UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

AMENDMENT NO. 2 TO FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

COHERUS BIOSCIENCES, INC.

(Exact name of Registrant as specified in its charter)

Delaware

(State or other jurisdiction of incorporation or organization)

2836

(Primary Standard Industrial Classification Code Number) **27-3615821** (I.R.S. Employer

(I.R.S. Employer Identification Number)

201 Redwood Shores Parkway, Suite 200 Redwood City, CA 94065 (650) 649-3530

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

Dennis M. Lanfear President and Chief Executive Officer Coherus BioSciences, Inc. 201 Redwood Shores Parkway, Suite 200 Redwood City, CA 94065 (650) 649-3530

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

Copies to:

Alan C. Mendelson, Esq. Latham & Watkins LLP 140 Scott Drive Menlo Park, CA 94025 Telephone: (650) 328-4600

Facsimile: (650) 463-2600

Alan F. Denenberg, Esq. Davis Polk & Wardwell LLP 1600 El Camino Real Menlo Park, CA 94025 Telephone: (650) 752-2000 Facsimile: (650) 752-2111

Approximate date of commencement of proposed sale to the public:

As soon as practicable after the effective date of this Registration Statement.

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

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

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act

registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act

registration statement number of the earlier effective registration statement for the same offering.

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

Large accelerated filer \square

Accelerated filer □

Non-accelerated filer ⊠

Smaller reporting company □

(Do not check if a smaller reporting company)

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered

Title of each class of securities to be registered

Title of each class of securities to be registered

Title of each class of aggregate offering price(1) registration fee

S86,250,000 \$11,109(2)

- Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(a) under the Securities Act of 1933, as amended. Includes shares that the underwriters have the option to purchase.
- (2) Previously paid.

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

EXPLANATORY NOTE	
This Amendment No. 2 to Form S-1 Registration Statement of Coherus BioSciences, Inc. is being filed solely to include certain exhibits to the Registration Statement. Accordingly, Part I, the form of prospectus, has been omitted from this filing.	on
Satisfied. Accordingly, Fact 1, the form of prospectus, has been offitted from this fining.	

PART II Information Not Required in Prospectus

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the costs and expenses, other than the underwriting discounts and commissions, payable by the registrant in connection with the sale of Common Stock being registered. All amounts are estimates except for the Securities and Exchange Commission, or SEC, registration fee, the Financial Industry Regulatory Authority, or FINRA, filing fee and The NASDAQ Global Market, or NASDAQ, listing fee.

Item SEC registration for	Amoun be pa	id
SEC registration fee	\$ 11,1	
FINRA filing fee	11,4	138
NASDAQ listing fee		*
Printing and engraving expenses		*
Legal fees and expenses		*
Accounting fees and expenses		*
Blue Sky qualification fees and expenses		*
Transfer agent fees and expenses		*
Miscellaneous expenses		*
Total	\$	*

Item 14. Indemnification of Directors and Officers.

As permitted by Section 102 of the Delaware General Corporation Law, we have adopted provisions in our amended and restated certificate of incorporation and bylaws that limit or eliminate the personal liability of our directors for a breach of their fiduciary duty of care as a director. The duty of care generally requires that, when acting on behalf of the corporation, directors exercise an informed business judgment based on all material information reasonably available to them. Consequently, a director will not be personally liable to us or our stockholders for monetary damages for breach of fiduciary duty as a director, except for liability for:

- any breach of the director's duty of loyalty to us or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- · any act related to unlawful stock repurchases, redemptions or other distributions or payment of dividends; or
- · any transaction from which the director derived an improper personal benefit.

These limitations of liability do not affect the availability of equitable remedies such as injunctive relief or rescission. Our amended and restated certificate of incorporation also authorizes us to indemnify our officers, directors and other agents to the fullest extent permitted under Delaware law.

As permitted by Section 145 of the Delaware General Corporation Law, our amended and restated bylaws provide that:

- we may indemnify our directors, officers and employees to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions;
- we may advance expenses to our directors, officers and employees in connection with a legal proceeding to the fullest extent permitted by the Delaware General Corporation Law, subject to limited exceptions; and
- the rights provided in our amended and restated bylaws are not exclusive.

Our amended and restated certificate of incorporation, attached as Exhibit 3.1(a), and our amended and restated bylaws, attached as Exhibit 3.3, provide for the indemnification provisions described above and elsewhere herein. We intend to enter into separate indemnification agreements with our directors and officers which may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements generally require us, among other things, to indemnify our officers and directors against liabilities that may arise by reason of their status or service as directors or officers, other than liabilities arising from willful misconduct. These indemnification agreements also generally require us to advance any expenses incurred by the directors or officers as a result of any proceeding against them as to which they could be indemnified. In addition, we have purchased a policy of directors' and officers' liability insurance that insures our directors and officers against the cost of defense, settlement or payment of a judgment in some circumstances. These indemnification provisions and the indemnification agreements may be sufficiently broad to permit indemnification of our officers and directors for liabilities, including reimbursement of expenses incurred, arising under the Securities Act of 1933, as amended, or the Securities Act.

The form of Underwriting Agreement, to be attached as Exhibit 1.1 hereto, provides for indemnification by the underwriters of us and our officers who sign this Registration Statement and directors for specified liabilities, including matters arising under the Securities Act.

Item 15. Recent Sales of Unregistered Securities.

The following list sets forth information as to all securities we have sold since January 1, 2011, which were not registered under the Securities Act.

- 1. In January 2011, we issued an aggregate of 1,615,000 shares of common stock to a service provider of the Company for aggregate cash consideration of \$8,075. These shares were subject to vesting restrictions which lapsed over time pursuant to the recipient's continued service to the Company. Such individual terminated services with the Company in March of 2013, at which time the Company repurchased 100,000 vested shares.
- 2. In January 2011, we issued an aggregate of \$159,840 in principal amount of unsecured convertible promissory notes and stock purchase warrants to purchase an aggregate of 106,560 shares of Series A convertible preferred stock at an exercise price of \$0.75 per share to five accredited investors. The warrants may be exercised at any time prior to their termination dates, which are five years from the date of issuance.
- 3. In March 2011, we issued an aggregate of 1,620,888 shares of our Series A convertible preferred stock at a price per share of \$0.75 for a combination of cash and conversion of \$160,699 in convertible debt, for an aggregate gross consideration of \$1.2 million, to 13 accredited investors.
- 4. From July 2011 through December 2011, in a series of closings, we issued an aggregate of \$10,394,477 in principal amount of unsecured convertible promissory notes and stock purchase warrants to purchase an aggregate of 587,543 shares of Series B convertible preferred stock at an exercise price of \$0.01 per share to 15 accredited investors. The warrants may be exercised at any time prior to their termination dates, which are seven years from the date of issuance.
- 5. In January 2012, we issued an aggregate of \$,754,742 shares of our Series B convertible preferred stock at a price per share of \$4.1841 for a combination of cash and conversion of \$10.6 million in convertible debt, for an aggregate gross consideration of \$36.6 million, to 18 accredited investors. An aggregate of 836,500 shares were issued as consideration for past and future services provided to the Company by one investor, for an aggregate value of \$3.5 million, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
- 6. In April 2012, we issued an aggregate of 95,600 shares of our Series B convertible preferred stock at a price per share of \$0.01, for an aggregate gross consideration of \$956, pursuant to the exercise of outstanding stock purchase warrants to two accredited investors.

- 7. In December 2012, we issued an aggregate of 4,788,365 shares of our Series B convertible preferred stock at a price per share of \$4.1841 for an aggregate gross consideration of \$20.0 million, to seven accredited investors. An aggregate of 2,876,365 shares were issued as consideration for past and future services provided to the Company by five investors, for an aggregate value of \$12.0 million, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
- 8. From July 2013 through September 2013, in a series of closings, we issued an aggregate of \$9,950,000 in principal amount of secured convertible promissory notes and stock purchase warrants to purchase an aggregate of 7,134,149 shares of Series B convertible preferred stock at an exercise price of \$0.01 per share to 19 accredited investors. The warrants may be exercised at any time prior to their termination dates, which are seven years from the date of issuance.
- 9. In February 2014, we issued an aggregate of 420,106 shares of our Series B convertible preferred stock at a price per share of \$4.1841 for an aggregate gross consideration of \$1.8 million, to two accredited investors. An aggregate of 13,623 shares were issued as consideration for past and future services provided to the Company by one investor, for an aggregate value of \$57,000, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
- 10. In February 2014, we issued an aggregate of 143,400 shares of our Series B convertible preferred stock in consideration for services rendered to four service providers.
- 11. In February 2014, we issued an aggregate of 1,051,286 shares of our Series B convertible preferred stock to certain stockholders of InteKrin Therapeutics Inc., or InteKrin, in connection with our acquisition of InteKrin.
- 12. In April and May 2014, we issued an aggregate of 7,420,944 shares of our Series B convertible preferred stock at a price per share of \$0.01, for an aggregate gross consideration of \$74,209, pursuant to the exercise of outstanding stock purchase warrants to 19 accredited investors.
- 13. In May 2014, we issued an aggregate of 10,930,508 shares of our Series C convertible preferred stock at a price per share of \$6.00 for a combination of cash and conversion of \$10.6 million in convertible debt, for an aggregate gross consideration of \$65.6 million, to 35 accredited investors. An aggregate of 16,667 shares were issued as consideration for past and future services provided to the Company by three investors, for an aggregate value of \$100,000.00, which was determined (i) exceeded the par value of such shares and (ii) was no less than the aggregate purchase price for such shares.
- 14. We granted stock options and stock awards to employees, directors and consultants under our 2010 Equity Incentive Plan, as amended, covering an aggregate of 9,748,372 shares of common stock, at a weighted-average exercise price of \$0.9713 per share. Of these, options covering an aggregate of 544,073 shares were canceled without being exercised.
- 15. We sold an aggregate of 87,062 shares of common stock to employees, directors and consultants for cash consideration in the aggregate amount of \$26,070 upon the exercise of stock options and stock awards.

We claimed exemption from registration under the Securities Act for the sale and issuance of securities in the transactions described in paragraphs (1)-(13) by virtue of Section 4(a)(2) and/or Regulation D promulgated thereunder as transactions not involving any public offering. All of the purchasers of unregistered securities for which we relied on Section 4(a)(2) and/or Regulation D represented that they were accredited investors as defined under the Securities Act. We claimed such exemption on the basis that (a) the purchasers in each case represented that they intended to acquire the securities for investment only and not with a view to the distribution thereof and that they either received adequate information about the registrant or had access, through employment or other relationships, to such information and (b) appropriate legends were affixed to the stock certificates issued in such transactions.

We claimed exemption from registration under the Securities Act for the sales and issuances of securities in the transactions described in paragraphs (14)-(15) above under Section 4(a)(2) of the Securities Act in that such sales and issuances did not involve a public offering or under Rule 701 promulgated under the Securities Act, in that they were offered and sold either pursuant to written compensatory plans or pursuant to a written contract relating to compensation, as provided by Rule 701.

Item 16. Exhibits and Financial Statement Schedules.

- (a) Exhibits. See the Exhibit Index attached to this Registration Statement, which is incorporated by reference herein.
- (b) Financial Statement Schedules. Schedules not listed above have been omitted because the information required to be set forth therein is not applicable or is shown in the financial statements or notes thereto.

Item 17. Undertakings.

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

The undersigned Registrant hereby undertakes that:

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

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

Signatures

Pursuant to the requirements of the Securities Act of 1933, as amended, the Registrant has duly caused this Amendment No. 2 to the Registration Statement on Form S-1 to be signed on its behalf by the undersigned, thereunto duly authorized, in Redwood City, California, on October 20, 2014.

COHERUS BIOSCIENCES, INC.

By: /s/ Dennis M. Lanfear

Dennis M. Lanfear President and Chief Executive Officer

Pursuant to the requirements of the Securities Act, this Amendment No. 2 to the Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	<u>Title</u>	<u>Date</u>
/s/ Dennis M. Lanfear Dennis M. Lanfear	Chairman, President and Chief Executive Officer (Principal Executive Officer)	October 20, 2014
Dennis M. Lanear	(1 rincipui Executive Officer)	
/s/ Jean-Frédéric Viret, Ph.D.	Chief Financial Officer	October 20, 2014
Jean-Frédéric Viret, Ph.D.	(Principal Financial Officer)	
/s/ Michael A. Nazak	Senior Vice President	October 20, 2014
Michael A. Nazak	Finance & Administration (Principal Accounting Officer)	
*	Director	October 20, 2014
James I. Healy, M.D., Ph.D.		
*	Director	October 20, 2014
V. Bryan Lawlis, Ph.D.	<u> </u>	,
*	Director	October 20, 2014
Christos Richards	<u> </u>	
*	Director	October 20, 2014
Ali J. Satvat		
*	Director	October 20, 2014
August J. Troendle, M.D.		
*	Director	October 20, 2014
Mats Wahlström		
*	Director	October 20, 2014
Mary T. Szela		•
*By: /s/ Dennis M. Lanfear		October 20, 2014
*By: /s/ Dennis M. Lanfear Dennis M. Lanfear	<u>—</u>	October 20, 2014
A		

Attorney-in-Fact

Exhibit Index

Exhibit <u>Number</u>	Description
1.1*	Form of Underwriting Agreement.
3.1(a)+	Fifth Restated Certificate of Incorporation, currently in effect.
3.1(b)*	Sixth Restated Certificate of Incorporation, effecting a stock split, to be in effect prior to the consummation of this offering.
3.2*	Form of Amended and Restated Certificate of Incorporation, to be in effect immediately prior to the consummation of this offering.
3.3+	Bylaws, currently in effect.
3.4*	Form of Amended and Restated Bylaws, to be in effect immediately prior to the consummation of this offering.
4.1	Reference is made to Exhibits 3.1 through 3.4.
4.2*	Form of Common Stock Certificate.
4.3+	Third Amended and Restated Investor Rights Agreement, dated as of May 9, 2014 by and among Coherus BioSciences, Inc. and certain investors named therein.
5.1*	Opinion of Latham & Watkins LLP.
10.1†	License Agreement, effective January 23, 2012, by and between Daiichi Sankyo Company, Limited and BioGenerics, Inc.
10.2(a)†	License Agreement, effective August 30, 2013, by and among Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA and Coherus BioSciences, Inc.
10.2(b)†+	First Amendment to License Agreement, effective February 7, 2014, by and among Baxter International Inc., Baxter Healthcare Corporation, and Baxter Healthcare SA and Coherus BioSciences, Inc.
10.3†+	Distribution Agreement, effective December 26, 2012, by and between Orox Pharmaceuticals B.V. and Coherus BioSciences, Inc.
10.4†+	Non-Exclusive License Agreement, effective July 10, 2013, by and between Genentech, Inc. and Coherus BioSciences, Inc.
10.5†+	Commercial License Agreement, effective April 8, 2011, by and between Selexis SA and BioGenerics, Inc.
10.6†+	Commercial License Agreement, effective June 25, 2012, by and between Selexis SA and Coherus BioSciences, Inc.
10.7+	Agreement and Plan of Merger, dated January 8, 2014, by and among Coherus BioSciences, Inc., Coherus Intermediate Corp., Coherus Acquisition Corp., InteKrin Therapeutics Inc., and Fortis Advisors LLC.
10.8(a)+	Office Lease, effective September 26, 2011, by and between CA-Towers at Shores Center Limited Partnership and BioGenerics, Inc.
10.8(b)+	First Amendment to the Office Lease, effective May 17, 2012, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.
10.8(c)+	Second Amendment to the Office Lease, effective September 11, 2013, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.
10.8(d)+	Third Amendment to the Office Lease, effective February 4, 2014, by and between CA-Towers at Shores Center Limited Partnership and Coherus BioSciences, Inc.
10.8(e)+	Fourth Amendment to the Office Lease, effective May 1, 2014, by and between CA-Towers at Shores Center Limited Partnership and

Coherus BioSciences, Inc.

