketing Approval or requirement for corrective actions), in any event due to FFFC's negligence, inadequate planning or implementation or failure to comply with Applicable Laws or other requirements under this Agreement, it shall immediately rectify such inadequacies and perform best efforts to prepare the Regulatory Submissions related to API Manufacturing and other services of FFFC provided hereunder. Except as specifically provided otherwise in this Agreement, FFFC shall bear the expense of establishing and maintaining its compliance with Applicable Laws and other requirements in their Agreement, including implementation of any corrective or other actions needed to bring about such compliance. FFFC shall allow Cempra's quality assurance team (or that of its Affiliates or its or its Affiliates' licensees) to conduct mock preapproval inspections upon their reasonable request.

8.10 Records. FFFC shall prepare and maintain all Records relating to its activities under this Agreement, including all Batch Records. Records shall be prepared and maintained in compliance with cGMP and all other Applicable Laws and other requirements under this Agreement. All Records shall be complete, accurate, legible, valid, verifiable and contemporaneous with the events or activities described. All Records shall be available for Cempra's, its Affiliates', and its and its Affiliates' licensees' inspection and audit upon advance notice during business hours, and Cempra, its Affiliates, and its and its Affiliates' licensees shall have the right to request and obtain copies thereof, which are accompanied by a written statement of an appropriate representative of FFFC certifying the authenticity and accuracy of such copies, during the Term and until the latest of (i) thirteen (13) years from the time of manufacture and release of the API to which the applicable Records relate, (ii) three (3) years from expiration of the Drug Product manufactured using such API, or (iii) such later date as may be required by Applicable Law, to the extent, in each case, such Records do not contain any information maintained as confidential in the DMF maintained by FFFC. Notwithstanding the foregoing, Cempra and/or its representative (including that of any Cempra Affiliate or licensee of Cempra or any Affiliate thereof) may at any time have access to the Records during business hours to the extent such the Records do not contain any information maintained as confidential in the DMF maintained by FFFC and the right to make copies thereof, in connection with investigation of any complaint or injury related to the API or the Drug Product or any dispute between the Parties. FFFC shall not destroy, alter (except for corrections as and in the manner permitted by Applicable Laws), remove or dispose of any Records without Cempra's prior written consent and in which case Cempra may take possession and custody of such Records to the extent not containing information not disclosed or required to be disclosed to Cempra (which may include information maintained as confidential from Cempra in the DMF).

8.11 Retention Samples, Analytical Verification, and Qualification. FFFC shall collect and retain samples as required by the API Specifications and Applicable Laws. In addition, as directed by Cempra, FFFC also shall retain sufficient quantities of samples of API (including production samples taken during the Manufacturing process) to twice replicate the quality control and release testing applicable to the sample. These additional samples shall be maintained by FFFC for the longest of (i) eight (8) years from the date of manufacture and release of the corresponding API, (ii) three (3) years from expiration of the Drug Product manufactured using such API, or (iii) such longer period as may be required under Applicable law and, upon request, furnished to Cempra at any testing facility designated by Cempra. There shall be no charge for preparing these additional samples, other than any reasonable, documented costs incurred with special packing requirements or courier services. FFFC shall notify Cempra before disposing of any such samples, and upon Cempra's request shall ship the requested samples to Cempra or any designee thereof at Cempra's cost (which shall be reasonable and documented).

8.12 Notice of Adverse Discovery. At any time following the Manufacture of a Lot of API, FFFC shall notify Cempra immediately in writing in the event FFFC discovers or has reason to believe that there may be defects or deviations of any kind whatsoever in such API, including any non-conformance with API Specifications, Applicable Law, or any requirements applicable to its Manufacture or any breach of the warranty in **Section 7.5** as to such API.

8.13 Inspection of Facility by Cempra. Cempra (or its Affiliate or any licensee of Cempra or any Affiliate thereof) shall have the right, and FFFC shall permit Cempra (or its Affiliate or any licensee of Cempra or any Affiliate thereof), from time-to-time, and at any time, to audit or inspect the portions of the Facility where API is Manufactured or stored and to review all Records and other documents relating to Manufacturing of API as is reasonably necessary for the purpose of assessing FFFC's compliance with the Manufacturing SOPs, cGMP, the API Specifications, the Regulatory Standards, applicable chemical manufacturing controls, and this Agreement to the extent such Records do not contain any information maintained as confidential in the DMF maintained by FFFC. Such audits or inspections shall not be limited in number or frequency, but in principle once or twice a year, and any such audit or inspection and document review shall be conducted upon reasonable prior written notice by Cempra prior to the proposed audit or inspection (except in the event of a reasonable, urgent concern by Cempra regarding the quality of API, in which case Cempra may conduct the audit or inspection as soon as possible), at a time and date determined by Cempra, taking into account FFFC's reasonable scheduling concerns. In addition, such audits or inspections shall be implemented during business hours of such Facility. Furthermore, Cempra shall have the right, from time-to-time, and at any time, to have an employee, agent, or representative of it, any Affiliate of Cempra, or any licensee of Cempra or any Affiliate thereof present at the Facility during the preparation for or conduct of any manufacturing or production run for Manufacture of a Batch of API, and such employee or agent shall be free to inspect and oversee all aspects of such preparation or production run and to comment to FFFC thereupon.

8.14 Regulatory Inspections.

(a) Inspection by Regulatory Authorities. Upon the request of any Regulatory Authority having jurisdiction over the manufacture of API hereunder or Drug Product to be manufactured using such API, such Regulatory Authority shall have access to observe and inspect FFFC's facilities and procedures used for all activities related to the manufacture and storage of the API including but not necessarily limited to the manufacture, testing and release, and/or warehousing of all API (and all Intermediates and Raw Material) and to audit such facilities for compliance with cGMP and/or other applicable Regulatory Standards. FFFC specifically agrees to cooperate with any inspection by a Regulatory Authority, whether prior to or after Regulatory Approval of a Drug Product, and to promptly provide Cempira a copy of any inspection or audit report resulting from any such inspection. If FFFC is purchasing Raw Materials from a Third Party manufacturer for use in manufacturing API, FFFC shall use commercially reasonable diligent efforts to ensure that such manufacturer's facilities and procedures are subject to the provisions of this **Section 8.14(a)**, or substantially similar contractual obligations, as to the manufacture of such Raw Materials, and to ensure that Cempira is provided copies of any inspection or audit report of such Third Party relating to such Raw Materials. For any Third Party manufacturers of Raw Materials selected by Cempira, FFFC will perform a reasonable and customary use test in accordance with relevant SOP or protocol with respect to any Raw Materials obtained from such Third Party.

(b) Notification of Inspections. FFFC agrees to notify Cempira in writing as soon as possible of any written or oral inquiries, notifications or inspection activity by any Regulatory Authority in regard to the API to be supplied to Cempira hereunder or to any Manufacturing activity related thereto. Cempira shall have the right to attend (or have any Affiliate thereof or licensee of Cempira or any Affiliate thereof attend) any such inspection that relates directly to Manufacturing (including testing) of API. FFFC shall provide a reasonable description of any such governmental or regulatory inquiries, notifications or inspections promptly, but in no event later than one (1) business day after such notification, inquiry or inspection. FFFC shall furnish to Cempira (i) as soon as possible and not to exceed within three (3) business days after receipt, any report or correspondence issued by any Regulatory Authority in connection with such notification, inquiry or inspection, including any List of Inspectional Observations, applicable portions of any Warning Letters, or any equivalent or similar form, letter, or notice in another country or jurisdiction which pertain to the API or any facility involved with the manufacture, handling, or storage thereof, and (ii) not later than ten (10) business days prior to the time it provides to any Regulatory Authority, copies of proposed responses or explanations relating to items set forth above (each, a "**Proposed Response**"), in each case redacted of trade secrets or other confidential or proprietary information of FFFC that are unrelated to the obligations under this Agreement or are unrelated to API or its manufacture. FFFC shall discuss with Cempira and consider in good faith any comments provided by Cempira on the Proposed Response. After the filing of a response with the Regulatory Authority, FFFC shall notify Cempira promptly in writing of any further contacts with such Regulatory Authority relating to the subject matter of the response until resolution and provide the final outcome (e.g. establishment inspection report (EIR)).