Exhibit Number	Description
10.9(a)+	Standard Industrial/Commercial Multi-tenant Lease-Gross, effective December 5, 2011, by and between Howard California Property Camarillo 5 and BioGenerics, Inc.
10.9(b)+	First Amendment to Lease, effective December 21, 2013, by and between Howard California Property Camarillo 5 and Coherus BioSciences, Inc.
10.10(a)#+	BioGenerics, Inc. 2010 Equity Incentive Plan, as amended.
10.10(b)#+	Form of Stock Option Grant Notice and Stock Option Agreement under the 2010 Equity Incentive Plan, as amended.
10.11#*	Coherus BioSciences, Inc. 2014 Equity Incentive Award Plan and forms of agreement thereunder.
10.12#*	Coherus BioSciences, Inc. 2014 Employee Stock Purchase Plan and forms of agreement thereunder.
10.13#*	Form of Indemnification Agreement between Coherus BioSciences, Inc. and each of its directors, officers and certain employees.
10.14#+	Separation Agreement, effective June 30, 2014, by and between Stephen C. Glover and Coherus BioSciences, Inc.
10.15†+	Master Services Agreement, effective January 23, 2012, by and between Medpace, Inc. and BioGenerics, Inc.
10.16(a)†+	Task Order Number 13, effective October 18, 2013, by and between Medpace, Inc. and Coherus BioSciences, Inc.
10.16(b)†+	Amendment Number 1 to Task Order Number 13, effective April 23, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.
10.16(c)†+	Amendment Number 2 to Task Order Number 13, effective May 21, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.
10.16(d)†+	Amendment Number 3 to Task Order Number 13, effective May 30, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.
10.16(e)†+	Amendment Number 4 to Task Order Number 13, effective August 19, 2014, by and between Medpace, Inc. and Coherus BioSciences, Inc.
23.1+	Consent of independent registered public accounting firm.
23.2*	Consent of Latham & Watkins LLP (included in Exhibit 5.1).
24.1+	Power of Attorney.

To be filed by amendment.

Portions of this exhibit (indicated by asterisks) have been omitted pursuant to a request for confidential treatment and this exhibit has been filed separately

Indicates management contract or compensatory plan.

Previously filed.

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

LICENSE AGREEMENT

by and between

BIOGENERICS, INC.

and

DAIICHI SANKYO COMPANY, LIMITED

dated

January 23rd, 2012

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is made and entered into as of January 23rd, 2012 (the "Effective Date") between BIOGENERICS, INC., a Delaware corporation with a principal place of business at 201 Redwood Shores Parkway, Suite 200, Redwood City, California 94065, United States of America ("BioGenerics"), and DAIICHI SANKYO COMPANY, LIMITED, a Japanese corporation with a principal place of business at 3-5-1 Nihonbashi-honcho, Chuo-ku, Tokyo, Japan 103-8426 ("Licensee"). BioGenerics and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, BioGenerics is a global biotechnology company that conducts research, development, manufacturing and commercialization, and is developing various biosimilar products for the potential treatment of cancer, rheumatoid arthritis, and other diseases and conditions;

WHEREAS, Licensee has existing development and commercialization capabilities in the Territory (as defined below);

WHEREAS, BioGenerics wishes to use data Developed by Licensee in the Territory for the purpose of supporting a regulatory approval application with the U.S. Food and Drug Administration;

WHEREAS, BioGenerics wishes to partner with Licensee for the development and commercialization of the Products (as defined below) in the Territory in accordance with the terms and conditions hereof; and

WHEREAS, Licensee wishes to partner with BioGenerics with respect to the development and commercialization of the Products in the Territory in accordance with the terms and conditions hereof.

AGREEMENT

Now, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties agree as follows:

- 1. **DEFINITIONS.** As used herein, the following terms shall have the following meanings:
 - 1.1 "AAA" has the meaning set forth in Section 14.3(b) (Arbitration).
 - 1.2 "Additional Supply Period" has the meaning set forth in Exhibit 12.3(C) (Licensee Opt-Out Rights).

- 1.3 "Affiliate" means a corporation, partnership, trust or other entity that directly, or indirectly through one or more intermediates, controls, is controlled by or is under common control with a specified Party but only for so long as such relationship exists. For such purposes, "control," "controlled by" and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract or otherwise. In the case of a corporation, the direct or indirect ownership of fifty percent (50%) or more of its outstanding voting shares or the ability otherwise to elect a majority of the board of directors or other managing authority of the entity shall in any event be presumptively deemed to confer control, it being understood that the direct or indirect ownership of a lesser percentage of such shares shall not necessarily preclude the existence of control. Anything to the contrary in this paragraph notwithstanding, [***] and any corporation, partnership, trust or other entity controlled directly or indirectly by [***], shall not be deemed an Affiliate of Licensee unless Licensee provides written notice to BioGenerics of its desire to include [***] as an Affiliate of Licensee and [***] agrees in writing to be bound by the terms and conditions of this Agreement. Notwithstanding the preceding provisions, once an entity ceases to be an Affiliate of Licensee, then such entity shall, without any further action, cease to have any rights, including license and sublicense rights, under this Agreement that it has by reason of being an Affiliate and any and all BioGenerics Know-How (excluding BioGenerics Generic Know-How) or Confidential Information of BioGenerics transferred to such entity while it was an Affiliate under this Agreement shall be returned to Licensee within thirty (30) days of the
- 1.4 "Applicable Laws" means all applicable laws, rules, and regulations, including without limitation any rules, regulations, guidelines or other requirements of the Regulatory Authorities or other governmental authorities, that may be in effect from time to time in any relevant legal jurisdiction.
- **1.5 "BioGenerics Generic Know-How"** means BioGenerics Know-How that (i) is not patentable, (ii) is not a trade secret, and (iii) includes only that portion of Information comprising practices, procedures, skill, or experience that is of a general nature not specific to any particular Product or Option Product.
 - 1.6 "BioGenerics Indemnitees" has the meaning set forth in Section 10.1 (BioGenerics' Right to Indemnification).
 - 1.7 "BioGenerics Inventions" has the meaning set forth in Section 8.3(c) (BioGenerics Inventions).

- **1.8 "BioGenerics Know-How"** means all Information that is (a) Controlled by BioGenerics as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be known, and (b) useful or necessary to (i) Develop and/or Commercialize Products in the Field in the Territory and/or (ii) Manufacture Products in the Field in the Territory . "BioGenerics Know-How" does not include BioGenerics Patent Rights.
- 1.9 "BioGenerics Patent Rights" means any Patent and/or Patent Application that (a) is Controlled by BioGenerics as of the Effective Date or during the Term and (b) claims a product, method, apparatus, material, manufacturing process, or other technology necessary or useful to (i) Develop and/or Commercialize Products in the Field in the Territory and/or (ii) Manufacture Products in the Field in the Territory. "BioGenerics Patent Rights" includes, but is not limited to, any of BioGenerics' interest in any Patents and Patent Applications covering Inventions. "BioGenerics Patent Rights" as of the Effective Date shall be set forth in Exhibit 1.9 (BioGenerics Patent Rights) which shall be updated from time to time upon approval by the JSC.
- **1.10 "BioGenerics Trademarks"** means the trademarks set forth in **Exhibit 1.10 (BioGenerics Trademarks)**, which may be updated by BioGenerics from time to time during the Term.
- **1.11 "Business Day"** means a day other than Saturday, Sunday or any day on which commercial banks located in the State of New York, U.S.A., or Japan are authorized or obligated by Applicable Laws to close.
- **1.12 "Calendar Quarter"** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; *provided, however*, that (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter and (b) the last Calendar Quarter of the Term will end upon the expiration or termination of this Agreement.
 - 1.13 "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.
 - 1.14 "CDA" has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).
 - 1.15 "Chairperson" has the meaning set forth in Section 3.1(b) (Membership; Meetings).
- **1.16 "Clinical Trials"** means any and all human clinical trial of a compound, including without limitation Phase 1 Clinical Trials, Phase 2 Clinical Trials, Phase 3 Clinical Trials, Phase 4 Clinical Trials, bioequivalence trials, and/or variations of such trials (for example, phase 2/3 studies).
 - 1.17 "Combined Royalty Rate" has the meaning set forth in Exhibit 7.1(C) (Royalties on Net Sales).

- 1.18 "Commercially Reasonable Efforts" means the carrying out of obligations or tasks consistent with the reasonable practices of the biopharmaceutical industry for the development or marketing of a biopharmaceutical product having similar market potential or profit potential in the Territory as the applicable Product, based on conditions then prevailing and taking into consideration issues of safety, efficacy, product profile, the competitiveness of the marketplace in the Territory, the regulatory structure involved and other relevant commercial factors. Commercially Reasonable Efforts requires that the Party, at a minimum: (a) determine the general industry practices in the Territory with respect to the applicable activities; (b) reasonably promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (c) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (d) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.
- 1.19 "Commercialization" or "Commercialize" means, with respect to a Product, any and all activities directed to the marketing, advertising, promotion, offering for sale, selling, distribution, and post market surveillance (including without limitation Clinical Trials commenced following Regulatory Approval for the purpose of marketing the Product and not conducted as a condition of obtaining Regulatory Approval), importing, exporting (but not exporting to outside the Territory) such Product for sale, and interacting with Regulatory Authorities regarding the foregoing.
- 1.20 "Commercialization Plan(s)" means, for each Product, the plan for Commercialization of such Product in the Field in the Territory and the activities to be conducted by Licensee relating thereto, including without limitation the long-term strategic plan, which includes the activities to be conducted prior to First Commercial Sale, planning for launch of such Product, and activities to be conducted after launch of such Product, as well as detailed near-term plans], for example detailed plans for sales and marketing after launch of such Product.
 - 1.21 "Competitor" has the meaning set forth in Section 2.2 (Sublicense Rights).
 - 1.22 "Confidential Information" has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).
- **1.23 "Control"** means, with respect to any item of Information, Patent, Patent Application, or other intellectual property right, the right to grant a license or sublicense with respect thereto as provided for in this Agreement without violating the terms of any agreement or other arrangement with, or any legal rights of, or without requiring the consent of, or payments to, any Third Party.
 - 1.24 "Damages" has the meaning set forth in Section 10.1 (BioGenerics' Right to Indemnification).

- 1.25 "Develop" or "Development" means all pre-clinical, clinical, and regulatory activities relating to obtaining or maintaining Regulatory Approval of a Product, excluding Process Development and Manufacturing. Development includes, for example, non-clinical studies, including without limitation non-human animal testing and toxicology studies, Clinical Trials, regulatory affairs activities, and the equivalent in the Territory of U.S. post-approval commitment studies and risk evaluation and mitigation strategies ("REMS") programs.
- 1.26 "Development Plan" means, for each Product, the plan for Licensee's conduct of Development activities with respect to such Product, and the activities to be carried out by each Party relating thereto.
 - 1.27 "Disputes" has the meaning set forth in Section 14.1 (Exclusive Dispute Resolution Mechanism).
 - 1.28 "Dollar" means a U.S. dollar, and "\$" shall be interpreted accordingly.
 - 1.29 "Enforcement Action" has the meaning set forth in Section 8.7(b) (Enforcement Actions Against Third Parties).
 - 1.30 "Field" means the treatment of human diseases and conditions.
- 1.31 "First Commercial Sale" means, with respect to each Product, the first sale of such Product by a Party or its Affiliates or Sublicensees to a Third Party end user (other than a Sublicensee) in a bona fide arms length transaction for which payment has been received in any country in the Territory after all applicable required Regulatory Approvals have been granted by the applicable Regulatory Authority in such country.
 - 1.32 "Formulated Bulk" means bulk purified Product which has not been filled and finished.
- **1.33 "GAAP"** means generally accepted accounting principles, consistently applied and employed by Licensee or its Affiliates or Sublicensees in the applicable country (excluding the Option Territory as to sublicensees) in the Territory.
 - 1.34 "Global Brand Trademark" has the meaning set forth in Section 6.3(b) (Global Brand Trademark).
 - 1.35 "Global Database" has the meaning set forth in Section 4.12(a) (BioGenerics Global Clinical Database).
 - 1.36 "Grant-Back IP" means any [***], or other [***] covering [***], derived or conceived [***] by [***].
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.37 "Indemnification Claim" has the meaning set forth in Section 10.3 (Process for Indemnification).
- 1.38 "Indemnitee" has the meaning set forth in Section 10.3 (Process for Indemnification).
- 1.39 "Indemnitor" has the meaning set forth in Section 10.3 (Process for Indemnification).
- **1.40 "Information"** means ideas, inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, designs, drawings, computer programs, skill, experience, documents, results, clinical and regulatory strategies, test data, including without limitation pharmacological, toxicological and clinical and non-clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, market data, financial data or descriptions, assay protocols, chemical formulas, sequence listings, specifications, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable.
- 1.41 "Inventions" means any and all inventions [***] by or on behalf of either Party, its Affiliates or Sublicensees in the course of activities performed under or contemplated by this Agreement.
 - 1.42 "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 3.4 (Joint Commercialization Committee).
 - 1.43 "Joint Development Committee" or "JDC" has the meaning set forth in Section 3.2 (Joint Development Committee).
 - 1.44 "Joint Inventions" has the meaning set forth in Section 8.3(b) (Joint Inventions).
 - 1.45 "Joint Patent Rights" has the meaning set forth in Section 8.5 (Joint Patent Filings).
- 1.46 "Joint Process and Manufacturing Committee" or "JPMC" has the meaning set forth in Section 3.3 (Joint Process and Manufacturing Committee).
 - 1.47 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 3.1(a) (General).
 - 1.48 "Licensee Indemnitees" has the meaning set forth in Section 10.2 (Licensee's Right to Indemnification).

- **1.49 "Licensee Know-How"** means all Information that is (a) Controlled by Licensee as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be known, and (b) useful or necessary to develop, make, use, sell, offer for sale, import or export Products. "Licensee Know-How" does not include Licensee Patent Rights.
- 1.50 "Licensee Patent Rights" means any Patent and/or Patent Application that is (a) Controlled by Licensee as of the Effective Date or during the Term and (b) claims a product, method, apparatus, material, manufacturing process, or other technology necessary or useful to develop, make, use, sell, offer for sale, import or export the Products. "Licensee Patent Rights" includes, but is not limited to, any of Licensee's interest in any Patents and Patent Applications covering Inventions.
- 1.51 "Licensee Trademarks" means any trademark, other than a Product Trademark, that is (a) Controlled by Licensee and (b) used in the Commercialization of Products.
- **1.52 "Manufacture"** or "**Manufacturing"** means all manufacturing activities, excluding Process Development, undertaken with respect to Products in support of clinical and commercial supply of Product, as applicable, including without limitation manufacture of Formulated Bulk, fill and finish operations, sterilization, lyophilization, packaging, labeling, quality control, quality assurance, and release.
 - 1.53 "Manufacturing and Supply Agreements" has the meaning set forth in Section 5.1(a) (Manufacturing and Supply Agreements).
 - 1.54 "Manufacturing Cost" means the [***] of Manufacturing, including without limitation the cost of [***], and [***] costs incurred in [***].
 - 1.55 "Manufacturing Option" has the meaning set forth in Section 5.2 (Licensee Manufacturing Option).
- 1.56 "Net Sales" means the actual gross amount invoiced on sales of each Product in the Territory by a Party and its Affiliates and permitted sublicensees to Third Party end users in bona fide arms length transactions, less the following deductions allowed and taken by Third Parties and not otherwise recovered by or reimbursed to such Party and its Affiliates and permitted sublicensees: (a) freight, insurance and other transportation charges to the extent added to the sales price and set forth separately as such on the total amount invoiced; (b) any sales, use, value-added, excise taxes and/or duties or allowances on the selling price of the Product which fall due and are paid as a consequence of such sale; (c) chargebacks, trade, quantity and cash discounts and rebates actually allowed and taken to the extent customary in the trade, including
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

without limitation governmental rebates; and (d) allowances or credits, including without limitation allowances or credits to customers on account of rejection, defects or returns of the such Products or because of a retroactive price reduction, and such other deductions actually taken by customers that are customary in the trade. Net Sales shall not include a sale or transfer of Products to an Affiliate or sublicensee or if done for clinical, regulatory or governmental purposes where no consideration is received, but the resale by such Affiliate or sublicensee shall be included in Net Sales of such Product.