(c) Remedial Actions. FFFC shall notify Cempira immediately in writing in the event any action is taken or threatened by a Regulatory Authority relating to the manufacture,

handling, or storage of API by FFFC, or relating to the FFFC Facility in which such manufacture, handling, or storage occurs, or which may impair the ability of FFFC to manufacture or store API (including without limitation any impairment to FFFC's ability to manufacture or store API conforming to the applicable API Specifications) in accordance with this Agreement. In any event, FFFC shall use best efforts to address and resolve as soon as possible any issues, concerns or warnings from any Regulatory Authority that might affect FFFC's ability to manufacture, supply, and store API in accordance with this Agreement. To the extent FFFC must implement a plan of remediation or for other modifications or changes to its FFFC Facility or its manufacturing processes in order to address and resolve any such issues, concerns or warnings from any Regulatory Authority, FFFC shall prepare such plan as soon as possible, shall provide a draft of the plan to Cempra for review and comment, and shall implement all reasonable comments of Cempra as soon as possible, and shall implement and complete all aspects of the agreed plan as soon as possible.

(d) Damages for Regulatory Failures. If FFFC fails to deliver on a timely basis API ordered by Cempra under this Agreement due to either: (i) failure of FFFC to obtain or maintain all needed Facilities Licenses or (ii) a determination by the MHLW or any other Regulatory Authority that the API is "misbranded or adulterated" within the meaning of the FD&C Act (or equivalent determination under any Applicable Law in the Territory) due to any manufacturing problem or issue at the Facility, or any other similar disability or determination raised, imposed, or made by a Regulatory Authority, each arising from any reason, act, or omission attributable to FFFC, its Affiliates, or its subcontractors, then FFFC shall indemnify and hold Cempra harmless from any and all losses resulting from lost sales caused directly by such failure to deliver within the limitation set forth in **Section 12.4**.

8.15 Other Conditions of Audits and Inspections. There shall be no charge for any inspections or audits as described in **Sections 8.13** or **8.14** above, and FFFC shall cooperate with both, including providing of reasonable space for review and copying of Records and assistance of key personnel. Cempra representatives, when on FFFC's premises, shall at all times comply with FFFC's internal policies to the extent reasonable and provided in advance to Cempra. It is agreed that, except to the extent audits and observation are implemented by Cempra unreasonably and excessively frequently or unreasonably and excessively rigidly or for an unreasonably long period and such implementation by Cempra directly results in any prevention or inhibition of FFFC's performance of its obligations under this Agreement, the audits and observation by Cempra representatives shall not in any way serve as a limitation on any of FFFC's obligations or liabilities under this Agreement; although Cempra reserves the right to audit the Facility annually or more frequently if reasonable under the circumstances and will provide FFFC with the results of any quality audit performed by Cempra.

9. R ECALLS AND R ECALL C OST S

9.1 Responsibility for Recalls. If a Recall (as defined in **Section 9.5** below) of any Drug Product distributed by Cempra or its Affiliate or any licensee of either of the foregoing is required or recommended by a Regulatory Authority or other governmental agency or authority of competent jurisdiction, or if a Recall is otherwise deemed advisable by Cempra (or its Affiliate or its or its Affiliate's licensee), Cempra, its Affiliate, or its or its Affiliate's licensee, as applicable shall, as between the Parties, be responsible for and determine, in their sole discretion, such Recall,

its planning, and its execution, provided that FFFC shall cooperate with Cempra, its Affiliates, and its or its Affiliates' licensees, as applicable, with respect to any such Recall, as reasonably requested thereby, and further provided that, to the extent permitted and reasonably possible in light of any applicable terms of Cempra's agreements with its licensees or distributors in the Territory (including but not limited to Toyama) without breach of such agreements, Cempra shall use reasonable efforts to consult with FFFC regarding any potential Recall prior to the initiation thereof. The costs of any Recall shall, as between the Parties, be borne by the Party or Parties whose actions or omissions caused the Recall to be necessary or deemed advisable, as provided in **Section 9.4**.

9.2 Communication. Each Party shall keep the other fully and promptly informed of any notification, event or other information, whether received directly or indirectly, which might affect the marketability, safety or effectiveness of Drug Products sold or distributed by Cempra, its Affiliate, or its or its Affiliate's licensee or might result in a Recall or Seizure (as defined in **Section 9.5** below) of Drug Products by the FDA, MHLW, or other Regulatory Authority.

9.3 Replacement; Refund. In the event of any Recall or Seizure of Drug Product arising out of or resulting from FFFC's supplying defective API or other breach of this Agreement by FFFC, FFFC shall, if and as elected by Cempra, and in addition to any other obligations of FFFC under the terms of this Agreement available to Cempra for any breach of this Agreement by FFFC, either:

(a) promptly supply replacement API that meets the API Specifications and otherwise conforms to the warranty in **Section 7.5**, without charge to Cempra, in an amount sufficient to replace the amount of API needed to manufacture the Drug Product that is Recalled or Seized (including that amount of API incorporated into any Drug Products that are Recalled or Seized), or

(b) refund to Cempra, or give credit to Cempra against outstanding receivables due from Cempra against the price of API to be delivered to Cempra in the future, in amounts equal to the price paid by Cempra to FFFC for the API needed to manufacture the amounts of Drug Product so Recalled or Seized (including that API incorporated in the Drug Product so Recalled or Seized) plus the reasonable, documented transportation costs incurred by Cempra and not recovered by Cempra in respect of such Recalled or Seized Drug Product.

9.4 Responsibility for Recall Costs. To the extent any Recall or Seizure of API or any Drug Product results from FFFC manufacturing defects in any API supplied by FFFC (for example, due to FFFC's failure to manufacture a API included in such Drug Product in accordance with the API Specifications or cGMP), or otherwise arises out of, or is connected with any inaccuracy in, breach of, or non-fulfillment of, any representation, warranty, covenant or other obligation of FFFC under this Agreement, or any negligence, recklessness, willful misconduct, or failure to conform with the explicit quality standards or quality obligations imposed on FFFC in the Quality Agreement on the part of FFFC, its Affiliates, or its or its Affiliates' directors, officers, employees, vendors or agents, then FFFC shall pay all the reasonable, documented, direct costs of such Recall or Seizure, including such costs incurred by Cempra, any Affiliate thereof, or any licensee of Cempra or any Affiliate with respect to the reasonable conduct of any such Recall or Seizure, including but not limited to shipping costs, repurchases, notification letters, direct

shipping expenses, and the costs of disposal and/or destruction of the Recalled items, and other direct costs and expenses directly related to such Recall or Seizure (such as costs of administering any Recall), provided that if such Recall or Seizure results from negligence, intentional misconduct, or failure of both Parties, Cempra and FFFC shall bear such costs and expenses pro rata in accordance with their share of fault, which shall be discussed in mutual good-faith and reasonable consultations between the Parties (for purpose of clarification, API, supplied by FFFC under this Agreement, that (x) was not manufactured, stored, or released by or on behalf of FFFC in accordance with the API Specifications or cGMP or (y) did not conform with the explicit quality standards or quality obligations imposed on FFFC in the Quality Agreement with respect to such API, shall, solely for purposes of this proviso, constitute such negligence, intentional misconduct, or failure on the part of FFFC). Notwithstanding the foregoing, FFFC shall have no obligation to pay costs of a Recall or Seizure of any Drug Product to the extent such Recall or Seizure is: (a) due to defects in the Drug Product other than those arising out of (x) manufacturing defects in the API as supplied by FFFC or (y) any inaccuracy in, breach of, or non-fulfillment of, any representation, warranty, covenant or other obligation of FFFC under this Agreement, or any negligence, recklessness, willful misconduct, or failure to conform with the explicit quality standards or quality obligations imposed on FFFC in the Quality Agreement on the part of FFFC, its Affiliates, or its or its Affiliates' directors, officers, employees, vendors or agents, (b) due to defects in the Drug Product caused by improper actions (such as incorrect storage) occurring after the API is delivered by FFFC to Cempra's carrier, (c) due to packaging or labeling defects for which Cempra or any Third Party has responsibility, or (d) due to and caused by any other breach by Cempra of its duties under this Agreement. For the avoidance of doubt and subject to the general limitations of liability under this Agreement, and without limitation of the foregoing, FFFC shall be solely responsible for the costs and expenses of a Recall or Seizure that is directly caused by a FFFC manufacturing defect in API supplied to Cempra.

9.5 Definition of Recall and Seizure . For purposes of this **Section 9** , “ **Recall** ” shall mean any action by Cempra and/or its Affiliates or licensees to recover title or possession or halt distribution, prescription or consumption of Drug Products sold or shipped to Third Parties by Cempra or its Affiliate or licensee, including any market withdrawal. The term “ **Recall** ” also applies to Drug Product which would have been subject to recall or withdrawal if it had been sold or shipped. “ **Seizure** ” shall mean any action by the MHLW or other Regulatory Authority or governmental agency or authority of competent jurisdiction to detain or destroy API or Final Products or prevent the distribution, prescription, consumption or release of any API or Final Products.