- 1.57 "Opt-out Date" has the meaning set forth in Exhibit 12.3(B) (Opt-Out During Commercialization).
- 1.58 "Opt-out Window" has the meaning set forth in Exhibit 12.3(A) (Opt-Out Prior to Commercialization).
- 1.59 "Opting In Party" has the meaning set forth in Section 8.4(b) (Opt-In Rights).
- 1.60 "Opting Out Party" has the meaning set forth in Section 8.4(b) (Opt-In Rights).
- 1.61 "Option Product" means any of the BioGenerics products set forth in Exhibit 1.61 (Option Products).
- 1.62 "Option Territory" means the country(ies) set forth in Exhibit 1.62 (Option Territory).
- 1.63 "Option Term" has the meaning set forth in Section 2.3 (Option to Obtain a License in Option Territory).
- 1.64 "Option Territory Option" has the meaning set forth in Section 2.3 (Option to Obtain a License in Option Territory).
- 1.65 "Patent" means (a) letters patent (or other equivalent legal instrument), including without limitation utility and design patents, and including without limitation any extension, substitution, registration, confirmation, reissue, re-examination or renewal thereof, and (b) all foreign or international equivalents of any of the foregoing in any country.
- **1.66 "Patent Application"** means (a) an application for letters patent [***], including without limitation a reissue application, a re-examination application, a continuation application, a continuation application, a continuation-in-part application, a divisional application or any equivalent thereof [***] and (b) all foreign or international equivalents of any of the foregoing in any country.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.67 "Phase 1 Clinical Trial" means a human clinical trial of a compound, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, as described in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.
- **1.68 "Phase 2 Clinical Trial"** means a human clinical trial of a compound in any country that would satisfy the requirements of 21 C.F.R. 312.21(b) and is intended to explore a variety of doses, dose response, and duration of effect, and to generate initial evidence of clinical safety and activity in a target patient population, or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.
- 1.69 "Phase 3 Clinical Trial" means a human clinical trial of a compound performed after evidence suggesting effectiveness of the compound has been obtained pursuant to one (1) or more Phase 2 Clinical Trial(s), conducted for inclusion in: (a) that portion of an FDA submission and approval process which provides for the continued trials of a product on sufficient numbers of human patients to confirm with statistical significance the safety and efficacy of a product sufficient to support a Regulatory Approval for the proposed indication, as more fully described in 21 C.F.R. 312.21(c), or (b) equivalent Regulatory Filings with similar requirements in a country other than the United States; or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.
- 1.70 "Phase 4 Clinical Trial" means a human clinical trial of a Product commenced after receipt of Regulatory Approval of the Product not for the purpose of satisfying a condition imposed by a Regulatory Authority to obtain Regulatory Approval, but only to support the marketing of such Product.
- 1.71 "Process Development" means all process development activities undertaken with respect to Products, including without limitation activities related to development and optimization of cell lines, expression systems, reagents, upstream process, downstream process, protein modification, development of the Manufacturing process, process scale-up, process characterization, and process validation for bulk drug substance and final dosage forms of the Products and their related placebos.
 - 1.72 "Product" means any of the BioGenerics products set forth in Exhibit 1.72 (Products).
 - 1.73 "Product Trademark" has the meaning set forth in Section 6.3(a) (Product Trademark; Licensee Trademark).
- **1.74 "Regulatory Approval"** means approval by the Regulatory Authority having jurisdiction in the applicable country of a Regulatory Approval Application and satisfaction of related applicable regulatory and notification requirements, if any, together with any other approvals necessary to make and sell a Product commercially in such country[***].
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.75 "Regulatory Approval Application" means (a) the single application or set of applications in the Territory comparable to a Biologic License Application, as defined by the United States Food and Drug Administration ("USFDA") in 21 CFR Part 601, or other applicable filing for each Product to Manufacture and sell commercially such Product, filed by Licensee, its Affiliates or Sublicensees with the applicable Regulatory Authority, and (b) any related registrations with or notifications to such Regulatory Authority, and any amendments or supplements thereto and any substitutes.
- 1.76 "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities, including without limitation the equivalent in the Territory to the USFDA or Japanese Ministry of Health, Labour and Welfare ("MHLW") regulating or otherwise exercising authority with respect to the Products in the Territory.
- 1.77 "Regulatory Filings" means any and all Regulatory Approval Applications and other regulatory applications, filings, approvals and associated correspondence required to Develop, Manufacture, Commercialize, and import Products in, or into, each country or jurisdiction in the Territory.
 - 1.78 "Renewal Period" has the meaning set forth in Section 12.2 (Extension of Term).
 - 1.79 "Responsible Party" has the meaning set forth in Section 8.5 (Joint Patent Filings).
 - 1.80 "Rules" has the meaning set forth in Section 14.3(b) (Arbitration).
- **1.81 "Sublicensee"** means any person or entity to which Licensee grants a sublicense to the extent permitted under **Section 2.2 (Sublicense Rights)** (other than BioGenerics or Affiliates of BioGenerics).
 - 1.82 "Technology Transfer Agreement" has the meaning set forth in Section 5.2(c) (Technology Transfer Agreement).
 - 1.83 "Term" has the meaning set forth in Section 12.1 (Term).
 - 1.84 "Territory" means the country(ies) set forth in Exhibit 1.84 (Territory).
 - 1.85 "Third Party" means any person or entity other than Licensee, BioGenerics, or an Affiliate of either of them.
 - 1.86 "Third Party Payments" has the meaning set forth in Exhibit 7.1(D) (Third Party Payments).

1.87 "Trademark" means any word, name, symbol, color, designation or device or any combination thereof, whether registered or unregistered, including without limitation any trademark, trade dress, service mark, service name, brand mark, trade name, brand name, logo or business symbol.

2. LICENSES.

2.1 License Grants.

- (a) Development and Commercialization License to Licensee. Subject to the terms and conditions of this Agreement, BioGenerics hereby grants to Licensee and its Affiliates an exclusive (subject to Section 2.1(d) (License to BioGenerics) and Section 2.4 (No Implied Rights or Licenses; Retained Rights)), royalty-bearing license, under the BioGenerics Know-How and BioGenerics Patent Rights, to Develop, Commercialize and use Products in the Field in the Territory. The foregoing license does not include the right to Manufacture, or have Manufactured, any Products, or to conduct, or have conducted, any Process Development.
- (b) Manufacturing License to Licensee. If Licensee exercises its Manufacturing Option with respect to a Product(s) pursuant to Section 5.2 (Licensee Manufacturing Option), then subject to the terms and conditions of this Agreement, BioGenerics shall grant to Licensee and its Affiliates, effective as of the effective date of such Manufacturing Option exercise, an exclusive (subject to Section 2.1(d) (License to BioGenerics) and Section 2.4 (No Implied Rights or Licenses; Retained Rights)), royalty-bearing license, under the BioGenerics Know-How and BioGenerics Patent Rights, to Manufacture and have Manufactured such Product(s) in the Field in Japan for Development, Commercialization and/or use in the Territory. Notwithstanding the foregoing, Licensee may [***]. The foregoing license does not include the right to conduct, or have conducted, any Process Development.
- (c) Generic Know-How License to Licensee. Subject to the terms and conditions of this Agreement, BioGenerics hereby grants to Licensee and its Affiliates a [***] license, under the BioGenerics Generic Know-How, to make, use, and sell any products other than Products or other biosimilars of the reference drugs on which the Products are based corresponding to such Products in the Field. [***].
- (d) License to BioGenerics. Subject to the terms and conditions of this Agreement, Licensee hereby grants to BioGenerics a non-exclusive license, under the Licensee Know-How and Licensee Patent Rights, to perform BioGenerics' obligations under this Agreement.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(e) Disclosure of Information. BioGenerics shall disclose to Licensee the BioGenerics Know-How described in and pursuant to the schedule in Exhibit 2.1(e) (BioGenerics Know-How Disclosure Schedule). In addition, [***] BioGenerics shall disclose BioGenerics Patent Rights and additional BioGenerics Know-How that is necessary for Development or Commercialization of the Products [***], including without limitation, [***].

2.2 Sublicense Rights. Licensee shall not have the right to grant sublicenses under the licenses granted to it under Section 2.1(a) (Development and Commercialization License to Licensee) and 2.1(b) (Manufacturing License to Licensee) without the prior written consent of BioGenerics, which consent may be withheld [***] except with respect to (i) [***], or (ii) [***], in which case [***]. For the avoidance of doubt, it shall be [***] with respect to any [***] shall mean a [***]. For clarity, a [***], such as [***], including, without limitation, [***] shall not be considered [***] for conducting those specific activities. If BioGenerics consents in writing to allow Licensee to grant a sublicense, then Licensee may grant such sublicense, through [***], subject to the following: (a) each Sublicensee shall agree to be bound by all of the applicable terms and conditions of this Agreement; (b) the terms of each sublicense granted by Licensee shall provide that the Sublicensee shall be subject to the terms and conditions of this Agreement; (c) Licensee's grant of any sublicense shall not relieve Licensee from any of its obligations under this Agreement; (d) Licensee shall remain jointly and severally liable for any breach of a sublicense by a Sublicensee to the extent that such breach would constitute a breach of this Agreement, and any breach of the sublicensee by such Sublicensee by all be deemed a breach of this Agreement by Licensee to the extent that such breach would constitute a breach of this Agreement as if Licensee had committed such breach; and (e) Licensee will notify BioGenerics of the identity of any Sublicensee, and the territory in which it has granted such sublicense, promptly after entering into any sublicense. Notwithstanding anything to the contrary in this Agreement, for clarity, Licensee shall not have the right to grant sublicenses under Section 2.1 (License Grants) to any Third Party to Manufacture Products, other than under Section 2.1(b) (Manufacturing License to Licensee) and in accordance w

2.3 Option to Obtain a License in Option Territory. Subject to the terms and conditions of this Agreement, BioGenerics hereby grants to Licensee the exclusive option (the "Option Territory Option"), exercisable [***] (a) within six (6) months after the Effective Date (the "Option Term"), on an Option Product-by-Option Product basis, to obtain an exclusive license to Develop and Commercialize and (b) subject to exercise of the Manufacturing Option pursuant to Section 5.2 (Licensee Manufacturing Option), at any time during the term of the license agreement for the Option Product(s) in the Option Territory to be executed between the Parties or its Affiliates, to Manufacture [***] ([***]), each Option Product for the Option Territory, under [***] terms and conditions to be negotiated in good faith by the Parties and set forth in a separate license agreement. Licensee shall exercise the Option Territory Option, if at all, by written notice to BioGenerics at any time during the Option Term (or, with respect to the Manufacturing Option, any time during the term of the license agreement for the Option Product(s) in the Option Territory to be executed between the Parties or its Affiliates) which notice shall make reference to this Agreement and the applicable Option Product(s) and shall state Licensee's decision to exercise the Option Territory Option with respect to such Option Product(s). Within three (3) months after the exercise by Licensee of the Option Territory Option, the Parties shall negotiate in good faith a definitive written license agreement, which will specify the terms of the licensing arrangement, and shall be consistent with all of the relevant provisions of this Agreement. Notwithstanding anything in this Agreement to the contrary, during the Option Term, [***].

2.4 No Implied Rights or Licenses; Retained Rights. BioGenerics grants to Licensee no rights or licenses in or to any Patent, Information, Trademark, or other intellectual property right, whether by implication, estoppel or otherwise, except to the extent expressly set forth in this Agreement. All rights not expressly granted to Licensee in this Agreement are hereby retained by BioGenerics. BioGenerics further retains the right, under the BioGenerics Know-How and BioGenerics Patent Rights, to perform BioGenerics' obligations under this Agreement. The Parties acknowledge that no rights are granted hereunder to Licensee with respect to Process Development inside or outside the Territory. The Parties further acknowledge that, except as expressly permitted under this Agreement, no rights are granted hereunder to Licensee with respect to any country outside the Territory, and that Licensee shall have no authority with respect to the development, manufacture, or commercialization of the Products outside the Territory. As between the Parties, BioGenerics shall have the sole right to conduct Process Development inside or outside the Territory, and subject to Section 2.3 (Option to Obtain a License in Option Territory), to research, develop, manufacture, and commercialize the Products outside the Territory.

3. GOVERNANCE.

3.1 Joint Steering Committee.

- (a) General. As soon as practicable after the Effective Date, the Parties shall establish a joint steering committee (the "Joint Steering Committee" or "JSC") to oversee the Development, Manufacturing, and Commercialization activities of the Parties with respect to Products in the Field in the Territory during the Term as set forth in this Section 3.1. The JSC shall have review and coordination responsibilities for Development, Manufacturing, and Commercialization of Products. The JSC shall review and provide advice regarding the overall progress of Licensee's efforts to Develop, Manufacture, and Commercialize Products. The JSC shall review and provide comments relating to the Development Plans, Commercialization Plans, and any modifications thereof, and shall be briefed by Licensee regarding the content, execution, and results achieved thereunder. The JSC shall also provide a forum for sharing advice, progress, and results relating to such activities and shall attempt to facilitate the resolution of any disputes between the Parties, as described in Section 3.1(c) (Decision-Making; Limitations on JSC). The JSC may establish and oversee other committees as it deems appropriate for carrying out activities under this Agreement.
- (b) Membership; Meetings. The JSC shall be composed of three (3) representatives of Licensee and three (3) representatives of BioGenerics or such number as the Parties may agree, and, during the Term, shall meet at least [***] per [***], or more often as the JSC shall determine, in person, by teleconference, or by video-teleconference. In-person meetings shall alternate between BioGenerics and Licensee locations whenever possible unless otherwise agreed by the Parties. The first such meeting shall be held within ninety (90) days after the Effective Date. Any member of the JSC may designate a substitute to attend with prior written notice to the other Party. There will be an annually rotating chairperson (the "Chairperson") with the first Chairperson to be designated by Licensee. Ad hoc guests who are employees of neither Licensee nor BioGenerics but who are subject to written confidentiality obligations commensurate in scope to the provisions in Article 11 (CONFIDENTIALITY) may be invited to the JSC meetings subject to the other Party's consent. Each Party may replace its JSC members with other of its employees, at any time, upon prior written notice to the other Party.
- (c) Decision-Making; Limitations on JSC. Except as otherwise expressly set forth in this Agreement, decisions of the JSC shall be made by consensus, with each Party having collectively one (1) vote in all decisions. The JSC shall have only such powers as are specifically delegated to it in this Agreement and such powers shall be subject to the terms and conditions set forth in this Agreement. Without limiting the generality of the foregoing, the JSC shall have no power to amend, modify or waive compliance with this Agreement. In the event that the JSC is unable to reach a consensus decision on a matter that is within its decision-making authority within thirty (30) days after it has met and attempted to reach such decision, then either Party may submit such matter for resolution to the Executive Officers in accordance

with Section 14.2 (Resolution by Executive Officers), and the dispute resolution procedure set forth in Article 14 (DISPUTE RESOLUTION) shall apply.

- (d) Secretary; Minutes. The Chairperson shall designate a secretary of the JSC who will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and circulating minutes within thirty (30) days after each meeting of the JSC setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions, or determinations approved by the JSC. Such minutes shall be effective only after being approved by both Parties. Definitive minutes of all JSC meetings shall be finalized no later than sixty (60) days after the meeting to which the minutes pertain.
- 3.2 Joint Development Committee. As soon as practicable after the Effective Date, the Parties shall establish a joint Development committee (the "Joint Development Committee" or "JDC"). The JDC will be composed of an equal number of representatives from BioGenerics and Licensee, except the case of BioGenerics' withdrawal set forth in Section 3.5 (BioGenerics' Membership in Committees). For clarity, either Party may invite its employees to the JDC. The JDC will be responsible for the coordination and review and consultation of the Development efforts with respect to each Product, including without limitation [***]. The JDC will report to the JSC, and any disagreement between the Parties' members on the JDC will be submitted for resolution to the JSC in accordance with Section 3.1(c) (Decision-Making; Limitations on JSC); provided, however, that if the Executive Officers are unable to reach resolution in accordance with Section 14.2 (Resolution by Executive Officers), then no further escalation of dispute resolution under Article 14 (DISPUTE RESOLUTION) shall apply and [***] shall have the final deciding vote, unless [***]. The JDC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to [***].
- 3.3 Joint Process and Manufacturing Committee. As soon as practicable after the Effective Date, the Parties shall establish a joint Process
 Development and Manufacturing committee (the "Joint Process and Manufacturing Committee" or "JPMC"). The JPMC will be composed of an equal number of representatives from BioGenerics and Licensee, except the case of BioGenerics' withdrawal set forth in Section 3.5 (BioGenerics' Membership in Committees). For clarity, either Party may invite its employees to the JPMC. The JPMC will be responsible for reviewing Process Development and Manufacturing improvements, progress and development of analytical methods and analysis, Product formulations, coordination of technology transfer from BioGenerics to Licensee as set forth in Section 5.2(c) (Technology Transfer Agreement), as well as other Process Development and Manufacturing related activities. The JPMC will report to the JSC, and any disagreement between the Parties' members on the JPMC will be submitted for resolution to the JSC in accordance with Section 3.1(c)

(Decision-Making; Limitations on JSC); provided, however, that if the JSC is unable to reach resolution within the thirty (30) day period allotted to it under Section 3.1(c) (Decision-Making; Limitations on JSC), then no further escalation of dispute resolution under Article 14 (DISPUTE RESOLUTION) shall apply and [***] shall have the final deciding vote, unless the dispute relates to [***], and [***]. The JPMC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to [***].

3.4 Joint Commercialization Committee. Upon a decision by the JSC to activate the joint Commercialization committee (the "Joint Commercialization Committee" or "JCC"), the Parties shall establish the JCC, but in no case later than eighteen (18) months prior to the first projected launch of a Product in the Territory. The JCC will be composed of an equal number of representatives from each of BioGenerics and Licensee, except the case of BioGenerics' withdrawal set forth in Section 3.5 (BioGenerics' Membership in Committees). For clarity, either Party may invite its employees to the JCC. The JCC will be responsible for the communication, review and discussion of the Commercialization Plans and other Commercialization matters, including but not limited to marketing strategy and planning, pricing, commercial manufacture, and medical affairs support. Without limiting the foregoing, the JCC shall be responsible for: (a) reviewing Commercialization Plans (and changes thereto) for the Products in the Territory prior to adoption of such plans or changes by a Licensee; (b) communicating with the JDC regarding the interrelationship between Development activities and potential Commercialization of the Products in the Territory; (c) reviewing and monitoring the activities and progress against the Commercialization Plans; (d) monitoring and reporting on the competitive landscape for the Products in the Territory; (e) establishing appropriate processes for coordinating review of promotional materials for the Territory to ensure compliance with Applicable Law and industry best practices; (f) overseeing the trademark and publication strategies for the Territory; and (g) communicating with the Parties regarding all of the foregoing. The JCC will report to the JSC, and any disagreement between the Parties' members on the JCC will be submitted for resolution to the JSC in accordance with Section 3.1(c) (Decision-Making; Limitations on JSC); provided, however, that if the Executive Officers are unable to reach resolution in accordance with Section 14.2 (Resolution by Executive Officers), then no further escalation of dispute resolution under Article 14 (DISPUTE RESOLUTION) shall apply and [***] shall have the final deciding vote, unless [***]. The JCC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to review and discuss material decisions and key activities that relate to such activities, with a first meeting no later than [***] prior to [***].

3.5 BioGenerics' Membership in Committees. BioGenerics' membership in the JSC, JDC, JPMC, JCC, and/or any other committee established by the JSC pursuant to Section 3.1(a) (General) shall be at its sole discretion, as a matter of right and not obligation, for the sole purpose of participation in governance, decision-making, and information exchange with respect to activities within the jurisdiction of such committee. At any time during the Term, BioGenerics shall have the right to withdraw from membership in any or all of such committees upon thirty (30) days' prior written notice to Licensee, which notice shall be effective as to the relevant committee upon the expiration of such thirty (30) day period. For clarity, any withdrawal by BioGenerics from a committee shall not affect any of its other obligations under this Agreement, including Process Development and Manufacturing. Following the issuance of such notice for a given committee, (a) BioGenerics' membership in such committee shall be terminated and (b) BioGenerics shall have the right to continue to receive the information it would otherwise be entitled to receive under this Agreement but shall have no decision making authority in such committee. If, at any time, following issuance of such a notice, BioGenerics wishes to resume participation in such committee, BioGenerics shall notify Licensee in writing and, thereafter, BioGenerics' representatives to such committee shall be entitled to attend any subsequent meeting of such committee and to participate in the activities of, and decision-making by, such committee as provided in this Article 3 as if such notice had not been issued by BioGenerics pursuant to this Section 3.5. If BioGenerics withdraws from membership in any or all of such committees, then any data and information that otherwise would have been provided by a Party to such committee(s) shall be provided by such Party directly to the other Party.

4. DEVELOPMENT AND REGULATORY MATTERS.

4.1 Development Activities and Funding. Licensee shall be responsible for the Development of the Products, the preparation and submission of Regulatory Filings for the Products, and obtaining and maintaining all Regulatory Approvals for the Products, each to the extent in the Field and in the Territory and each in accordance with the Development Plan, subject to Section 5.1(b) (Regulatory Filings for Manufacturing). Licensee shall use Commercially Reasonable Efforts to conduct all Development activities with respect to the Products, in accordance with the applicable Development Plans. Except as stated otherwise in this Agreement, Licensee shall [***], including without limitation [***]. Licensee's responsibility with respect to the Products in the Field in the Territory shall include without limitation: (a) filing for and seeking Regulatory Approvals (subject to Section 5.1(b)) in the name of Licensee from the relevant Regulatory Authorities; (b) carrying out all major Development tasks to be conducted prior to submission of filings for Regulatory Approval of the Products in the Field in the Territory and any post-Regulatory Approval Development activities to be conducted for any such Product; (c) identifying key Development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (d) carrying out all aspects of all Clinical

Trials (including but not limited to bioequivalence Clinical Trials) in the Territory necessary to obtain Regulatory Approval in the Territory for each Product pursued (including without limitation post-Regulatory Approval Clinical Trials), including, but not limited to, (i) designing study protocols, (ii) establishing and contracting with Clinical Trial sites, investigators and clinical research organizations, (iii) enrolling Clinical Trial subjects, (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings, and (v) analyzing and summarizing Clinical Trial results; (e) performing any other additional clinical research in support of the Development of the Products; (f) forecasting clinical manufacturing production requirements; (g) reporting on study design, study outcome, other communications and Regulatory Filings to the appropriate Regulatory Authority; and (h) submitting all Clinical Trial results and any other clinical data to the Global Clinical Database pursuant to Section 4.12 (BioGenerics Global Clinical Database).

Notwithstanding the foregoing, BioGenerics shall be responsible for carrying out non-clinical studies expressly set forth in Exhibit 4.1 (Non-Clinical Studies) relating to obtaining or maintaining Regulatory Approval of the Product and preparing the filing documents thereof, each at BioGenerics' sole cost and expense in accordance with the timeline agreed by the JDC; provided, however, that for all non-clinical studies not set forth in Exhibit 4.1 and requested by Licensee, which are required solely for Regulatory Approval in the Territory, BioGenerics shall conduct any such studies at its sole discretion and Licensee shall [***]. Licensee shall have [***] after the Effective Date to [***], and [***]. Licensee shall promptly, and in no event more than fifteen (15) days after [***], provide [***], and BioGenerics shall [***]. For the avoidance of doubt, BioGenerics shall [***]. Some examples for which it would be considered [***] include, wi

4.2 Development Plans. Not later than three (3) months after the Effective Date, Licensee shall provide to the JDC for review its Development Plan for Development of each Product in the Field in the Territory. The Development Plan shall include, with respect to each Product, a multi-year plan for conducting anticipated Development activities with respect to such

Product, including without limitation the following anticipated activities or events: [***], [***], [***], and [***], if applicable. Licensee may [***]. No Development Plan may be implemented by Licensee if [***]. The Development Plans shall be consistent with and shall not contradict the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between any of the Development Plans and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Law requires a change to a Development Plan, Licensee shall revise the Development Plan to the extent necessary to comply with such requirement and shall promptly provide to the JDC the revised Development Plan.

- 4.3 Efforts. Licensee and its Affiliates and Sublicensees, at Licensee's sole cost and expense, shall use Commercially Reasonable Efforts to Develop the Products in the Field in the Territory in accordance with the Development Plan and the terms of this Agreement, including without limitation by using Commercially Reasonable Efforts to prepare, obtain, and maintain all Regulatory Filings and Regulatory Approvals covering the Products in the Field in the Territory. Subject to the requirements of Section 12.5 (Termination for Material Breach) including the requirement of providing written notice and the entitlement of a cure period, if Licensee does not comply in any material way (including all material aspects of the Development Plan) with the obligations set forth in this Section 4.3 with respect to a Product in a country in the Territory, BioGenerics shall have the right to terminate the rights granted to Licensee under Section 2.1 (License Grants) with respect to such Product in such applicable country, and Section 12.7 (Consequences of Expiration or Termination) shall apply with respect to such Product in such country.
- **4.4 Standard of Performance.** Licensee, in performing its activities in connection with the Development of the Products, shall comply with all Applicable Laws.
- **4.5 Regulatory Filings.** Except with respect to Regulatory Filings controlled by BioGenerics under **Section 5.1(b)** (**Regulatory Filings for Manufacturing**), Licensee or its designee shall be the owner of any and all Regulatory Filings and Regulatory Approvals covering the Products in the Field in the Territory and shall be responsible for all interactions with Regulatory Authorities relating thereto; *provided, however*, that, at all times during the Term, BioGenerics shall have the opportunity to have one (1) representative attend all key meetings, solely as an observer, with Regulatory Authorities relating to the Products, [***]. Licensee and its Affiliates and Sublicensees, shall provide BioGenerics, at BioGenerics' request [***], with summary documents of Regulatory Filings and Regulatory Approvals. BioGenerics will cooperate with Licensee, at its reasonable request, with respect to any Regulatory Filings for which Licensee is responsible. In addition to Licensee's other obligations under this **Section 4.5**, Licensee shall keep BioGenerics informed on a regular basis (but no less frequently than [***]) of Regulatory Filings related to the Products. As

between the Parties, BioGenerics shall be the owner of any and all regulatory filings by BioGenerics, its Affiliates or licensees with the USFDA or its equivalent in each country outside the Territory pertaining to the Products and shall be responsible for all interactions with such regulatory authorities relating thereto. [***].

- 4.6 Development Subcontracting. Subject to Section 2.2 (Sublicense Rights), Licensee may perform any activities in support of its Development of Products through subcontracting to a Third Party contractor or contract service organization; provided that: (a) none of the rights of BioGenerics hereunder is materially adversely affected as a result of such subcontracting; (b) any such Third Party subcontractor to whom Licensee discloses Confidential Information has entered into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in Article 11 (CONFIDENTIALITY); (c) Licensee will retain or obtain ownership or a license of any and all intellectual property (and patent rights covering such intellectual property) made by such Third Party in performing such services for Licensee that are necessary for the Development, Manufacturing, and/or Commercialization; and (d) Licensee shall at all times be responsible for the performance of such subcontractor.
- 4.7 Development Reports. Licensee will provide, at least [***] per [***], the JDC with written Development reports or presentations at JDC meetings. Each report or presentation shall include, but not be limited to, the Development activities accomplished by or on behalf of Licensee since the previous JDC meeting, including without limitation a summary of significant results and Information generated, significant challenges anticipated and [***] relating to each Product. Upon request by BioGenerics, Licensee shall provide BioGenerics additional Information with respect to the material experimental data underlying such summary, summaries of available clinical protocols, investigator brochures, regulatory submissions and correspondence from Regulatory Authorities with respect to Products. Upon request of either Party, the other Party's JDC members shall meet with the requesting Party's JDC members to discuss any aspects of such reports within a reasonable time period after such request.
- 4.8 Records. Licensee shall, and shall require its Affiliates, its subcontractors and Sublicensees to, maintain accurate records of all work, in accordance with Applicable Laws, conducted in furtherance of the Development of Products and all results, Information, and developments made in conducting such activities. Such records shall be accurate and shall fully and properly reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.
- 4.9 Notice of Communication with Regulatory Authorities. Except with respect to Regulatory Filings controlled by BioGenerics under Section 5.1(b) (Regulatory Filings for Manufacturing), Licensee shall be responsible for reporting all adverse events and handling all complaints and communications (including without limitation with Regulatory Authorities) relating to the Products in the Field in the Territory. Except as otherwise provided for in this
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

Section 4.9, each Party shall provide summaries [***] to the other Party of any oral or written major communications to or from Regulatory Authorities on matters relating to the Products in the Territory. Notwithstanding the foregoing, each Party shall notify the other Party of any oral communications, and provide such other Party with copies of any written communications, to or from Regulatory Authorities on matters which may reasonably be deemed to impact Development, Manufacture, Commercialization or Regulatory Approval of Products within five (5) Business Days of receipt of such communication, or such earlier date as required by Applicable Laws or Regulatory Authority. Moreover, in each such case, [***], and provide such other Party with a copy of the final response as specified herein.

4.10 Trial Master File. Notwithstanding any other provision in this Agreement regarding the return or transfer of Confidential Information or clinical trial data or documents, any Party that is a sponsor of a Clinical Trial involving the Products shall retain all documents and data, including, but not limited to the Trial Master File, to the extent required to be retained under Applicable Laws. [***].

4.11 Right of Reference.

- (a) BioGenerics hereby grants to Licensee, its Affiliates and Sublicensees a right of reference [***] to any regulatory filings [***].
- (b) Licensee hereby grants to BioGenerics, its Affiliates and licensees a right of reference [***] to any Regulatory Filings [***].

4.12 BioGenerics Global Clinical Database.

(a) Subject to Section 4.14 (Pharmacovigilance), BioGenerics may, in BioGenerics' sole discretion, create a global database for all Clinical Trial results and clinical data submitted by BioGenerics and its exclusive licensees throughout the world to applicable regulatory authorities (the "Global Clinical Database"). The purpose of the Global Clinical Database will be for BioGenerics and its exclusive licensees who submit data to the Global Clinical Database to share such data in support of their regulatory filings, and, in the case of BioGenerics, for use in Process Development activities.