10. T E R M A N D T E R M I N A T I O N

10.1 Term. Unless earlier terminated as provided for in **Section 10.2** or **Section 15.4(b)** , the initial term of this Agreement shall commence on the Effective Date and shall remain in full force and effect for a period of ten (10) years from the Effective Date (the “ **Initial Term** ”). The term shall be automatically renewed thereafter for one year periods (each, a “ **Renewal Term** ” and together with the Initial Term, the “ **Term** ”) unless either Party gives the other Party prior written notice of non-renewal at least [*] months prior to the end of the then-current Term.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

10.2 Termination.

(a) Mutual Consent. The Parties may at any time terminate this Agreement by mutual written agreement.

(b) Material Breaches.

(i) A Party shall have the right to terminate this Agreement on written notice to the other Party if the other Party commits a material breach of its obligations under this Agreement and fails to remedy such breach within [*] days after notice of such breach. After the end of the applicable cure period, if the breach has not been cured, the Party having the right to termination may terminate in whole or in part immediately upon notifying the breaching Party in writing. Any termination of this Agreement shall not release the breaching Party from its obligations or otherwise affect or limit the Parties' rights and remedies. For clarity, Cempra's breach of its minimum purchase obligations under Section 2.6(d) of this Agreement shall be construed as a material breach of Cempra enabling termination as set forth in this **Section 10.2 (b)(i)**.

(ii) Each Party shall notify the other Party in writing as soon as reasonably possible of any claim, threatened claim, or allegation made against it or any Affiliate thereof concerning any alleged, potential, or actual infringement, violation, or misappropriation of any Third Party's intellectual property rights (including but not limited to Patents) in the Manufacture of API or performance of FFFC's other obligations under this Agreement. Upon such notice, the Parties shall enter into good faith discussions concerning such claimed, alleged, possible, or actual infringement, violation, or misappropriation and potential appropriate or necessary measures that may enable FFFC to continue to perform this Agreement without infringing, violating, or misappropriating any Third Party's intellectual property rights (including but not limited to Patents). If FFFC fails to propose a reasonable, feasible and practical solution embodying appropriate and necessary measures enabling such non-infringing, non-violating, and non-misappropriating continued performance by FFFC that (i) would not require any additional cost or expenditure by Cempra or otherwise adversely affect Cempra's, its Affiliates', or any of its or its Affiliates' licensees', sublicensees', or distributors' development, manufacture, or commercialization of API or Drug Product and (ii) is reasonably approved in writing by Cempra in its sole discretion within [*] days after one Party provides such notice to the other Party of the applicable claim, threatened claim, or allegation, then Cempra shall have the right to terminate this Agreement on written notice to FFFC.

(c) Bankruptcy. A Party shall have the right to terminate this Agreement effective upon written notice to the other Party in the event that: (a) such other Party files a petition in bankruptcy or makes a general assignment for the benefit of creditors, or is adjudged bankrupt, and such other Party (i) fails to assume this Agreement in any such bankruptcy proceeding within [*] days after filing or (ii) assumes and assigns this Agreement to a Third Party; (b) such other Party goes into or is placed in a process of complete liquidation; or (c) a trustee or receiver is appointed for any substantial portion of such Party's business and such trustee or receiver is not discharged within [*] days after appointment.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(d) Supply Failure. This Agreement may be terminated by Cempra by written notice to FFFC at any time following the occurrence of a Supply Failure.

(e) Product Failure. This Agreement may be terminated immediately by either Party on [*] days written notice to the other Party in the event of a Product Failure.

(f) Purchase Quantity Cause. This Agreement may be terminated by FFFC by written notice to Cempra at any time following the end of a complete Month Period during which the total quantity of API ordered by Cempra for delivery during such Month Period is less than a thousand (1,000) kg.

(g) Validation or Process Issues. This Agreement may be terminated by Cempra on written notice to FFFC if there are manufacturing process issues that make it commercially impracticable to manufacture API at the Facility, such as, without limitation of any other circumstances enabling termination under this **Section 10.2(g)**, that FFFC is unable to complete successfully the Validation Studies on a timely basis, or the registration or engineering Batches fail and cannot be completed to Cempra's reasonable satisfaction.

10.3 Effect of Termination.

(a) Remaining Portion of Forecast. Upon any termination of this Agreement, Cempra shall be obligated to purchase, and FFFC shall be obligated to deliver, API in accordance with any binding portion of the then current Forecast for which Purchase Orders have not been submitted, but Cempra shall not be obligated to submit any Purchase Orders or purchase any API in accordance with any non-binding portion of the then current Forecast for which Purchase Orders have not been submitted, except to the extent, with respect to all of the foregoing, explicitly provided for below.

(b) Elective Purchase of Inventories. In the event of this Agreement's termination, Cempra shall be entitled, if and as elected by Cempra, to (i) purchase, at the lowest price indicated in **Exhibit J**, all remaining API in FFFC's inventory that it would not otherwise be obligated to purchase under this Agreement and/or (ii) purchase, at FFFC's reasonable, documented, direct purchase or production cost, as applicable, its Raw Materials or Intermediates (valued on a pro-rata basis to manufacturing cycle-time) reasonably purchased or produced for Manufacturing that, with the exercise of reasonable efforts by FFFC, are not reasonably able to be returned for credit or used for producing products for FFFC's other customers, plus reasonable, documented shipping costs. In no event shall Cempra be charged an amount for Raw Materials or Intermediates that exceeds the purchase price set forth hereunder for the corresponding amounts of API specified by Cempra's relevant Purchase Orders in effect at the date this Agreement is terminated (the "**Termination Date**").

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(c) Effects of Termination by Cempra for Product Failure or by FFFC for Cempra's Breach or Bankruptcy. If this Agreement is terminated by Cempra under **Section 10.2(e)** or by FFFC under **Section 10.2(b)** or **10.2(c)**, then, except to the extent otherwise agreed to in writing by the Parties, (i) all amounts of completed API existing as of the date the termination notice is provided Manufactured under Purchase Orders previously accepted by FFFC shall be delivered and paid for by Cempra in accordance with the terms of this Agreement, (ii) all other Manufacturing work under this Agreement shall immediately cease and all other pending Purchase Orders shall be automatically cancelled, and (iii) Cempra shall, within thirty (30) days of an invoice from FFFC, reimburse FFFC for FFFC's reasonable, documented direct cost of all unused Intermediates and all unused Raw Materials reasonably procured by FFFC prior to such notice of termination as necessary to manufacture API in satisfaction of the binding and non-binding portion of the most recent Forecast provided by Cempra, except to the extent (a) such Product Failure results from FFFC's, its Affiliates', or its or its Affiliates' contractors' negligence, intentional misconduct, breach of this Agreement, or failure to comply with Applicable Law or (b) such Intermediates or Raw Materials can, with the exercise of reasonable efforts, be used by FFFC in any other portions of its business. If and as requested by Cempra, any unused Intermediates or Raw Materials for which Cempra reimburses FFFC's cost shall be promptly delivered (and all right, title, and interest therein assigned) to Cempra or its designee, at Cempra's expense for such delivery.

(d) Additional Effect of Termination by FFFC for Cempra's Breach. If this Agreement is terminated by FFFC under **Section 10.2(b)** and, prior to such termination, (i) FFFC has constructed a facility located at 1-34, Iwasawa, Kamikitaba, Hirono-machi, Futaba-gun, Fukushima 979-0401, Japan for the primary purpose of manufacturing API for Cempra hereunder and (ii) such facility is completed and fully operational and qualified for the manufacture of API for delivery hereunder, then, except to the extent otherwise agreed to in writing by the Parties, Cempra shall, within ninety (90) days of such termination and FFFC's provision of a report accurately detailing and certifying to the facts, circumstances, and accounting supporting Cempra's obligation hereunder (and the amount thereof), pay FFFC an amount equal to (a) the "Remaining Book Value" set forth on **Exhibit L** (which is denominated in millions of US dollars) less (b) the product of the number of kilograms of API ordered by Cempra under this Agreement prior to such termination times US\$[*], provided that (x) if the amount described in clause (b) exceeds the amount described in clause (a), Cempra shall have no payment obligation under this **Section 10.3(d)**, (y) if the total direct costs incurred by FFFC in the construction of the facility referenced above, net of any tax credits, tax refunds, government subsidies, or similar financial, monetary, or in-kind benefits provided by any governmental agency or authority (the "Construction Costs"), do not equal or exceed US\$17,500,000, then the "Remaining Book Value" shall be reduced by a pro rata amount, based on the ratios of the various amounts set forth in **Exhibit L**, based on the ratio of such lesser cost to \$17,500,000, and (z) no amount shall be payable hereunder if the Agreement terminates following December 31, 2025; provided, however, that if FFFC manufactures any product or performs any activities (other than the manufacture of API for Cempra under this Agreement) in, by, or using such facility prior to such termination and makes any profit thereby, the total amount of such profits shall be subtracted from the total payment amount due from Cempra to FFFC under this **Section 10.3(d)**. As two examples of the payment requirements of this **Section 10.3(d)** (and in these examples, the total amount of such profits shall be assumed as zero (0)), (I) if the requirements for payment set forth in the first sentence of this **Section 10.3(d)** are satisfied, the Construction Costs equal US\$17,500,000, this Agreement is terminated in 2018, and Cempra has ordered [*] kg of API hereunder prior to such termination, Cempra shall owe FFFC US\$13,430,000 under this **Section 10.3(d)** and (II) if the requirements for payment set forth in the first sentence of this **Section 10.3(d)** are satisfied, the Construction Costs equal US\$8,750,000, this Agreement is terminated in 2018, and Cempra has ordered [*] kg of API hereunder prior to such termination, Cempra shall owe FFFC US\$6,215,000 under this **Section 10.3(d)**.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