- **(b)** If BioGenerics decides to create the Global Clinical Database, BioGenerics shall notify Licensee of such decision, and Licensee shall be obligated to submit all clinical data pertaining to the Products in the Territory [***] in a form to be [***], and subject to Applicable Laws, including any obligations to de-identify patient specific data, to the Global Clinical Database.
- (c) BioGenerics shall be responsible for managing, maintaining, and updating the Global Clinical Database in accordance with Applicable Laws and shall have the right to share any and all de-identified information received from Licensee under this **Section 4.12** with [***] outside the Territory relating to the Products [***].
- (d) Following Licensee's submission of and BioGenerics' acceptance of Licensee's clinical data for the Global Clinical Database, Licensee shall have reasonable access to the Global Clinical Database for use in its Regulatory Filings. Licensee's continued access to the Global Clinical Database shall be conditioned on Licensee's timely submission of additional data under this **Section 4.12** to the extent such data is generated by or on behalf of Licensee. Subject to Licensee's compliance with this **Section 4.12**, Licensee shall have the right to share any and all Information in the Global Clinical Database with Licensee's Affiliates and Sublicensees in the Territory.
- **4.13 BioGenerics Global Development Plan.** The Parties acknowledge that [***]. The Parties agree to [***]. Upon the request of either Party, the Parties shall [***].
- **4.14 Pharmacovigilance.** In no event later than six (6) months after the Effective Date, the Parties shall enter into a pharmacovigilance agreement concerning all matters relating to the pharmacovigilance and the exchange of all relevant Information that relates to the safety of each Product worldwide and especially all adverse events. Generally, (a) Licensee shall be responsible for reporting all adverse drug reaction experiences required to be reported to the appropriate Regulatory Authorities in the countries in the Territory in which such Product is being Developed or Commercialized, in accordance with the Applicable Laws of the relevant countries and Regulatory Authorities; and (b) BioGenerics, its Affiliates or licensees or sublicensees shall be responsible for submitting all regulatory filings, including without limitation any post-marketing reports of adverse drug experiences, relating to such Product required to be reported to the appropriate regulatory authorities outside of the Territory in

accordance with the Applicable Laws of the relevant countries. BioGenerics shall have the right to share any and all information received from Licensee under this **Section 4.14** (and/or such pharmacovigilance agreement) with BioGenerics' Affiliates and licensees and sublicensees outside the Territory. Licensee shall have the right to share any and all information received from BioGenerics under this **Section 4.14** and/or such pharmacovigilance agreement with Licensee's Affiliates and Sublicensees in the Territory. The JSC shall review from time to time Licensee's pharmacovigilance policies and procedures.

5. MANUFACTURING.

- 5.1 Manufacturing by BioGenerics. BioGenerics, either directly or through its designee, shall be responsible for the Manufacture and supply of Products to Licensee or its designated Affiliate or Sublicensee or a Third Party logistics provider, freight forwarder or contract research organization, designated by Licensee for Development in the Territory in conformance with the specifications set forth in the respective Regulatory Approval Application. Unless Licensee exercises the Manufacturing Option set forth in Section 5.2 (Licensee Manufacturing Option), BioGenerics, either directly or through its designee, shall be responsible for the Manufacture and supply of Products to Licensee for Commercialization in the Territory in conformance with the specifications set forth in the respective Regulatory Approval Application. Such Products shall be provided to Licensee as set forth in Exhibit 5.1 (Manufacturing and Supply by BioGenerics).
- (a) Manufacturing and Supply Agreements. Within six (6) months after the Effective Date, the Parties shall negotiate in good faith and enter into a definitive written clinical supply agreement, which will specify the terms of the Manufacturing and supply of Products by BioGenerics to Licensee or its designee to be used in non-clinical and Clinical Trials. The Parties shall negotiate in good faith and enter into a definitive written commercial supply agreement[***], which will specify the terms of the Manufacturing and supply of Products by BioGenerics to Licensee or its designee for commercial use (together with the clinical supply agreement, the "Manufacturing and Supply Agreements"). The Manufacturing and Supply Agreements shall be consistent with all of the terms and conditions in this Section 5.1, Exhibit 5.1 (Manufacturing and Supply by BioGenerics), and all other relevant provisions of this Agreement, and shall be agreements to supply all of Licensee's, its Affiliates' and Sublicensees' requirements for the Products in the Territory and contain customary market terms including, without limitation, [***].
- **(b) Regulatory Filings for Manufacturing.** BioGenerics shall be solely responsible for the preparation and submission of all Regulatory Filings with respect to the Manufacture of the Products provided to Licensee pursuant to this **Section 5.1**, including without limitation with respect to the use of any Third Party to Manufacture and supply the Products. Licensee shall provide BioGenerics any cooperation reasonably requested by BioGenerics in
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

connection with any such Regulatory Filings, and BioGenerics shall [***].

- **5.2 Licensee Manufacturing Option (a).** Licensee shall have the option to obtain the right to Manufacture Product in Japan for Development and/or Commercialization in the Territory (the "Manufacturing Option"), which Licensee may exercise on a Product-by-Product basis at any time during the Term, by providing to BioGenerics written notice thereof.
- (a) Grant of License. Upon the effective date of Licensee's exercise of the Manufacturing Option, BioGenerics shall grant to Licensee the license to Manufacture or have Manufactured the applicable Product(s) set forth in Section 2.1(b) (Manufacturing License to Licensee), and shall disclose to Licensee, pursuant to a schedule to be included in the Technology Transfer Agreement, the BioGenerics Know-How that is necessary to Manufacture the Products in the Field;
- **(b) Process Development.** BioGenerics shall be responsible for any and all Process Development reasonably necessary for Licensee, its Affiliates and Sublicensees to Manufacture, Develop, or Commercialize the Products or to support Regulatory Approval in the Territory;
- (c) Technology Transfer Agreement. As soon as reasonably practicable, but no later than six (6) months after Licensee's exercise of the Manufacturing Option [***], the JPMC shall agree on a process for, and prepare a schedule pertaining to the implementation of, the technology transfer of BioGenerics Know-How necessary for Licensee to Manufacture or have Manufactured the applicable Product, and the Parties shall execute an agreement thereon (the "Technology Transfer Agreement"). The Technology Transfer Agreement shall specify, among other items, [***]; and
- (d) Supply by Licensee. If Licensee is Manufacturing Product pursuant to this Section 5.2 (Licensee Manufacturing Option) (which Manufacturing for purposes of this Section 5.2(d) [***]), and the Parties mutually agree that BioGenerics will purchase Product Manufactured by Licensee, BioGenerics may purchase Product Manufactured by Licensee[***] for sale in markets outside of the Territory, the Parties shall negotiate in good faith and enter into a separate definitive written Licensee manufacturing and supply agreement. Such Licensee manufacturing and supply agreement shall contain customary market terms including, without limitation, [***].
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.3 Manufacturing Subcontracting. Subject to Section **2.2 (Sublicense Rights)**, Licensee may perform any activities in support of its Manufacturing of Products through subcontracting to a Third Party contractor or contract manufacturing organization; provided that: (a) none of the rights of BioGenerics hereunder is materially adversely affected as a result of such subcontracting; (b) any such Third Party subcontractor to whom Licensee discloses Confidential Information has entered into an appropriate written agreement obligating such Third Party to be bound by obligations of confidentiality and restrictions on use of such Confidential Information that are no less restrictive than the obligations in **Article 11 (CONFIDENTIALITY)**; (c) Licensee will retain or obtain ownership or a license of any and all intellectual property (and patent rights covering such intellectual property) made by such Third Party in performing such manufacturing services for Licensee that are necessary for the development, manufacturing, and/or commercialization of Products; and (d) Licensee shall at all times be responsible for the performance of such subcontractor.

5.4 Records. The Parties shall, and shall require its Affiliates, subcontractors and sublicensees to, maintain records of all work conducted by such Party in furtherance of the Manufacture of Products and all results, Information, and developments made in conducting such activities in accordance with Applicable Laws. Such records shall be complete and accurate and shall fully and properly reflect all such work done and results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.

6. COMMERCIALIZATION.

6.1 Efforts. Licensee shall be responsible for the Commercialization of Products, and, as between the Parties, shall book all sales of Products in the Territory in the Field. Licensee shall use Commercially Reasonable Efforts to Commercialize the Products in the Territory in accordance with the Commercialization Plan and terms of this Agreement. Subject to the requirements of Section 12.5 (Termination for Material Breach) including the requirement of providing written notice and the entitlement of a cure period, if Licensee does not comply in any material way (including all materials aspects of the Commercialization Plan) with the obligations set forth in this Section 6.1 with respect to a Product in a country in the Territory, BioGenerics shall have the right to terminate the rights granted to Licensee under Section 2.1 (License Grants) with respect to such Product in such applicable country, and Section 12.7 (Consequences of Expiration or Termination) shall apply with respect to such Product in such country.

6.2 Commercialization Plan.

(a) Not later than three [***] after submission of Regulatory Filings for each Product in each country of the Territory, Licensee will provide to the JCC for review its initial Commercialization Plan for each Product for each country in the Territory. Such initial Commercialization Plan will describe Licensee's plans for activities to be conducted for such Product for such country. Each Commercialization Plan shall include the details of obligations to be performed by Licensee to achieve the specific activities that are applicable to the stage of

Commercialization (e.g., pre-launch, launch planning, launch, or post-launch) of the applicable Product during the time period covered by such Commercialization Plan and subsequent time periods.

- **(b)** Prior to the First Commercial Sale for such Product in such country, Licensee will provide to the JCC for review an updated Commercialization Plan for such Product for such country. Such updated Commercialization Plan will include, but not be limited to, Licensee's updated plans for activities to be conducted for such Product for such country prior to launch as well as activities to be conducted in connection with such launch.
- (c) Promptly after each anniversary of the First Commercial Sale of such Product during the Term, Licensee will provide to the JCC for review updated Commercialization Plans for such Product for such country. Such further updated Commercialization Plan will include, but not be limited to, Licensee's plans for Commercialization activities for such Product and such country for the twelve (12) month period following the date of delivery of such Commercialization Plan.

No Commercialization Plan may be implemented by Licensee if [***]. Each Commercialization Plan shall be consistent with and shall not contradict the terms of this Agreement [***], and in the event of any inconsistency between the Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a [***], Licensee shall [***] and shall promptly [***].

6.3 Trademarks.

(a) Product Trademark; Licensee Trademark. Subject to Section 6.3(d) (Use of BioGenerics Trademarks), each Product, including without limitation all packaging, promotional materials, package inserts, and labeling for such Product, shall bear one or more Trademark(s) that pertain specifically to such Product chosen and owned by Licensee ("Product Trademark") and to the extent allowed by Applicable Laws, the Licensee Trademark.

- **(b) Global Brand Trademark.** Licensee shall have the option[***] to use one or more Trademark(s) Controlled by BioGenerics that pertain specifically to a particular Product outside of the Territory for such Product in the Territory (the "Global Brand Trademark") in place of using the Product Trademark under Section 6.3(a) (Product Trademark; Licensee Trademark). Such Global Brand Trademark may be used on all Products in the Territory including without limitation all packaging, promotional materials, package inserts, and labeling for such Product.
- (c) Trademark Prosecution and Maintenance. Licensee shall [***] be responsible for filing, prosecuting and maintaining, including without limitation searching and policing, any and all Product Trademarks and Licensee Trademarks, and conducting litigation with respect thereto. BioGenerics shall [***] be responsible for filing, prosecuting and maintaining, including without limitation searching and policing, any and all Global Brand Trademarks and BioGenerics Trademarks, and conducting litigation with respect thereto.
- (d) Use of BioGenerics Trademark. To the extent allowed by Applicable Laws, at BioGenerics' request, each Product, including without limitation all packaging, promotional materials, package inserts, and labeling for such Product, shall bear the BioGenerics Trademark as set forth in this Section 6.3(d). Subject to the terms and conditions of this Agreement, BioGenerics hereby grants to Licensee a non-exclusive, royalty-free license, under the BioGenerics Trademarks and, subject to Licensee's option under Section 6.3(b) (Global Brand Trademark), under the Global Brand Trademarks, with the right to grant sublicenses in accordance with Section 2.2 (Sublicense Rights), throughout the Territory, to use and display the BioGenerics Trademarks in connection with the Commercialization of each Product in the Field throughout the Territory, as provided under and in accordance with this Section 6.3. All representations of the BioGenerics Trademark(s) that Licensee so uses, if intended to be disclosed to Third Parties and not previously approved by BioGenerics, will first be submitted to BioGenerics for approval[***], and BioGenerics will have [***] to review and approve each such representation of the BioGenerics Trademark(s). [***]. Licensee shall not use any BioGenerics Trademark outside the scope of this Agreement, and shall not knowingly take any action that would materially adversely affect the value of any BioGenerics Trademark. BioGenerics shall retain the right to monitor the quality of the goods on or with which any BioGenerics Trademark is used solely to the extent necessary to maintain BioGenerics' Trademark rights. For clarity, should Applicable Laws only permit one Trademark (i.e. Licensee Trademark or BioGenerics Trademark) on the Products, that Trademark shall be Licensee Trademark.

(e) Packaging. BioGenerics shall be responsible for filling Product into syringes or vials and labeling of such Product, with a label or package design provided by Licensee, until such time that Licensee has exercised the Manufacturing Option and such Manufacturing for purposes of this Section 6.3(e) has commenced and includes the manufacture of Formulated Bulk. For the avoidance of doubt, packaging, shipping, novel administration devices and other such costs will be borne by Licensee. In case that Licensee exercises the Manufacturing Option for a Product, then Licensee shall be responsible for all packaging and labeling of each Product Manufactured by Licensee, its Affiliates or Sublicensees after completion of the technology transfer from BioGenerics to Licensee, its Affiliates or Sublicensees. [***].

7. PAYMENT OBLIGATIONS.

- **7.1 Payment Structure.** In consideration for the rights granted to Licensee under this Agreement, Licensee shall pay BioGenerics the amounts set forth in **Exhibit 7.1 (Payment Structure)**.
- **7.2 Reports and Payments.** During the Term following the First Commercial Sale of any Product, within [***] after the end of each Calendar Quarter, Licensee shall pay to BioGenerics royalty and other fees payable for such Calendar Quarter and shall provide a report showing, on a Product-by-Product and country-by-country basis:
- (a) the gross amount invoiced for and the Net Sales during such Calendar Quarter reporting period, including without limitation the specific deductions applied in the calculation of such Net Sales amounts;
 - (b) the royalties and other fees payable in Dollars which shall have accrued hereunder with respect to such Net Sales;
 - (c) the rate of exchange used by Licensee in determining the amount of Dollars payable hereunder.

If no royalty or other payment is due for any period hereunder, Licensee shall so report. Licensee shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with GAAP), complete and accurate records in sufficient detail to properly reflect the Net Sales and to enable the royalties and other fees payable hereunder to be determined for a period of at least five (5) Calendar Years or as otherwise necessary to permit the audits contemplated under **Section 7.7 (Audit Request)**.

- **7.3** Sublicensing. In the event Licensee grants a sublicense under Section 2.2 (Sublicense Rights) to a Sublicensee to offer to sell or sell Products in the Territory such sublicenses shall require the Sublicensee to account for and report its Net Sales of such Product on the same basis as if such sales were Net Sales of such Product by Licensee, and Licensee shall pay royalties on such sales as if the Net Sales of the Sublicensees were Net Sales of Licensee.
- **7.4** Currency of Payment. All payments to be made under this Agreement shall be made in Dollars. Net Sales made in foreign currencies shall be converted into Dollars using [***].