(e) Effects of Termination by FFFC for Product Failure or by Cempra for FFFC-Caused Product Failure, FFFC's Breach, Supply Failure, or Validation or Process Issues. If this Agreement is terminated (x) by Cempra under **Section 10.2(b), 10.2(c), 10.2(d), 10.2(g)**, or **15.4(b)**, (y) by Cempra under **Section 10.2(e)** for a Product Failure resulting, in whole or in material part from FFFC's, its Affiliates', or its or its Affiliates' contractors' negligence, intentional misconduct, breach of this Agreement, or failure to comply with Applicable Law, or (z) by FFFC under **Section 10.2(e)**, then, except to the extent otherwise agreed to in writing by the Parties or elected by Cempra under **Section 10.3(b)**, Cempra shall not have any obligations to purchase any API in accordance with any binding or non-binding portion of the then current Forecast for which Purchase Orders have not been submitted or to purchase, or reimburse FFFC's costs for, any API, Intermediates, or Raw Materials remaining in FFFC's possession or control as of such termination, except, in the event of a termination by Cempra under **Section 10.2(e)**, to the extent the applicable Product Failure did not result from FFFC's, its Affiliates', or its or its Affiliates' contractors' negligence, intentional misconduct, breach of this Agreement, or failure to comply with Applicable Law.

(f) Return of Materials. Upon termination of this Agreement, FFFC shall immediately return to Cempra copies of all documentation and information and materials relating to API Manufacturing (including copies of development reports and Master Batch Records to the extent not containing any information maintained as confidential in the DMF maintained by FFFC), the Product, and the Specifications. Any original documents provided by or on behalf of Cempra to FFFC during the Term shall be returned to Cempra, along with any copies thereof, provided that FFFC may keep one archival copy if required by a Regulatory Authority. Documents and materials shall be packaged and shipped in the manner reasonably requested by Cempra as needed to preserve their integrity and acceptability to Regulatory Authorities.

(g) Survival. Termination of this Agreement shall not operate to release any Party from any obligation or liability incurred under the terms of this Agreement before or upon termination hereof, nor shall it relieve the Parties of their obligations with respect to API supplied by FFFC under this Agreement. In addition **Articles 1, 4, 5, 7, 9, 11, 12, 13, 14, and 15** and **Sections 2.2, 2.7, 2.10, 3.3, 6.3(b)** (for Drug Product manufactured with API supplied under this Agreement), **8.1, 8.4, 8.5, 8.6, 8.7, 8.8, 8.9, 8.10, 8.11, 8.12, 8.13, 8.14, 8.15,** and **10.3** shall survive the expiration or termination of this Agreement on account of any cause.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

11. CONFIDENTIALITY & INTELLECTUAL PROPERTY

11.1 Treatment of Confidential Information. The Parties acknowledge and agree that during the Term, either Party may disclose to the other Party its Confidential Information as needed for the conduct of this Agreement and that all “Confidential Information” (as defined in the Confidentiality Agreement) disclosed by either Party pursuant to the Non-Disclosure Agreement between Cempra and FFFC dated October 1, 2013, as amended (the “**Confidentiality Agreement**”) shall be deemed to be such Party’s Confidential Information hereunder. With respect to all such Confidential Information of a Disclosing Party, the Receiving Party agrees that (except as otherwise provided in **Section 11.2** below) during the Term and for a period of [*] years after this Agreement expires or terminates, such Receiving Party shall (a) maintain in confidence such Confidential Information; (b) not disclose such Confidential Information to any Third Party without prior written consent of the Disclosing Party, except for, in the case of each Party, disclosures permitted of such Party under **Section 11.2** ; and (c) not use such Confidential Information for any purpose other than the performance of or exercise of rights under this Agreement, or, in the case of Cempra as the Receiving Party, to the extent necessary or useful in developing, manufacturing, or commercializing Drug Products.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

11.2 Authorized Disclosures. If a Receiving Party is required to disclose specific Confidential Information of the Disclosing Party to comply with Applicable Law, or order of a government authority or court of competent jurisdiction, such Receiving Party may disclose such Confidential Information only to the person(s) or entity(ies) required to receive such disclosure; provided, however, that the Receiving Party required to disclose such Confidential Information shall (a) to the extent reasonably practicable and permitted by such Applicable Law or order, first have given reasonable advance notice to such Disclosing Party to enable it to seek any available exemptions from or limitations on such disclosure requirement, and shall reasonably cooperate in such efforts by the Disclosing Party as reasonably requested thereby, (b) furnish only the portion of such Confidential Information which is legally required to be disclosed, (c) use reasonable efforts to secure confidential protection of such Confidential Information, and (d) continue to perform its obligations of confidentiality set out herein. Further, Cempra (or its Affiliate or its or its Affiliate's licensee) shall be entitled to disclose Confidential Information of FFFC to the extent not containing any information maintained as confidential in the DMF maintained by FFFC (other than such information maintained as confidential in the DMF that is subject to disclosure pursuant to Section 2.2 (if any)) to: (i) Regulatory Authorities to the extent such disclosure is reasonably necessary or useful in Regulatory Submissions required for the development, manufacture, and/or commercialization of Drug Products; (ii) licensees, contractors, employees, and consultants who need to know such information for the development, manufacture and/or commercialization of Drug Products, (iii) potential or actual bankers, underwriters, lawyers, accountants, agents or other Third Parties in connection with due diligence or similar investigations, and (iv) potential or actual investors, licensees, acquirers, merger or acquisition targets, or other strategic partners; provided that any such Third Party is bound by obligations of confidentiality and non-use materially as protective as those set forth herein. Also, FFFC shall be entitled to disclose Confidential Information of Cempra under obligations of confidentiality and non-use materially as protective as those set forth herein to FFFC's Affiliate or subcontractors set forth in Section 2.7 who have been approved by Cempra in writing and need to know such information for the performance of supply obligation in this Agreement; provided that any such Affiliate or Third Party is bound by obligations of confidentiality and non-use materially as protective as those set forth herein. In the case of each foregoing disclosure, the Party making such disclosure shall obtain reasonably appropriate confidential treatment of any such disclosure on its own responsibility, and shall not disclose Confidential Information of the other Party other than is reasonably necessary. Notwithstanding anything to the contrary, FFFC shall not disclose any of Cempra's Confidential Information concerning any API Manufacturing Procedures to Toyama, any Affiliate thereof, or any other Affiliate of FFFC except to the extent approved in advance and in writing by Cempra (such approval not to be unreasonably withheld).

11.3 Disclosure of Agreement. Except as otherwise provided below, neither Cempra nor FFFC shall release any information to any other person regarding the terms of this Agreement without the prior written consent of the other Party, which consent shall not be withheld unreasonably. The foregoing consent requirement includes, but is not limited to, press releases, educational and scientific conferences, promotional materials and discussions with the media. However, each Party shall be entitled to disclose the terms of this Agreement and specific information and terms relating to this Agreement to the extent such disclosure is required by applicable law or regulation or securities exchange rules or regulations, provided that, to the extent reasonably practicable, such Party shall notify the other Party of this requirement before releasing the information. The notice to the other Party shall include the text of the information proposed for

release, and the basis for the required disclosure. The other Party shall, to the extent reasonably practicable, be provided a reasonable opportunity to confer with the notifying Party regarding the necessity for the disclosure and the text of the information proposed for release. A Party shall further be entitled to disclose this Agreement in securities filings with the U.S. Securities and Exchange Commission (the “**SEC**”) or equivalent foreign agency to the extent required by Applicable Law. In such event, the Party seeking such disclosure shall prepare a proposed redacted version of this Agreement to request confidential treatment for this Agreement, and the other Party shall, to the extent reasonably practicable, be provided a reasonable opportunity (not in any event to be required to exceed two (2) business days after receipt of such proposed redactions) to promptly provide its comments. In addition, FFFC and Cempra shall each have the right to disclose the terms of this Agreement in confidence to persons engaged or proposing engagement in fiduciary relationships, such as banks extending credit with the Party, investors, and legal counsel, and potential investors, merger targets or acquirors and their legal counsel and professional advisors, if such persons are subject to reasonable confidentiality and non-use obligations. Further, FFFC shall have the right to disclose the terms of this Agreement in confidence to directors, officers, employees and agents of FUJIFILM Corporation and FUJIFILM Holdings Corporation, both parent companies of FFFC, who need to know such information for the conduct of this Agreement if they are subject to reasonable confidentiality and non-use obligations.