7.5 Accounting.

- (a) Licensee shall determine Net Sales with respect to the Products using its standard accounting procedures, consistent with GAAP, as if the Products were solely owned products of Licensee, except as specifically provided in this Agreement. In the case of amounts to be determined by Third Parties (for example, Net Sales by Sublicensees), such amounts shall be determined in accordance with GAAP in effect in the country in which such Third Party is engaged. The Parties also recognize that such procedures may change from time to time and that any such changes may affect the definition of Net Sales. The Parties agree that, where such changes are economically material to BioGenerics, adjustments shall be made to compensate BioGenerics in order to preserve the same economics as are reflected under this Agreement under Licensee's accounting procedures in effect prior to such change. Where the change is or would be material to BioGenerics, Licensee shall provide an explanation of the proposed change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.
- (b) In the event of the payment or receipt of non-cash consideration in connection with the performance of activities under this Agreement, Licensee shall advise BioGenerics of such transaction, including without limitation Licensee's assessment of the fair market value of such non-cash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by the Parties in good faith.
- **7.6 Withholding Tax.** Licensee shall bear any and all taxes required to be paid on amounts due to BioGenerics, and Licensee shall not be entitled to deduct such payments from such amounts payable to BioGenerics under **Section 7.1 (Payment Structure)**. For clarity, amounts due to BioGenerics under **Section 7.1** shall be based on amounts due to BioGenerics prior to any deduction as a result of taxes payable by Licensee. BioGenerics shall reasonably cooperate Licensee to facilitate appropriate proceedings required by tax authorities in the Territory relating to the payments hereunder.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

7.7 Audit Request. Each Party shall, at its expense (except as provided below), have the right to audit during regular business hours the books and records maintained by the other Party to determine with respect to any Calendar Year, the accuracy of any report or payment made or expense charged by one Party to the other under this Agreement in the [***] preceding Calendar Years. If a Party desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to the other Party, to examine such records under conditions of confidentiality. Such accountant shall be instructed to provide to the auditing Party a report verifying any report made or payment submitted or expense charged by the other Party during such period, but shall not disclose to the auditing Party any Confidential Information of the other Party not necessary therefor. The expense of such audit shall be borne by the auditing Party; provided, however, that, if an error of more than five percent (5%) is discovered, then such expenses shall be paid by the other Party. If such accountant concludes that additional payment amounts were owed or additional expenses were charged to the auditing Party during any period, the other Party shall pay such payment amount (including without limitation interest thereon pursuant to Section 7.8 (Interest) from the date such amounts were payable) within thirty (30) days after the date the auditing Party delivers to the other Party such accountant's written report so concluding, unless such other Party notifies the auditing Party of any dispute regarding the audit and commences proceedings under Article 14 (DISPUTE RESOLUTION) within thirty (30) days after delivery of the accountant's report (in which case the payment shall be delayed until conclusion of the proceeding). Such auditors shall not be paid on a contingency basis.

7.8 Interest. Licensee shall pay BioGenerics interest on any payments that are not paid on or before the date such payments are due under this Agreement at [***].

8. INTELLECTUAL PROPERTY AND INVENTIONS.

- **8.1 Intellectual Property.** Except as otherwise expressly set forth in this Agreement, neither Party grants any right, title, or interest in any Patent, Information, Trademark, or other intellectual property right Controlled by such Party to the other Party.
- **8.2 Disclosure.** Each Party shall promptly disclose to the other Party any Inventions that it or its employees, sublicensees, Affiliates, independent contractors or agents solely or jointly make, conceive, reduce to practice, author, or otherwise discover.

8.3 Ownership of Inventions.

- (a) Sole Inventions. All Inventions made, conceived, reduced to practice, or otherwise discovered solely by employees, independent contractors, or agents of either Licensee or BioGenerics, or their respective Affiliates or sublicensees, excluding any such Inventions owned solely by BioGenerics pursuant to Section 8.3(c) (BioGenerics Inventions), shall be solely owned by such Party. Patents and Patent Applications covering Inventions that are solely owned by BioGenerics shall be included in the BioGenerics Patent Rights. Patents and Patent Applications covering solely Inventions that are solely owned by Licensee shall be included in the Licensee Patent Rights.
- **(b) Joint Inventions.** All Inventions made, conceived, reduced to practice, or otherwise discovered by employees, independent contractors, or agents of each of Licensee and BioGenerics, or their respective Affiliates or sublicensees, excluding any such Inventions owned solely by BioGenerics pursuant to **Section 8.3(c)** (**BioGenerics Inventions)**, shall be owned jointly by the Parties ("**Joint Inventions**"). Each Party shall own an undivided one-half (1/2) interest in each such Joint Invention, and all Patents and Patent Applications claiming it and other intellectual property rights therein, and, with no duty of accounting to the other Party, shall have the right to practice such Joint Invention and grant licenses under such Party's interest in such Patents and Patent Applications and other intellectual property rights in such Party's interest in such Joint Inventions without the consent of the other Party. BioGenerics' interest in any Patents and Patent Applications covering Joint Inventions shall be included in the BioGenerics Patent Rights, and Licensee's interest in any Patents and Patent Applications covering Joint Inventions shall be included in the Licensee Patent Rights.
- (c) BioGenerics Inventions. Notwithstanding Sections 8.3(a) (Sole Inventions) and Section 8.3(b) (Joint Inventions), as between the Parties, BioGenerics shall solely own all right, title, and interest in and to all Inventions that claim, cover, or relate to (i) [***], and all Patents and Patent Applications claiming them and all other intellectual property rights therein, including without limitation all rights to enforce such Patents and Patent Applications ("BioGenerics Inventions"). BioGenerics shall be responsible, at its sole expense and discretion (subject to Section 8.4 (Individual Patent Filings)), and if necessary with the cooperation of Licensee [***], for the preparation, filing, prosecution, and maintenance of Patents and Patent Applications claiming such Inventions as set forth in Section 8.4. BioGenerics Inventions covering Inventions under subsection (i) above shall be included in the BioGenerics Patent Rights; provided, however, that Inventions related to [***] shall be included in the BioGenerics Patent Rights [***].

- (d) Ownership Disputes. The [***] shall attempt in good faith to resolve any disputes arising hereunder regarding ownership of Inventions, Patents and any other intellectual property. In the event the [***] is unable to resolve such dispute within thirty (30) days after its receipt of notice of the dispute, the dispute resolution procedure set forth in Article 14 (Dispute Resolution) shall apply.
- (e) Assignment and Perfection of Interests. Without additional consideration, each Party hereby assigns to the other Party such of its right, title, and interest in and to any Inventions, Patents, and Patent Applications claiming them, and all other intellectual property rights therein, and shall require its sublicensees and Affiliates, and all independent contractors, employees, or agents of such Party, its Affiliates, or its sublicensees to so assign to the other Party such of their right, title, and interest in and to them, as is necessary to effectuate the allocation of right, title, and interest in and to Inventions as set forth in this Section 8.3. Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees, and agents of such Party, its Affiliates, or its sublicensees to, cooperate with the other Party and take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required to perfect the other Party's right, title, and interest in and to Inventions, Patents, and Patent Applications and other intellectual property rights thereon or therein as such other Party has pursuant to this Section 8.3. If a Party is unwilling or unable to execute any such agreements, instruments, and documents, it hereby appoints the other Party as its attorney-in-fact, which shall be coupled with an interest, to execute the same on its behalf. [***].
- **(f) License.** Licensee shall and hereby does grant to BioGenerics the non-exclusive, perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP, to develop, make, use, sell, offer to sell, and import any Products outside of the Territory.
- **8.4 Individual Patent Filings.** Each Party will, to the maximum extent practicable, strive to separate any claims within Patents and Patent Applications that claim Inventions into separate Patents and Patent Applications consisting of claims that claim solely BioGenerics owned Inventions, solely Licensee owned Inventions, or solely Joint Inventions.
- (a) Solely Owned Inventions. BioGenerics shall have sole discretion and responsibility to prepare, file, prosecute, and maintain any and all Patents and Patent Applications solely claiming Inventions within the BioGenerics Patent Rights and any and all other Patents and Patent Applications within the BioGenerics Patent Rights, and shall be responsible for [***] proceedings. Licensee shall have sole discretion and responsibility to prepare, file, prosecute, and maintain any and all Patents and Patent Applications solely claiming Inventions within the Licensee Patent Rights, and shall be responsible for [***] proceedings. The Parties shall file any such Patent Application outside of the United States before any oral, written, or electronic disclosure of the Inventions claimed therein to maintain the validity of such Patents and Patent Applications. At
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

least sixty (60) days prior to the contemplated filing date of any Patent Application in the Territory claiming its solely-owned Invention, each Party shall [***], [***], and [***], and shall [***] with respect to such Patent Application. Licensee shall [***] pursuant to this **Section 8.4(a)** for Patents and Patent Applications within the Licensee Patent Rights, and BioGenerics shall [***] pursuant to this **Section 8.4(a)** for Patents and Patent Applications within the BioGenerics Patent Rights.

(b) Opt-In Rights. If a Party elects, in any country, not to file or not to continue to prosecute and thereby abandon a Patent or Patent Application within the patent rights licensed to the other Party in the Territory, or not to maintain and thereby abandon such a Patent or Patent Application, without the intent to file a continuing or divisional filing or an equivalent thereof or upon advice of patent counsel to optimize the overall patent protection on Products or Process Development, such Party (the "Opting Out Party") shall notify the other Party (the "Opting In Party") not less than ninety (90) days before any relevant deadline, and thereafter such Opting In Party shall have the right, but not the obligation, to pursue, [***] preparation, filing, prosecution, and maintenance of such Patent or Patent Application; provided, however, that the Opting In Party provides the Opting Out Party with [***] at least thirty (30) days prior to the proposed submission date and such Opting Out Party determines[***] that any such submission will not prejudice any other Patents and Patent Applications of such Opting Out Party.

8.5 Joint Patent Filings. With respect to all Patents and Patent Applications claiming Joint Inventions, but not solely owned Inventions, (the "Joint Patent Rights"), BioGenerics shall have the first right, but not the obligation, to file, prosecute, maintain, and defend such Joint Patent Rights on behalf of both Parties (the "Responsible Party"). At least sixty (60) days prior to the contemplated filing of any Joint Patent Right, BioGenerics shall submit a substantially completed draft of such Joint Patent Right to Licensee for its approval, which shall not be unreasonably withheld, delayed, or conditioned]. Except as set forth in this Section 8.5, below, the Parties shall [***], pursuant to [***] ([***]). If BioGenerics does not wish to file, prosecute, or maintain any Joint Patent Right or maintain or defend such a Joint Patent Right in a particular country, it shall grant Licensee any necessary authority to file, prosecute, and maintain such Joint Patent Right or maintain or defend such Joint Patent Right in the name of both Parties if Licensee so requests. If either Party elects [***], it shall so notify the other Party, in which case the other Party may proceed with respect to such Joint Patent Right in its own name [***]. In such case, the [***] shall [***] such Joint Patent Right [***].

8.6 Defense of Infringement Claims by Third Parties.

- (a) In the event of the institution or threatened institution of any suit by a Third Party against Licensee for infringement involving the Development, Manufacture (only if Licensee has exercised the Manufacturing Option), or Commercialization of the Product in the Territory, Licensee shall have the right to defend such suit at its own expense and shall be responsible for all damages incurred as a result thereof. BioGenerics hereby agrees to assist and cooperate with Licensee, at Licensee's reasonable request, and Licensee shall reimburse BioGenerics any reasonable, documented, out-of-pocket costs incurred in connection therewith. Licensee shall solely control the defense of such a claim and shall also have the right to control settlement of such claim; provided, however, that any such settlement shall not adversely affect BioGenerics' rights or interests without BioGenerics' prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. Subject to such control, BioGenerics may join any defense and settlement pursuant to this Section 8.6 with its own counsel at its sole cost.
- (b) In the event of the institution or threatened institution of any suit by a Third Party against BioGenerics for infringement involving the development, manufacture, or commercialization of the Product in the Territory, BioGenerics shall have the right to defend such suit at its own expense and shall be responsible for all damages incurred as a result thereof. Licensee hereby agrees to assist and cooperate with BioGenerics, at BioGenerics' reasonable request, and BioGenerics shall reimburse Licensee any reasonable, documented, out-of-pocket costs incurred in connection therewith. BioGenerics shall solely control the defense of such a claim and shall also have the right to control settlement of such claim; provided, however, that any such settlement shall not adversely affect Licensee's rights or interests without Licensee's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. Subject to such control, Licensee may join any defense and settlement pursuant to this Section 8.6 with its own counsel at its sole cost.
- (c) If such Third Party asserts that a patent or other intellectual property right owned by it is infringed by the manufacture or commercialization of the Product in the Territory by both of the Parties, then the Parties shall meet and confer, and both Parties shall have the sole right to defend against any such assertions with respect to its activities at its respective sole cost. Regardless of which Party is the defending Party (or if both Parties are a defending Party), the defending Party shall seek and reasonably consider the other Party's comments before determining the strategy for such matter. Without limiting the foregoing, the defending Party shall keep the other Party advised of all material communications and actual and prospective filings or submissions regarding such action, and shall provide the other Party copies of and an opportunity to review and comment on any such communications, filings and submissions. Each Party shall keep the other reasonably informed of all claims and actions governed by this **Section 8.6**.

8.7 Enforcement Actions Against Third Parties.

- (a) If either Party learns of an infringement, unauthorized use, misappropriation, ownership claim, threatened infringement, or other similar claim by a Third Party with respect to the BioGenerics Patent Rights in the Territory, such Party shall promptly notify the other Party in writing and shall promptly provide such other Party with available evidence of such infringement or other such claim.
- (b) BioGenerics shall have the first right, but not the obligation, to institute an infringement suit or take other appropriate action against such Third Party in the Territory. If BioGenerics does not secure actual cessation of such infringement or institute an infringement proceeding (which may include sending a cease and desist letter if appropriate), against an offending Third Party with respect to infringement of such BioGenerics Patent Rights as a result of the development, manufacture, commercialization or use of a product that is competitive with a Product in the Field in the Territory ("Enforcement Action"), BioGenerics shall notify Licensee of such determination as soon as reasonably practicable but in any case no later than sixty (60) days of learning of such infringement. Upon receipt of such notice or absent such notice within such sixty (60) days, Licensee shall have the right at its sole discretion to institute an Enforcement Action in the name of either or both Parties. Each Party shall execute all necessary and proper documents, take such actions as shall be appropriate to allow the other Party to institute and prosecute such infringement actions and shall otherwise cooperate in the institution and prosecution of such actions (including without limitation consenting to being named as a nominal party thereto).
- (c) The costs and expenses of any such Enforcement Action (including without limitation fees of attorneys and other professionals) shall be borne [***]. Any award paid by Third Parties as a result of such an Enforcement Action (whether by way of settlement or otherwise) shall be applied [***].

9. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

- 9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other, as of the Effective Date, as follows:
- (a) such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (b) the execution and delivery of this Agreement and the performance by such Party of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate (i) such Party's certificate of incorporation or bylaws, (ii) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (iii) any requirement of any Applicable Laws, or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;
- (c) this Agreement is a legal, valid and binding obligation of such Party enforceable against such Party in accordance with its terms and conditions:
- (d) such Party is not under any obligation, contractual or otherwise, to any person or entity that conflicts with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder;
- (e) to such Party's knowledge, all of its employees, officers, contractors, and consultants have executed agreements requiring assignment to such Party of all inventions made during the course of and as a result of their association with such Party and obligating each such employee, officer, contractor, and consultant to maintain as confidential the Confidential Information of such Party; and
- (f) neither such Party, nor any of its employees, officers, subcontractors or consultants who have rendered or will render services relating to the Products: (i) has ever been debarred or is subject or debarment or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or its foreign equivalent or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under any such provision.
- **9.2 Additional Representations, Warranties, and Covenants of BioGenerics.** BioGenerics hereby represents, warrants, and covenants to Licensee that:
 - (a) as of the Effective Date, BioGenerics is entitled to grant the rights and licenses granted to Licensee as set forth in this Agreement;
- **(b)** BioGenerics has not granted in the Territory as of the Effective Date, and will not grant during the Term, any right or license in or to any of the BioGenerics Patent Rights in the Territory that is in conflict with the rights or licenses granted to Licensee under this Agreement;
- (c) to the actual knowledge of BioGenerics it has not granted in the Territory as of the Effective Date, and will not knowingly grant during the Term, any right or license in or to any of the BioGenerics Know-How in the Territory that is in conflict with the rights or licenses granted to Licensee under this Agreement;

- (d) BioGenerics has not granted any liens or security interests to the BioGenerics Know-How or BioGenerics Patent Rights other than under any licenses or sublicenses;
 - (e) all BioGenerics Know-How and BioGenerics Patent Rights existing as of the Effective Date are Controlled by BioGenerics;
- (f) BioGenerics has not received, with respect to the BioGenerics Know-How or BioGenerics Patent Rights, any written notice of infringement or misappropriation or any other written communication relating to an alleged infringement or misappropriation of any patent rights or any know-how Controlled by a Third Party;
- (g) All inventors named in the BioGenerics Patent Rights have assigned their entire right, title and interest in and to the inventions claimed in such BioGenerics Patent Rights to BioGenerics, and to the actual knowledge of BioGenerics, the inventors listed are correct;
- (h) BioGenerics has not received any claims or assertions in writing regarding the inventorship of the BioGenerics Patent Rights alleging that additional or alternative inventors ought to be listed; and
 - (i) [***].
 - 9.3 Additional Representations, Warranties, and Covenants of Licensee. Licensee hereby represents, warrants, and covenants to BioGenerics that:
 - (a) as of the Effective Date, Licensee is entitled to grant the rights and licenses granted to BioGenerics as set forth in this Agreement; and
- **(b)** Licensee has not granted in the Territory as of the Effective Date, and will not grant during the Term, any right or license in or to any of the Licensee Patent Rights or Grant-Back IP that is in conflict with the rights or licenses granted to BioGenerics under this Agreement.
 - 9.4 Additional Covenants of the Parties (a). Each Party hereby covenants to the other Party that:
- (a) if, during the Term such Party has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (a) is or will be debarred or convicted of a crime under 21 U.S.C. Section 335a or its foreign equivalent, or (b) is or will be under indictment under any such provision, then such Party shall immediately notify the other Party in writing; and
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(b) all of such Party's employees and officers involved in development of the Products shall be obligated to assign to such Party all Inventions and to maintain as confidential any and all Confidential Information.