11.4 No Implied Licenses. Only licenses explicitly granted pursuant to the express terms of this Agreement or any separate agreement executed by the Parties shall be of any legal force and effect. No other license or any other proprietary rights shall be created by implication or estoppel, in the patents, know-how, trade-secrets, copyrights, trade and other marks, or other intellectual property rights, owned or licensed to the respective Parties. No other licenses are granted by Cempra to FFFC under this Agreement.

11.5 Trade Names and Trademarks. Cempra hereby acknowledges that except as otherwise set forth in this Agreement, it does not have, and shall not acquire by virtue of this Agreement, any rights to or under any goodwill, trademark or trade name of FFFC, nor in any of FFFC's trademark or trade names appearing on the label or packaging materials of API. FFFC hereby acknowledges that it does not have, and shall not acquire by virtue of this Agreement, any rights to or under any goodwill, trademark or trade name of Cempra, any Affiliate thereof, or any licensee of Cempra or any Affiliate thereof, nor in any of Cempra's, its Affiliates', or its or their licensees' trademarks or trade names appearing on the label or packaging materials of API or Drug Product.

12. INDEMNIFICATION ; L IMITATION OF L IABILITY

12.1 FFFC's Obligation to Indemnify. FFFC shall indemnify, defend and hold Cempra, its Affiliates, and its and their respective directors, officers, employees and agents (the " **Cempra Indemnitees** ") harmless against any and all Losses incurred by any of them as a result of any Third Party claim, demand, suit, action or proceeding (" **Claims** ") resulting from, arising out of, or connected with: (a) liability or personal injury claims arising directly from the manufacture of the API supplied hereunder or Drug Products incorporating the API supplied hereunder to the extent, in either case, caused only by or resulting only from the breach of any of FFFC's obligations under this Agreement; (b) a breach of any of FFFC's warranties or other obligations under this Agreement; (c) the clean-up, remediation and restoration arising out of or related to FFFC's storage, handling, transportation, incineration or disposal of any Waste that may be generated by Manufacturing; (d) the alleged or actual infringement or misappropriation of a Third Party's intellectual property rights (including but not limited to Patents) in the Manufacture of API or performance of FFFC's other obligations under this Agreement; or (e) any negligence, intentional misconduct, or failure to comply with Applicable Law on the part of FFFC, its Affiliates, its or their contractors, or any employees, agents, or representatives of any of the foregoing with respect to this Agreement or the subject matter thereof. FFFC's obligations set forth in this **Section 12.1** shall not include Losses on any Claims to the extent that such Losses or Claims arise from the (x) alleged or actual infringement or misappropriation of a Third Party's intellectual property rights (including but not limited to Patents) to the extent solely and directly (i) resulting from FFFC's following any of Cempra's clear technical instructions for the Manufacture of API hereunder or (ii) based on FFFC's practice, in the Manufacture of API for Cempra hereunder, of the technology Covered by and described in the claims of the Cempra Licensed Patents (and not any technology not Covered or described in such claims); (y) breach by any Cempra Indemnitee of its obligations under this Agreement or (z) any negligence, intentional misconduct, or failure to comply with Applicable Law on the part of any Cempra Indemnitee.

12.2 Cempra's Obligation to Indemnify. Cempra shall indemnify, defend and hold harmless FFFC, its Affiliates, and its and their directors, officers, employees and agents (" **FFFC Indemnitees** ") against any and all Losses incurred by any of them as a result of any Third Party Claim resulting from, arising out of, or connected with: (a) product liability claims arising from Cempra's, its Affiliates', or its or their licensees' testing, manufacturing, sale or use of Drug Product; (b) a breach of any of Cempra's warranties or other obligations under this Agreement; (c) any negligence, intentional misconduct, or failure to comply with Applicable Law on the part of Cempra with respect to this Agreement or the subject matter thereof; or (d) alleged or actual infringement or misappropriation of a Third Party's intellectual property rights (including but not limited to Patents) to the extent solely and directly (i) resulting from FFFC's following any of Cempra's clear technical instructions for the Manufacture of API hereunder or (ii) based on FFFC's practice, in the Manufacture of API for Cempra hereunder, of the technology Covered by and described in the claims of Cempra Licensed Patents (and not any technology not Covered or described in such claims). Cempra obligations set forth in this **Section 12.2** shall not include Losses on any Claims to the extent such Losses or Claims arise from the any of the circumstances described in clauses (a), (b), (c), (d), or (e) of the first sentence of **Section 12.1** .

12.3 Indemnification Procedures. Each Party's agreement to indemnify, defend, and hold harmless under **Section 12.1** or **12.2** , as applicable, is conditioned upon the indemnified party (a) providing written notice to the indemnifying Party of any claim, demand or action arising out of the allegedly or actually indemnified matter as soon as reasonably possible, and in any event no later than within [*] days after the indemnified Party has actual knowledge of such claim, demand or action, (b) permitting the indemnifying Party to assume control over the investigation of, preparation and defense against, and settlement or voluntary disposition of any such claim, demand or action, (c) assisting the indemnifying Party, as reasonably requested by the indemnifying Party and at the indemnifying Party's reasonable expense, in the investigation, preparation, defense, and settlement or voluntary disposition of any such claim, demand or action, (d) not compromising, settling, or entering into any voluntary disposition of any such claim, demand or action without the indemnifying Party's prior written consent, which consent shall not be unreasonably withheld, and (e) furnishing promptly to the indemnifying Party copies of all notices and documents (including court papers) received by any indemnified party in connection with the Claim for which indemnification is being sought; provided, however, that, if the party entitled to indemnification hereunder fails to comply with any of the foregoing conditions, the indemnifying Party will only be relieved of its indemnification obligation under this Agreement to the extent materially prejudiced by such failure. In no event may the indemnifying Party compromise, settle, or enter into any voluntary disposition of any claim, demand or action subject to indemnification under this **Section 12** in any manner that admits material fault or wrongdoing on the part of the indemnified party or incurs non-indemnified liability on the part of the indemnified party without the prior written consent of the indemnified party, and in no event may the indemnifying Party settle, compromise, or agree to any voluntary disposition of any matter subject to indemnification hereunder in any manner which may materially and adversely affect Cempra's (or its Affiliates' or its or its Affiliates' licensees) ability to develop, manufacture, or commercialize API or Drug Products without Cempra's prior written consent.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

12.4 Limitation of Liability . IN NO EVENT SHALL EITHER PARTY OR ANY AFFILIATE THEREOF BE LIABLE TO THE OTHER PARTY OR ANY AFFILIATE THEREOF FOR ANY CONSEQUENTIAL, INCIDENTAL, LIQUIDATED, SPECIAL OR INDIRECT DAMAGES OR LOSSES, HOWEVER CAUSED AND ON ANY THEORY OF LIABILITY, REGARDLESS OF ANY FAILURE OF ESSENTIAL PURPOSE OF ANY REMEDY AVAILABLE UNDER THIS AGREEMENT; PROVIDED THAT, NOTWITHSTANDING ANYTHING TO THE CONTRARY, THE FOREGOING SHALL NOT BE CONSTRUED TO LIMIT THE INDEMNITY OBLIGATIONS SET FORTH IN SECTIONS 12.1 AND 12.2 ABOVE, EITHER PARTY'S LIABILITY FOR PATENT INFRINGEMENT OR BREACH OF ARTICLE 11, OR FFFC'S LIABILITY FOR ANY BREACH OF SECTION 6.4 OR 7.2.