9.5 Covenant Not to Challenge Patents. Licensee hereby covenants: (a) not to challenge the validity, scope, or enforceability of or otherwise oppose any Patent or Patent Application included in the BioGenerics Patent Rights or any foreign counterparts thereof; (b) that it shall include in all of its sublicense agreements the obligation binding on the Sublicensee under such sublicense agreement not to challenge the validity, scope, or enforceability of or otherwise oppose any such Patent or Patent Application; (c) that is shall include provisions in all sublicense agreements providing that, if the Sublicensee challenges the validity, scope, or enforceability of or otherwise opposes any such Patent or Patent Application, Licensee may terminate its sublicense agreement with such Sublicensee; and (d) if any such Sublicensee challenges the validity, scope, or enforceability of or otherwise opposes any such Patent or Patent Application, Licensee shall terminate such sublicense agreement, and such Sublicensee shall no longer have any rights under any such Patent or Patent Application. In the event that all or any portion of this Section 9.5 is invalid, illegal, or unenforceable, then the Parties will use their best efforts to replace the invalid, illegal, or unenforceable provision(s) with valid, legal, and enforceable provision(s).

10. INDEMNIFICATION AND INSURANCE.

10.1 BioGenerics' Right to Indemnification. Licensee shall indemnify, defend, and hold harmless BioGenerics and its Affiliates, and their respective officers, directors, employees, agents, and their respective successors, heirs and assigns and representatives (the "BioGenerics Indemnitees"), from and against any and all damages, losses, suits, proceedings, liabilities, costs (including without limitation reasonable legal expenses, costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind ("Damages") resulting from Third Party claims or actions, to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness, or wrongful intentional acts or omissions of Licensee, its Affiliates, and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement; (b) any breach by Licensee of any obligation, representation, warranty, or covenant in this Agreement; (c) the Development, Commercialization, transfer, importation or exportation, Manufacture (only if manufactured by Licensee in the Territory), labeling, handling or storage, or use of, or exposure to, any Product by or for Licensee or any of its Affiliates, Sublicensees, agents, and contractors in the Territory; and (d) the failure to comply with Applicable Law by Licensee, or any of its Affiliates, Sublicensees, agents, or subcontractors; except in any such case for Damages to the extent reasonably attributable to any BioGenerics Indemnitee (i) having committed an act or acts of negligence, recklessness, or willful misconduct; (ii) having failed to materially comply with Applicable Laws; (iii) having materially breached this Agreement; or (iv) to the extent such Damages result from or arise out of any act or omission for which BioGenerics is found to have an indemnity obligation under Section 10.2 Licensee's Right to Indemnification).

10.2 Licensee's Right to Indemnification. BioGenerics shall indemnify, defend, and hold harmless Licensee and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives (the "Licensee Indemnitees"), from and against any and all Damages resulting from Third Party claims or actions, to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness, or wrongful intentional acts or omissions of BioGenerics and its Affiliates and its or their respective directors, officers, employees, and agents, in connection with BioGenerics' performance of its obligations or exercise of its rights under this Agreement; (b) any breach by BioGenerics of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) the development, commercialization, transfer, importation or exportation, Manufacture, labeling, handling or storage, or use of, or exposure to, any Product by BioGenerics or any of its Affiliates, Sublicensees, agents, and contractors outside of the Territory; (d) [***] by BioGenerics or any of its Affiliates, sublicensees, agents, and contractors inside or outside of the Territory, and (e) the failure to comply with Applicable Laws by BioGenerics, or any of its Affiliates, agents, or subcontractors; except in any such case for Damages to the extent reasonably attributable to any Licensee Indemnitee (i) having committed an act or acts of negligence, recklessness or willful misconduct; (ii) having failed to materially comply with Applicable Laws; (iii) having materially breached this Agreement; or (iv) to the extent such Damages result from or arise out of any act or omission for which Licensee is found to have an indemnity obligation under Section 10.1 (BioGenerics' Right to Indemnification).

10.3 Process for Indemnification. A claim to which indemnification applies under **Section 10.1 (BioGenerics' Right to Indemnification)** or **Section 10.2 (Licensee's Right to Indemnification)** shall be referred to herein as an "**Indemnification Claim**". If a party (collectively, the "**Indemnitee**") intends to claim indemnification under **Section 10.1** or **Section 10.2**, the Indemnitee shall notify the other Party (the "**Indemnitor**") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; *provided, however*, that an Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this **Section 10.3** above, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the Indemnification Claim in any manner that would have an

adverse effect on the Indemnitee's interests, without the prior written consent of the Indemnitee, which consent, in each case, shall not be unreasonably withheld, delayed, or conditioned. The Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor's expense and shall make available to the Indemnitor all pertinent information under the control of the Indemnitee, which information shall be subject to **Article 11** (CONFIDENTIALITY).

10.4 Insurance. During the Term and for [***] years thereafter, each Party shall maintain, at its sole expense, such types and amounts of insurance coverage as is appropriate and customary in the biopharmaceutical industry in light of the nature of the activities to be performed by such Party hereunder.

11. CONFIDENTIALITY.

- 11.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Article 11 or otherwise agreed in writing, each Party hereby agrees that, during the Term and for ten (10) years thereafter, it shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as explicitly provided for in this Agreement any confidential and proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party or otherwise received or accessed by a Party under this Agreement [***], including, but not limited to, any trade secrets, know-how, Product specifications, formulae, processes, techniques and information relating to a Party's past, present and future marketing, financial, and research and development activities for any product of the other Party and the pricing thereof (collectively, "Confidential Information"). Notwithstanding the foregoing, any Confidential Information that constitutes a trade secret shall not be subject to such ten (10) year term, but shall continue to be subject to the obligations of confidentiality and non-use set forth in this Agreement for as long as such Confidential Information remains a trade secret under New York law (including New York's version of the Uniform Trade Secrets Act if and when adopted). The terms and conditions of this Agreement shall be deemed to be Confidential Information of each Party. In addition, and notwithstanding the foregoing, if, under Article 8 (INTELLECTUAL PROPERTY AND INVENTIONS), Information relating specifically to inventions and discoveries are to be owned by one Party, such Information shall be deemed to be Confidential Information of such Party, even if such Information or materials that a Party can demonstrate by contemporaneous written records:
- (a) is already lawfully known to such Party, other than under an obligation of confidentiality at the time of disclosure by the other Party as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by such Party;
 - (b) is generally available to the public or otherwise part of the public domain at the time of its disclosure to such Party;

- (c) becomes generally available to the public or otherwise part of the public domain after its disclosure to such Party and other than through any act or omission of such Party or its Affiliates in violation of this Agreement;
- (d) is independently developed by such Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or
- (e) is lawfully disclosed to such Party, other than under an obligation of confidentiality, by a Third Party who had no obligation not to disclose such information to others;

[***].

- 11.2 Degree of Care; Permitted Use. Each Party shall take reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own Information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including without limitation all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to [***].
- 11.3 Authorized Disclosure. Notwithstanding Section 11.1 (Confidentiality; Exceptions) and Section 11.2 (Degree of Care; Permitted Use), each Party may disclose Confidential Information of other Party:
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (a) in its publicly-filed financial statements or other public statements pursuant to Applicable Laws, regulations, and stock exchange rules or otherwise disclosed pursuant to Applicable Law; provided, that [***];
 - (b) to the extent it is required to be disclosed in response to a valid order by a court or other governmental body and provided that [***];
- (c) to the extent it is required to be disclosed in connection with any legal or regulatory requirements or obligations, including without limitation SEC filings or Regulatory Filings, provided that [***];
- (d) to Regulatory Authorities to facilitate the issuance of Regulatory Approvals for a Product; provided that reasonable measures shall be taken to assure confidential treatment of such Confidential Information;
 - (e) [***]
 - (f) to Third Parties in connection with such Party's efforts to secure financing or enter into strategic partnerships, [***].

11.4 Publications.

- (a) In the event either Party proposes a publication or presentation to a Third Party that includes Confidential Information relating to a Product in the Field in the Territory, or which otherwise includes Confidential Information of the other Party, such Party shall first submit to [***] an early draft of such publication or presentation, whether they are to be presented orally or in written form, prior to submission for publication or presentation. [***] shall review such proposed publication or presentation in order to avoid the unauthorized disclosure of its Confidential Information and to preserve the patentability of Inventions and shall, as soon as reasonably possible, inform such Party if its proposed publication or presentation:
- (i) contains Confidential Information of the other Party, in which case such Party shall delete such Confidential Information from its proposed publication or presentation; or
- (ii) could be expected to have a material adverse effect on any Patent or Information of the other Party, then such Party shall delay such proposed publication or presentation sufficiently long to permit the timely preparation and first filing of Patent Application(s) on the Information involved.
 - (b) This Section 11.4 shall not apply to any disclosures pursuant to Section 11.3 (Authorized Disclosure).
- 11.5 Press Release. Neither Party shall issue any press release relating to this Agreement without obtaining the other Party's prior written approval, which approval shall not be unreasonably withheld, delayed, or conditioned.
- 11.6 Irreparable Injury. The Parties acknowledge that either Party's breach of this Article 11 would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the nonbreaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity[***].

12. TERM AND TERMINATION.

12.1 Term. The term of this Agreement shall commence on the Effective Date and, unless sooner terminated or extended as specifically provided in this Article 12, shall continue in effect on a Product-by-Product and country-by-country basis until the tenth (10th) anniversary of the receipt of Regulatory Approval for the applicable Product in each country in the Territory (the "Term").

- 12.2 Extension of Term. If this Agreement has not been earlier terminated with respect to a particular country in the Territory and Licensee is Manufacturing a Product in such country pursuant to Section 5.2 (Licensee Manufacturing Option) prior to the tenth (10th) anniversary of the receipt of Regulatory Approval for such Product for such country, at Licensee's sole and exclusive option, the Term shall be renewed for an additional three (3) years with respect to such country (the "Renewal Period"). Thereafter, at Licensee's sole and exclusive option, for as long as this Agreement has not been earlier terminated with respect to a particular country in the Territory and Licensee is still Manufacturing a Product in such country pursuant to Section 5.2 (Licensee Manufacturing Option), the Term shall continue to be renewed for additional Renewal Periods with respect to such country. If Licensee has not exercised its Manufacturing Option, then the Term may only be extended for additional three (3) years periods on a Product-by-Product and country-by-country basis, upon mutual written consent of the Parties, based upon the JSC's approval of a Commercialization Plan for the applicable Product for the applicable country in the year immediately preceding the tenth (10th) anniversary of the receipt of Regulatory Approval for such Product for such country or in the year immediately preceding the third year of a Renewal Period.
- 12.3 Termination by Licensee. Licensee shall have the right to terminate this Agreement on a Product-by-Product and country-by-country basis only as set forth in Exhibit 12.3 (Licensee Opt-Out Rights).
- 12.4 Termination by BioGenerics. BioGenerics shall have the right to terminate this Agreement, at any time, immediately upon written notice to Licensee in the event that Licensee or any of its Affiliates challenges in a court of competent jurisdiction, the validity, scope or enforceability of, or otherwise opposes, any Patent included in the BioGenerics Patent Rights. If a Sublicensee of Licensee or its Affiliate challenges the validity, scope or enforceability of or otherwise opposes any Patent included in the BioGenerics Patent Rights under which such Sublicensee, then Licensee or its Affiliate, as applicable, shall, upon written notice from BioGenerics, terminate such sublicensee. Licensee and each of its Affiliates shall include without limitation provisions in all agreements under which a Third Party obtains a license under any Patent included in the BioGenerics Patent Rights providing that, if the Sublicensee challenges the validity or enforceability of or otherwise opposes any such Patent under which the Sublicensee is sublicensed, then Licensee may terminate such sublicense agreement with such Sublicensee, and Licensee shall, upon request by BioGenerics, enforce such right if such Sublicensee breaches such restriction.

12.5 Termination for Material Breach. If either Party believes the other Party is in breach of this Agreement, it may give notice of such breach to the other Party, which other Party shall have sixty (60) days in which to remedy any such material breach, or thirty (30) days in the case of breach (whether material or not) of any payment obligation hereunder; provided, however, if the breach (excluding payment obligations) cannot be reasonably cured within such time period, Licensee shall not be in breach or default of this Agreement if Licensee commences to cure the breach within such time period and in good faith continues to cure the breach, but in no event shall such time period be extended beyond one hundred eighty (180) days. If such alleged breach is not remedied in the time period set forth above, the nonbreaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the other Party. In the event of a dispute regarding any payments due and owing hereunder, all undisputed amounts shall be paid when due, and the balance, if any, shall be paid promptly after settlement of the dispute, including without limitation any accrued interest thereon.

12.6 Termination upon Insolvency. To the extent permitted under Applicable Law, either Party may terminate this Agreement if, at any time, the other Party (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, (d) proposes or is a party to any dissolution or liquidation, or (e) makes an assignment for the benefit of its creditors.