Further, the total aggregate liability of a Party to the other Party with respect to all claims under this Agreement shall be limited to the greater of (i) an amount equal to the total Transfer Price paid by Cempra to FFFC for the API hereunder in the twelve (12) months preceding the first such claim or (ii) US\$10,000,000; provided that, notwithstanding anything to the contrary, the foregoing shall not (x) be applicable to any claim under this Agreement resulting from FFFC's gross negligence or intentional misconduct or (y) be construed to limit FFFC's indemnity obligations set forth in **Sections 12.1** and **12.2** above, either Party's liability for patent infringement or breach of **Article 11** , or FFFC's liability for any breach of **Section 6.4** or **7.2** , except, with respect to clause (y), with respect to such obligations under clause (b) of Section 12.1 of this Agreement with respect to claims made by, or losses of, Third Parties with respect to any breach of contract or similar arrangement, any failure to perform under or comply with any contractual provision or similar obligation, or similar occurrence or on the basis of any similar theory or cause of action.

13. INSURANCE

13.1 Coverage. During the period starting from the date prior to validation campaign and ending at the date [*] years after the term of this Agreement, if issued on a claims made basis, FFFC shall maintain Commercial General Liability Insurance (including products liability insurance) providing not less than \$[*] per occurrence and \$[*] in the aggregate. All coverage shall be underwritten by reputable underwriters. Promptly after the Effective Date, FFFC shall add Cempra as an additional insured under FFFC's policy. FFFC shall provide Cempra with a certificate of insurance upon request. FFFC shall provide Cempra with at least thirty (30) days prior written notice of any material change, cancellation or expiration of the above-required insurance.

13.2 Review. On an annual basis, FFFC shall provide Cempra with a current certificate of coverage demonstrating that the coverage specified in **Section 13.1** is in force and shall immediately notify Cempra of any actual or threatened reduction, termination, non-renewal or materially adverse change in terms of coverage. FFFC shall provide Cempra with thirty (30) days' written notice of any cancellation or material change in the coverage specified in **Section 13.1** . FFFC represents and warrants that it has obtained and shall maintain all coverage, including its preparation of any applications and endorsements in compliance with its obligations under the terms of coverage of such policies and shall otherwise comply with all requirements under such policies. Failure to maintain the insurance coverage as set forth in this **Section 13** shall be deemed a material breach of this Agreement.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

14. DISPUTE RESOLUTION

14.1 Internal Mediation of Dispute. In the event of any controversy or claim arising out of or relating to any provision of this Agreement or otherwise between the Parties or their Affiliates, the Parties shall try to settle the differences amicably through the Chief Executive Officers of each Party (or, if none, highest ranking executive officer of a Party) for a period of [*] days. The designees shall be individuals who possess the authority to settle the dispute but who do not have direct responsibility for administration of this Agreement. Any disputes not resolved by the Parties' executive officers as set forth above within [*] days shall, upon written notice from either party to the other Party as set forth below, be finally and exclusively resolved by confidential binding arbitration as provided in **Section 14.2**.

14.2 Arbitration. If the Chief Executive Officers (or, if none, highest-ranking executive officers) are unable to resolve the dispute in accordance with **Section 14.1**, either Party will have the right to have the dispute resolved by binding arbitration, initiated by either Party on [*] Business Days notice to the other party following expiration of the [*] day period referenced above (such notice, the “**Initiation Notice**”), under the Rules of Arbitration of the International Chamber of Commerce (“**ICC**”) then pertaining, except where those rules conflict with this provision, in which case this provision controls, applying the laws of the State of New York, without regard to its conflicts of law provisions, before three (3) independent, neutral arbitrators experienced in the pharmaceutical industry and manufacturing relationships in such industry. Cempra and FFFC shall each be entitled to select one (1) such arbitrator, with the two (2) such arbitrators so selected selecting the third (3rd) such arbitrator. In the event either Party fails to select its arbitrator in accordance with the foregoing within [*] Business Days of the Initiation Notice, the arbitrator selected by the other Party within such [*] Business Day period shall be entitled to select such arbitrator, and, to the extent all three such arbitrators are not selected within [*] Calendar Days of the Initiation Notice, such arbitrators shall be appointed by the International Court of Arbitration of the ICC. Prior to the commencement of hearings, each of the arbitrators appointed must provide an oath of undertaking of impartiality. The decision of the arbitrators will be final and binding on the Parties, and judgment upon the award or determination rendered by the arbitrators may be entered and enforced in any court of competent jurisdiction. The arbitration shall be conducted in English, and the place of arbitration shall be New York, New York, USA. Each Party shall bear its own expenses and an equal share of the reasonable, documented expenses of the arbitration panel and any fees required by ICC to submit such matter to arbitration, unless the panel determines that any such fees or expenses are to be paid by the non-prevailing Party, and the Parties hereby agree that the panel shall be entitled and empowered to make such a determination.

14.3 Injunctions. Notwithstanding anything to the contrary in this Agreement, either Party will have the right to seek injunctive or equitable relief in any court of competent jurisdiction as may be available to such Party under the laws and rules applicable in such jurisdiction with respect to any matters arising out of this Agreement. A Party seeking and/or obtaining injunctions shall not be required to prove the amount, irreparability, immediacy or likelihood of damages, nor shall it be required to post any bond (the posting of which is irrevocably waived).

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

14.4 Choice of Law. This Agreement shall be construed and the rights of the Parties shall be determined in accordance with the laws of the State of New York, USA, without regard to its conflict of law provisions; *provided, however*, that patents and other intellectual property rights shall be construed and determined in accordance with the laws of the country under which such rights are granted. In no event shall the provisions of this Agreement be governed by the United Nations Convention on Contracts for the International Sale of Goods.

15. GENERAL PROVISIONS

15.1 Integration & Severability. This Agreement, including its Exhibits, the Quality Agreement, and the Confidentiality Agreement, is the full and final negotiated agreement between the Parties regarding its subject matter. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original, but all of which together shall constitute a single agreement. In the event that any provision of this Agreement is judicially determined to be unenforceable, in part or in whole, the remaining provisions or portions of this Agreement shall be valid and binding to the fullest extent possible, and the Parties shall endeavor to negotiate modified or additional terms, as feasible, in a timely manner so as to fully effectuate the original intent of the Parties to the extent possible.

15.2 Waivers & Amendment. Any failure by a Party to enforce any right which it may have hereunder in any instance shall not be deemed to waive any right which it or the other Party may have with respect to any provision of this Agreement, including the provision which such Party has failed to enforce. A waiver of a breach shall not act as a waiver or release of any other breach, regardless if prior, contemporaneous or subsequent, known or unknown or of the same or different nature, cause, effect or provision of this Agreement. No provision of this Agreement shall be waived, amended, supplemented or otherwise modified except in a writing signed by a duly authorized officer of each Party.

15.3 Legal Relationship. The Parties acknowledge, agree, and declare that the relationship hereby established between them is solely that of provider and recipient of manufacturing services and that each Party hereto is an independent contractor with respect to the other, and not as a joint venturer, partner, distributor or any other type of relationship, and shall not be construed as an authorization of either Party to act as an agent of the other. Each may enter into similar or dissimilar arrangements with others and engage in activities for its own account, subject to their compliance with confidentiality and other provisions of this Agreement. The Parties agree that they have performed and shall at all times perform this Agreement in good faith.

15.4 Force Majeure.

(a) Occurrences. Neither Party shall be responsible to the other Party for any failure, delay or interruption in the performance of any of its obligations under this Agreement if such failure, delay or interruption is caused by a matter reasonably outside of the control of the Party, which may include, but shall not be limited to, fire, flood, typhoon, earthquake, epidemic, riot, terrorist act, insurrection, war, failure or delay of normal sources of supply of materials, failure or delay of public utilities or carriers (“**Force Majeure**”), *provided that* the Party affected has used its best efforts to avoid the effects of such occurrence and to perform its obligations notwithstanding such occurrence, and such occurrence is not due to any fault or neglect of such

Party. If a Party believes that the performance of any of its obligations under this Agreement will be delayed or interrupted as a result of any Force Majeure event, then it shall promptly notify the other Party of the delay or interruption and the cause, shall use best efforts to perform its obligations notwithstanding the Force Majeure event, and shall provide the other Party with a good faith estimate of when performance of its obligations will resume. When the Party affected by a Force Majeure event is able to recommence the performance of obligations delayed or interrupted as a result of the Force Majeure event, it shall notify the other Party and, except as otherwise provided in this Agreement, it shall promptly resume performing its obligations.

(b) Production Assurance. For clarity, FFFC shall not be entitled to invoke the provisions of this **Section 15.4** as an excuse for default or delay in performance of its obligations under this Agreement based upon its need to do work for others or on its own behalf resulting in constraints upon the availability of its manufacturing and packaging capacity, unless such constraints resulted from an event of Force Majeure as defined herein. In such an event, FFFC shall equitably allocate its available resources among its various customers, including Cempra. Additionally, in the event FFFC cannot provide Cempra with API for more than [*] days due to a Force Majeure event, FFFC will notify Cempra and Cempra shall be entitled, at its option, to terminate or suspend this Agreement in whole or in part upon written notice to FFFC. For clarification, during suspension of this Agreement as permitted in this **Section 15.4(b)**, or if this Agreement is terminated pursuant to this **Section 15.4(b)**, Cempra may utilize one or more other sources for all of Cempra's API requirements and shall not be obligated to purchase API that was ordered for delivery from FFFC during such time. Furthermore, a suspension of this Agreement shall only be lifted, and the obligations of the parties resumed, after FFFC has demonstrated to the reasonable satisfaction of Cempra that FFFC has resolved the Force Majeure and can meet its obligations hereunder in full.

15.5 Notice; Use of English. Any notice required or permitted to be given under this Agreement shall be in writing and shall be given in person, delivered by recognized overnight delivery service, sent by mail (certified or registered or air mail for addresses outside of the continental United States), or by telefax (or other similar means of electronic communication), the receipt of which is confirmed by confirming telefax, and addressed as indicated in **Exhibit E**, or such other person and/or address as may have been furnished in writing to the notifying Party of the change to such Exhibit. Except as otherwise provided herein, any notice shall be deemed delivered upon the earlier of: (a) actual receipt; (b) three (3) business days after delivery to such recognized overnight delivery service; (c) five (5) business days after deposit in the mail (ten (10) days for international mail); or (d) the date of receipt of the confirming telefax. All notices and other correspondence between the Parties shall be in English and English translations of all documents originally prepared, provided, or obtained in Japanese or any other non-English language shall be provided to Cempra simultaneously with the non-English originals thereof at FFFC's expense.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

15.6 Assignment. Neither Party may assign this Agreement, or any of its rights or obligations hereunder, without the other Party's prior written consent, which consent shall not be unreasonably withheld or delayed; *provided that*, notwithstanding the foregoing, Cempra shall be entitled, without FFFC's prior written consent, to assign or transfer this Agreement and Cempra's rights and obligations hereunder: (i) in connection with the transfer or sale of all or substantially all of Cempra's or any of its Affiliates' assets or business (or that portion thereof related to the subject matter of this Agreement), (ii) in the event of Cempra's or any of its Affiliates' merger, consolidation, reorganization, change of control or similar transaction, or (iii) to an Affiliate of Cempra. Any purported assignment by a Party of this Agreement, or any of such Party's rights or obligations hereunder, in violation of this **Section 15.6** shall be null and void ab initio.

15.7 Interpretation. All references to Sections shall refer to the Sections contained in this Agreement. All references to Exhibits shall, except as otherwise explicitly provided, refer to the Exhibits of this Agreement, which are appended to and made part of this Agreement. The captions of the Sections of this Agreement are for general information and reference only and shall not affect the interpretation of this Agreement. Where applicable in this Agreement, the singular includes the plural and vice versa. The term "including" shall be interpreted to mean "including without limitation". English shall be the official language of this Agreement and all communications between the Parties hereto shall be conducted in that language. Both Parties acknowledge that they were represented by competent legal counsel and advisors, and fully negotiated the contract and each of its terms, and that 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.

«Signatures on Next Page»

I N W ITNESS W HEREOF , the Parties hereto have caused this Agreement to be executed as of the Effective Date.

Cempra Pharmaceuticals, Inc.

By: /s/ Prabhavathi Fernandes
Name: Prabhavathi Fernandes
Title: President and CEO
Date: December 16, 2015

FUJIFILM Finechemicals Co., Ltd.

By: /s/ Masatoshi Kato
Name: Masatoshi Kato
Title: President and CEO
Date: January 18, 2016

API M ANUFACTURING AND S UPPLY A GREEMENT
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Test	Method	Oral Grade	Parenteral Grade
		Acceptance Criteria (Specification FP/IH/304995/4)	Acceptance Criteria (Specification FP/IH/304994/2)
[*]	[*]	[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]	[*]	[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]		[*]	[*]
[*]	[*]	[*]	[*]

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

E X H I B I T C**C E M P R A L I C E N S E D P A T E N T S**

<u>Title</u>	<u>Country</u>	<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Patent No.</u>
Copper-Catalysed Ligation of Azides and Acetylenes	USA	60/385,041	30 May 2002	n/a
Copper-Catalysed Ligation of Azides and Acetylenes	PCT	PCT/US03/17311	30 May 2003	n/a
Copper-Catalysed Ligation of Azides and Acetylenes	Japan	2004-509665	30 May 2003	4638225
Process for the Preparation of Macrolide Antibacterial Agents	USA	60/982,446	25 Oct 2007	n/a
Process for the Preparation of Macrolide Antibacterial Agents	PCT	PCT/US2008/080936	23 Oct 2008	n/a
Process for the Preparation of Macrolide Antibacterial Agents	Japan	2010-531238	23 Oct 2008	5698979
Process for the Preparation of Macrolide Antibacterial Agents	Japan	2014-227753	23 Oct 2008	
Morphological Forms of CEM-101, and Uses Therefor	USA	61/316,063	22 Mar 2010	n/a
Crystalline Forms of a Macrolide, and Uses Therefor	PCT	PCT/US2011/029424	22 Mar 2011	n/a
Crystalline Forms of a Macrolide, and Uses Therefor	Japan	2013-501396	22 Mar 2011	5711352
Crystalline Forms of a Macrolide, and Uses Therefor	Japan	2014-231987	22 Mar 2011	
Process For Preparing Triazole-Containing Ketolide Antibiotics	USA	61/346,664	20 May 2010	n/a
Processes for Preparing Macrolides and Ketolides and Intermediates Therefor	PCT	PCT/US2011/037330	20 May 2011	n/a
Processes for Preparing Macrolides and Ketolides and Intermediates Therefor	Japan	2013-511385	20 May 2011	
Hydrogen Bond Forming Fluoro Ketolides for Treating Diseases	USA	61/381,794	10 Sep 2010	n/a
Hydrogen Bond Forming Fluoro Ketolides for Treating Diseases	PCT	PCT/US2011/051064	9 Sep 2011	n/a

C O N F I D E N T I A L

<u>Title</u>	<u>Country</u>	<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Patent No.</u>
Hydrogen Bond Forming Fluoro Ketolides for Treating Diseases	JP	2013-528344	9 Sep 2011	
Convergent Process for the Preparation of Macrolide Antibacterial Agents	USA	61/786,914	15-Mar-2013	n/a
Convergent Process for the Preparation of Macrolide Antibacterial Agents	PCT	PCT/US2014/29932	15-Mar-2014	n/a
Stabilized Forms and Compositions of 4-ABA	USA	62/084,876	Nov 26, 2014	n/a
Stabilized Forms and Compositions of 4-ABA	USA	62/112,672	06-Feb-2015	n/a
Process for Preparing Fluorinated Ketolide Antibiotics	USA	62/129,305	06-Mar-2015	n/a

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E XHIBIT D

Form of Certificate of Analysis

[Manufacturer Logo]

[Manufacturer Contact Information]

CERTIFICATE OF ANALYSIS

Drug Substance Name:	Solithromycin	Lot. No.:	[XXXX]
Manufacture Date:	[XXXX]	Batch Size:	[XXXX]
Analysis Date:	[XXXX]	Retest Date:	[XXXX]
COA No.:	[XXXX]	Page No.:	Page 1 of 2
Storage Conditions:	[XXXX]		

<u>Test</u>	<u>Method</u>	<u>Limits</u>	<u>Results</u>
A) Description			
B) Solubility			
C) Identification			
D) Loss On Drying			
E) Melting Range			
F) Residue On Ignition			
G) Heavy Metals			
H) ID by HPLC			
I) Particle Size			
J) Assay (on dried basis)			
K) Impurities:			
L) Residual Solvents:			

Only tests A, D, J & K required for retesting; other test performed during original release testing only.

CERTIFICATE OF ANALYSIS

Drug Substance Name:	Solithromycin	Lot. No.:	[XXXX]
Manufacture Date:	[XXXX]	Batch Size:	[XXXX]
Analysis Date:	[XXXX]	Retest Date:	[XXXX]
COA No.:	[XXXX]	Page No.:	Page 2 of 2
Storage Conditions:	[XXXX]		

REFERENCES:

Specification

DOCUMENT HISTORY:

- Complies with specifications above
- Does not comply with specifications above

PREPARED BY:

_____ Date: _____

APPROVED BY:

_____ Date: _____

E XHIBIT E

FFFC Facilities, Notices, Project Managers and Other Key Personnel

Facility: [*]

Address: [*]

TEL: [*] FAX: [*]

Notices:

To Cempra:

To FFFC:

Project Managers:

For Cempra:

For FFFC:

[*]

[*]

Executive Vice President, Business Development

General Manager, Marketing Department

E-mail [*]

E-mail [*]

TEL: [*] FAX: [*]

TEL: [*] FAX: [*]

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

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Other Key Personnel:

For Cempra:

[*]

Senior Vice President, Chemistry

E-mail [*]

TEL: [*] FAX: [*]

[*]

Vice President, Supply Chain

E-mail [*]

TEL: [*] FAX: [*]

[*]

Director, Chemistry

E-mail [*]

TEL: [*] FAX: [*]

[*]

Associate Director, Analytical Chemistry

E-mail [*]

TEL: [*] FAX: [*]

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

For FFFC:

[*]

General Manager,
Production Engineering & Development Dept.

E-mail [*]

TEL: [*] FAX: [*]

[*]

Manager,
Organic Synthesis Research Laboratories

E-mail [*]

TEL: [*] FAX: [*]

[*]

General Manager,
HIRONO Factory Quality Assurance Department

E-mail [*]

TEL: [*] FAX: [*]

E X H I B I T F

Copy of Quality Agreement

To be attached once agreed upon by the Parties.

C O N F I D E N T I A L

E X H I B I T G

Work Plan for Registration Batches Manufacturing

To be attached once agreed upon by the Parties.

C O N F I D E N T I A L

E XHIBIT H

Work Plan for Validation Campaign

To be attached once agreed upon by the Parties.

C O N F I D E N T I A L

E XHIBIT I

Stability Study Protocols

To be attached once agreed upon by the Parties.

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E XHIBIT J

Transfer Price

<u>Transfer Price per kg</u> *1	<u>Quantities of API Ordered for Delivery</u> <u>Per Month Period</u> *2
No more than US\$[*]	Equal or more than [*] kg
No more than US\$[*]	Equal or more than [*] kg and less than [*] kg
No more than US\$[*]	Equal or more than [*] kg and less than [*] kg
No more than US\$[*]	Equal or more than [*] kg and less than [*] kg
No more than US\$[*]	Equal or more than [*] kg and less than [*] kg
Subject to the reasonable quotation made by FFFC, and accepted in writing by Cempra, separately on an as-needed basis	Less than [*] kg

* 1 Each price does not include Japanese consumption tax imposed on the sale of API to Cempra under this Agreement.

* 2 If the Agreement terminates or expires on any day other than the last day of a Month Period, the Transfer Price for API ordered for delivery during that portion of the Term following the end of the last complete Month Period ending prior to such expiration or termination (such portion of the Term, the “Final Period”) shall, notwithstanding anything to the contrary, be calculated by dividing the quantity of API ordered for delivery during such Final Period by the number of the days of such Final Period and multiplying the number of such calculation’s result by 365, with the result of such calculation being used as the “Quantities of API Ordered for Delivery Per Month Period” in the table above to calculate the Transfer Price of API ordered for delivery during such Final Period.

Provided, however, that:

- If the above Transfer Price becomes apparently unreasonable because of significant change of the economic environment applicable to the manufacture of API by FFFC, and either Party requests to the other Party the revision of such Transfer Price, the Parties shall use reasonable efforts to negotiate about a new Transfer Price applicable to the next Month Period or thereafter in good faith, provided that (i) the above-referenced obligation shall not require either party to agree to any new Transfer Price and (ii) the Transfer Price shall not be changed unless and until written agreement is reached by both Parties.

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

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- If any change of API Manufacture Procedures, quality requirements, API Specifications, or other related matters of API requested pursuant to Cempra's (or its Affiliate's or its or its Affiliate's licensee's) instruction or direction following the Effective Date increases, by an amount greater than [*] percent ([*]%) of FFFC's prior manufacturing cost (as calculated for the certain pricing tier set forth in the table above that will be applicable based on the quantities of API which are forecasted and/or scheduled to be ordered for delivery during the Month Period to which such increase applies and as compared to the previously-effective costs for such quantities of API during the prior Month Period), the manufacturing cost born by FFFC, FFFC shall notify Cempra promptly in writing of any such increase in FFFC's direct cost of manufacturing API hereunder (including the amount of such increase) and, if Cempra elects in writing to proceed with such change following receipt of such notice, the Transfer Price shall be revised by mutual reasonable good-faith consultation between the Parties based on the new quotation issued by FFFC, provided that (i) any such increase in Transfer Price shall not exceed the increase in direct cost to FFFC of any such change and (ii) FFFC shall not proceed with any such change unless directed to do so by Cempra following Cempra's receipt of notice of the relevant proposed change in Transfer Price. For clarity, in the absence of any agreement between the Parties regarding any increase in Transfer Price as a result of any requested changes of Cempra under this paragraph, FFFC shall not be required to manufacture any API pursuant to any such change in API Manufacture Procedures, quality requirements, API Specifications, or other related matters of API, and Cempra shall not be required to bear any increase in Transfer Price resulting therefrom.

The Transfer Price in the table above to be applied pursuant to this Exhibit J for purposes of Sections 1.46, 4, 5.4, and 6.2 shall initially be (i) for the [*] [*] Month Periods, US\$[*] per kilogram of API and, for all Month Periods other than the [*] [*] Month Periods, (ii) calculated based on the amounts of API forecasted for order and delivery during a particular Month Period based on the initial Forecast covering all twelve (12) months of such Month Period (such initial Forecast, the “**Initial Forecast**”, such initial price under the preceding clause (i) or clause (ii), the “**Forecast-Based Price**”) and then, following the end of such Month Period, recalculated based on the actual amounts of API actually ordered for delivery during such Month Period pursuant to Purchase Orders placed by Cempra (such recalculated price, the “**Final Price**”). If the amount of API forecasted for order and delivery during a particular Month Period, as reflected by any Forecasts, following the Initial Forecast, covering any portion of such Month Period, are materially inconsistent with the corresponding amount forecasted in the Initial Forecast (or any other previous Forecast following the Initial Forecast), the Parties shall, upon written notice from either Party to the other Party, use reasonable efforts to work together in good faith to mutually agree on a revised Forecast-Based Price for the remaining portion of such Month Period intended to minimize the difference between the total Forecast-Based Prices paid or due for API delivered in such Month Period and the total Final Price applicable to API delivered in such Month Period.

Wire Instructions

FFFC Account Number [*]

Bank Name: [*]

Branch Name: [*]

Account Name: [*]

Account #: [*] [*]

[*] **Confidential treatment requested; certain information omitted and filed separately with the SEC.**

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E XHIBIT K**Cempra API Patents**

<u>Title</u>	<u>Country</u>	<u>Application Serial No.</u>	<u>Filing Date</u>	<u>Patent No.</u>
Process for the Preparation of Macrolide Antibacterial Agents	Japan	2010-531238	23 Oct 2008	5698979
Process for the Preparation of Macrolide Antibacterial Agents	Japan	2014-227753	23 Oct 2008	
Crystalline Forms of a Macrolide, and Uses Therefor	Japan	2013-501396	22 Mar 2011	5711352
Crystalline Forms of a Macrolide, and Uses Therefor	Japan	2014-231987	22 Mar 2011	
Processes for Preparing Macrolides and Ketolides and Intermediates Therefor	Japan	2013-511385	20 May 2011	
Convergent Process for the Preparation of Macrolide Antibacterial Agents	PCT	PCT/US2014/29932	15-Mar-2014	n/a
Process for Preparing Fluorinated Ketolide Antibiotics	USA	62/129,305	06-Mar-2015	n/a

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E X H I B I T L

Depreciation Schedule

[million dollar]

<u>Year</u>		<u>2017</u>	<u>2018</u>	<u>2019</u>	<u>2020</u>	<u>2021</u>	<u>2022</u>	<u>2023</u>	<u>2024</u>	<u>2025</u>
Construction investment		17.50								
Depreciation cost	Machine ([*] Years)	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
	Building ([*] Years)	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]	[*]
Remaining book value		16.18	14.43	12.67	10.91	9.15	7.39	5.63	3.88	3.33

FFFC would require that Cempra have obligation of compensation until 2025 for FFC's investment, depreciation cost.

[*] Confidential treatment requested; certain information omitted and filed separately with the SEC.

C O N F I D E N T I A L

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Prabhavathi Fernandes, Ph.D., certify that:

- (1) I have reviewed this annual report on Form 10-K/A of Cempra, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Dated: June 17, 2016

/s/ Prabhavathi Fernandes, Ph.D.

Prabhavathi Fernandes, Ph.D.

Chief Executive Officer (Principal Executive Officer)

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO
SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark W. Hahn, certify that:

- (1) I have reviewed this annual report on Form 10-K/A of Cempra, Inc.;
- (2) Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

Dated: June 17, 2016

/s/ Mark W. Hahn

Mark W. Hahn

Chief Financial Officer (Principal Financial Officer)