12.7 Consequences of Expiration or Termination.

- (a) Consequences of Expiration or Termination of this Agreement with Respect to One Product in a Country but Not in the Entire Territory. Upon expiration of this Agreement under Section 12.1 (Term) with respect to a Product in a country (but not all countries in a Territory), or early termination of this Agreement pursuant to Section 12.3 (Termination by Licensee) with respect to a Product in a country (but not all countries in a Territory):
- (i) the licenses granted to Licensee pursuant to Section 2.1 (License Grants) and Section 6.3 (Trademarks) with respect to such Product shall terminate in such terminated or expired country, except as otherwise necessary to conduct the activities expressly set forth in Section 12.7(a)(ii) and/or Section 12.7(a)(viii);

(ii) promptly after the effective date of such termination or expiration, Licensee shall commence winding down its Development, Commercialization, and Manufacturing (subject to Section 12.7(a)(viii)) activities for such Product for such country under the oversight of the JSC, and shall use best efforts to complete any and all such Development, Commercialization, and Manufacturing (subject to Section 12.7(a)(viii)) activities within three (3) months after the effective date of such termination or expiration;

- (iii) Licensee shall disclose to BioGenerics all Inventions Controlled by Licensee relating to such Product, including without limitation any Inventions relating to or useful for the development, manufacturing, or commercialization of such Product;
- (iv) Licensee shall and hereby does grant to BioGenerics, effective as of the effective date of such termination or expiration, the exclusive, perpetual, royalty-bearing, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP to develop, make, use, sell, offer to sell, and import such Product in such country. Any royalties due under this Section 12.7(a)(iv) shall be paid in accordance with Exhibit 12.3(D) (Additional Obligations) in the case of Licensee opt-out pursuant to Section 12.3 or Exhibit 12.7(e) (Licensee Expiration or Termination Rights), in the case of expiration pursuant to Section 12.1, in either case, with respect to Net Sales by BioGenerics, its Affiliates or sublicensees for such expired or terminated Product in the expired or terminated country in the Territory, as the case may be;
- (v) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to BioGenerics, effective as of the effective date of such termination or expiration, all of Licensee's (or its Affiliate's) rights, title and interests in and to the Product Trademark for such Product and all relevant applications and registrations, and all intellectual property rights and other rights and goodwill with respect thereto in such terminated or expired country. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this **Section 12.7(a)(v)**;
- (vi) Licensee shall assign to or permit access by BioGenerics or BioGenerics' designee its entire right in all clinical and related study data based on use or research on such Product and all Regulatory Filings and Regulatory Approvals relating to such Product in such terminated or expired country, and shall provide assistance to BioGenerics or its designee to become the holder of such Regulatory Approvals;

(vii) Licensee shall promptly notify BioGenerics of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Manufacturing activities for any and all Products terminated. At BioGenerics' request, which request shall be made within three (3) months after the expiration or termination of this Agreement, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to BioGenerics, and BioGenerics shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Manufacturing activities for such Product in such terminated or expired country, including without limitation agreements with contract research organizations, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals in such country(ies), unless such agreement (A) expressly prohibits such assignment, (B) covers clinical trials for products in addition to the Products, (C) covers Products in a country or countries in respect of which this Agreement has not been terminated or expired, or (D) is required to be maintained by Licensee in order for Licensee to comply with its obligations to supply Products during any Additional Supply Period set forth in Exhibit 12.3 (Licensee Opt-out Rights), provided that Licensee shall utilize Commercially Reasonable Effort to assign such agreement to BioGenerics promptly after such Additional Supply Period. In all cases (A)–(D), Licensee shall cooperate with BioGenerics in all reasonable respects to facilitate the execution of a new agreement between the BioGenerics and the Third Party; and

(viii) if Licensee is Manufacturing such Product for such terminated or expired country pursuant to Section 5.2 (Licensee Manufacturing Option) (which Manufacturing for purposes of this Section 12.7(a) [***]), prior to the effective date of such termination or expiration, then Licensee shall continue to supply BioGenerics in a timely manner with its requirements for such Product in such country during any Additional Supply Period set forth in Exhibit 12.3 (Licensee Opt-out Rights), and promptly following the effective date of such termination or expiration, Licensee shall provide to BioGenerics any and all documentation and/or data Controlled by Licensee as of the effective date of such termination or expiration relating to the Manufacture of such Product for such terminated or expired country.

- **(b)** Consequences of Expiration or Termination of this Agreement with Respect to One Product in Entire Territory. Upon expiration of this Agreement under Section 12.1 (Term) with respect to a Product in all countries in a Territory (but not this Agreement in its entirety), or early termination of this Agreement pursuant to Section 12.3 (Termination by Licensee) with respect to a Product in all countries in a Territory (but not this Agreement in its entirety):
- (i) the licenses granted to Licensee pursuant to Section 2.1 (License Grants) and Section 6.3 (Trademarks) with respect to such Product shall terminate in the Territory, except as otherwise necessary to conduct the activities expressly set forth in Section 12.7(b)(iii) and/or Section 12.7(b)(ix);

- (ii) Licensee shall return to BioGenerics within three (3) months of the effective date of such expiration or termination any and all BioGenerics Know-How or Confidential Information of BioGenerics transferred to Licensee under this Agreement, that relates to such Product and not to Products for which this Agreement has not expired or been terminated;
- (iii) promptly after the effective date of such termination or expiration, Licensee shall commence winding down its Development, Commercialization, and Manufacturing (subject to Section 12.7(b)(ix)) activities for such Product under the oversight of the JSC, and shall use best efforts to complete any and all such Development, Commercialization, and Manufacturing (subject to Section 12.7(b)(ix)) activities within three (3) months after the effective date of such termination or expiration;
- (iv) Licensee shall disclose to BioGenerics all Inventions Controlled by Licensee relating to such Product, including without limitation any Inventions relating to or useful for the development, manufacturing, or commercialization of such Product;
- (v) Licensee shall and hereby does grant to BioGenerics, effective as of the effective date of such termination or expiration, the exclusive, worldwide, royalty-bearing, perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP to develop, make, use, sell, offer to sell, and import such Product in the Territory. Any royalties due under this Section 12.7(b)(v) shall be paid in accordance with Exhibit 12.3(D) (Additional Obligations) in the case of Licensee opt-out pursuant to Section 12.3 or Exhibit 12.7(e) (Licensee Expiration or Termination Rights), in the case of expiration pursuant to Section 12.1, in either case, with respect to Net Sales by BioGenerics, its Affiliates or sublicensees for such expired or terminated Product, as the case may be, in the Territory;
- (vi) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to BioGenerics, effective as of the effective date of such termination or expiration, all of Licensee's (or its Affiliate's) rights, title and interests in and to the Product Trademark for such Product and all relevant applications and registrations, and all intellectual property rights and other rights and goodwill with respect thereto. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this Section 12.7(b)(vi);
- (vii) Licensee shall assign to BioGenerics or BioGenerics' designee its entire right in all clinical and related study data based on use or research on such Product and all Regulatory Filings and Regulatory Approvals relating to such Product, and shall provide assistance to BioGenerics or its designee to become the holder of such Regulatory Approvals;

(viii) Licensee shall promptly notify BioGenerics of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Manufacturing activities for any and all Products terminated. At BioGenerics' request, which request shall be made within three (3) months after the expiration or termination of this Agreement, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to BioGenerics, and BioGenerics shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Manufacturing activities for such Product, including without limitation agreements with contract research organizations, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals, unless such agreement (A) expressly prohibits such assignment, (B) covers Clinical Trials for products in addition to the Products, or (C) is required to be maintained by Licensee in order for Licensee to comply with its obligations to supply Products during any Additional Supply Period set forth in Exhibit 12.3 (Licensee Opt-out Rights), provided that Licensee shall utilize Commercially Reasonable Effort to assign such agreement to BioGenerics promptly after such Additional Supply Period. In all cases (A)–(C), Licensee shall cooperate with BioGenerics in all reasonable respects to facilitate the execution of a new agreement between the BioGenerics and the Third Party; and

- (ix) if Licensee is Manufacturing such Product pursuant to Section 5.2 (Licensee Manufacturing Option) (which Manufacturing for purposes of this Section 12.7(b) [***]), prior to the effective date of such termination or expiration, then Licensee shall continue to supply BioGenerics in a timely manner with its requirements for such Product in the Territory during any Additional Supply Period set forth in Exhibit 12.3 (Licensee Opt-out Rights), and promptly following the effective date of such termination or expiration, Licensee shall provide to BioGenerics any and all documentation and/or data Controlled by Licensee as of the effective date of such termination or expiration relating to the Manufacture of such Product.
- (c) Consequences of Expiration or Termination of this Agreement in its Entirety. Upon expiration of this Agreement under Section 12.1 (Term) with respect to all Products in all countries in the Territory, or early termination of this Agreement in its entirety pursuant to Section 12.4 (Termination by BioGenerics), Section 12.5 (Termination for Material Breach), or Section 12.6 (Termination upon Insolvency):
- (i) the licenses granted to Licensee pursuant to Section 2.1 (License Grants) and Section 6.3 (Trademarks) shall terminate, except as otherwise necessary to conduct the activities expressly set forth in Section 12.7(c)(iii) and/or Section 12.7(c)(ix);
- (ii) Licensee shall return to BioGenerics within three (3) months of the effective date of such expiration or termination any and all BioGenerics Know-How or Confidential Information of BioGenerics transferred to Licensee under this Agreement;
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(iii) promptly after the effective date of such termination or expiration, Licensee shall commence winding down its Development, Commercialization, and Manufacturing (subject to Section 12.7(c)(ix)) activities for all Products under the oversight of the JSC, and shall use best efforts to complete any and all such Development, Commercialization, and Manufacturing (subject to Section 12.7(c)(ix)) activities within three (3) months after the effective date of such termination or expiration;

- (iv) Licensee shall disclose to BioGenerics all Inventions Controlled by Licensee, including without limitation any Inventions relating to or useful for the development, manufacturing, or commercialization of any and all Products;
- (v) Licensee shall and hereby does grant to BioGenerics, effective as of the effective date of such termination or expiration, the exclusive, worldwide, royalty-bearing (only with respect to expiration pursuant to **Section 12.1 (Term)** or termination by Licensee for BioGenerics' uncured material breach pursuant to **Section 12.5 (Termination for Material Breach)**), perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP, to develop, make, use, sell, offer to sell, and import any and all Products in or for the Territory. Any royalties due under this Section 12.7(c)(v) shall be paid solely in accordance with **Exhibit 12.7(e)** (**Licensee Expiration or Termination Rights**), and solely in the case of (i) expiration pursuant to **Section 12.1** or (ii) termination by Licensee for BioGenerics' uncured material breach pursuant to **Section 12.5**, in both cases with respect to Net Sales by BioGenerics, its Affiliates, or sublicensees of Products in the Territory;
- (vi) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to BioGenerics, effective as of the effective date of such termination or expiration, all of Licensee's (or its Affiliate's) rights, title and interests in and to any and all Product Trademarks and all relevant applications and registrations, and all intellectual property rights and other rights and goodwill with respect thereto. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this Section 12.7(c)(vi);
- (vii) Licensee shall assign to BioGenerics or BioGenerics' designee its entire right in all clinical and related study data based on use or research on any and all Products and all Regulatory Filings and Regulatory Approvals relating to any and all Products, and shall provide assistance to BioGenerics or its designee to become the holder of such Regulatory Approvals;

(viii) Licensee shall promptly notify BioGenerics of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Manufacturing activities for any and all Products terminated. At BioGenerics' request, which request shall be made within three (3) months after the expiration or termination of this Agreement, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to BioGenerics, and BioGenerics shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Manufacturing activities for any and all Products, including without limitation agreements with contract research organizations, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals, unless such agreement (A) expressly prohibits such assignment, (B) covers clinical trials for products in addition to the Products, or (C) is required to be maintained by Licensee in order for Licensee to comply with its obligations to supply Products during any Additional Supply Period set forth in Exhibit 12.3 (Licensee Opt-out Rights), provided that Licensee shall [***]. In both cases (A)–(C), Licensee shall cooperate with BioGenerics in all reasonable respects to facilitate the execution of a new agreement between the BioGenerics and the Third Party; and

(ix) except with respect to a termination of the Agreement by Licensee under Section 12.5 (Termination for Material Breach) due to BioGenerics' uncured material breach, if Licensee is Manufacturing any Products pursuant to Section 5.2 (Licensee Manufacturing Option) (which Manufacturing for purposes of this Section 12.7(c) [***]), prior to the effective date of such termination or expiration, and in order for BioGenerics to smoothly continue the commercialization of Products, then Licensee shall, for a maximum period of two (2) years from the effective date of such termination or expiration, supply BioGenerics in a timely manner with its requirements for any and all such Products in the Territory. BioGenerics shall [***]. Additionally, promptly following the effective date of such termination or expiration, Licensee shall provide to BioGenerics any and all documentation and/or data that Controlled by Licensee as of the effective date of termination relating to the Manufacture of such Products;

(d) Expiration or termination of this Agreement for any reason shall not (i) release any Party from any obligation that has accrued prior to the effective date of such expiration or termination (including without limitation the obligation to pay amounts accrued and due under this Agreement prior to the effective date of such expiration or termination but that are unpaid or become payable thereafter (including without limitation any payments then accrued because the event has occurred but the payment is not yet due)), (ii) preclude any Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (iii) terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive expiration or termination

(e) Upon expiration of this Agreement under Section 12.1 (Term), (i) with respect to a Product in a country (but not all countries in a Territory) under Section 12.7(a), (ii) with respect to a Product in all countries in a Territory (but not this Agreement in its entirety) under Section 12.7(b), or (iii) with respect to all Products in all countries in the Territory under Section 12.7(c); or upon termination of the Agreement by Licensee due to BioGenerics' uncured material breach under Section 12.5 (Termination for Material Breach), with respect to a Product in a particular country or all countries, or with respect to all Products in all countries in the Territory, as the case may be, BioGenerics shall pay a residual royalty to Licensee only as set forth in Exhibit 12.7(e) (Licensee Expiration or Termination Rights).

12.8 General Surviving Obligations. The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of this Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: Section 2.1(c) (Generic Know-How License to Licensee), Section 2.4 (No Implied Rights or Licenses; Retained Rights), Section 4.9 (Notice of Communication with Regulatory Authorities), Section 4.10 (Trial Master File), Section 8.1 (Existing Intellectual Property), Section 8.2 (Disclosure), Section 8.3 (Ownership of Inventions), Section 8.4 (Individual Patent Filings), Section 8.5 (Joint Patent Filings), Section 8.6 (Defense of Infringement Claims by Third Parties), Section 12.7 (Consequences of Expiration or Termination) (as applicable), this Section 12.8, Exhibit 12.3 (Licensee Opt-out Option) (as applicable), Exhibit 12.7(e) (Licensee Expiration or Termination Rights), Article 1 (DEFINITIONS), Article 10 (INDEMNIFICATION AND INSURANCE), Article 11 (CONFIDENTIALITY) (for the period set forth in Section 11.1 (Confidentiality; Exceptions)), Article 13 (LIMITATION OF LIABILITY; DISCLAIMER OF WARRANTY), Article 14 (DISPUTE RESOLUTION), and Article 15 (MISCELLANEOUS).

13. LIMITATION OF LIABILITY; DISCLAIMER OF WARRANTY.

13.1 LIMITATION OF LIABILITY. EXCEPT IN THE CASE OF A BREACH OF ARTICLE 11 (CONFIDENTIALITY), AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 10 (INDEMNIFICATION AND INSURANCE), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING WITHOUT LIMITATION DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

13.2 DISCLAIMER OF WARRANTY. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING THE PRODUCTS USED IN PRECLINICAL STUDIES OR CLINICAL TRIALS OR FOR COMMERCIAL USE, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

14. DISPUTE RESOLUTION.

14.1 Exclusive Dispute Resolution Mechanism. In the event that the Parties cannot reach agreement on a matter arising out of or in connection with this Agreement and any other agreement entered into pursuant hereto or in connection herewith (including without limitation matters relating to any Party's rights and/or obligations hereunder and/or regarding the construction, interpretation, and enforceability of such agreements), the procedures set forth in this Article 14 shall be the exclusive mechanism for resolving any dispute, controversy, or claim in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement (collectively, "Disputes") between the Parties or the JSC that may arise from time to time that cannot be resolved through good faith negotiation between the Parties, except as set forth in Section 14.4 (Preliminary Injunctions) and/or Section 14.5 (Patent Disputes) or unless otherwise set forth herein.

14.2 Resolution by Executive Officers. Except as otherwise provided in this Agreement, in the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party may, by written notice to the other Party, refer such Dispute to the other Party for attempted resolution by good faith negotiation within thirty (30) days after such notice is received. Such Disputes shall be referred to the executive officers for attempted resolution. In the event that any Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Section 14.3 (Arbitration), as applicable.

14.3 Arbitration.

(a) Except as set forth in Section 14.4 (Preliminary Injunctions) and/or Section 14.5 (Patent Disputes), or unless otherwise set forth herein, any Dispute that is not resolved pursuant to Section 14.2 (Resolution by Executive Officers) shall be [***] resolved by [***] arbitration pursuant to this Section 14.3.

- **(b)** Any such arbitration shall be conducted [***].
- (c) Within ten [***] after receipt of an arbitration notice from a Party, the Parties shall attempt in good faith to agree on a single neutral arbitrator with relevant industry experience to conduct such arbitration. If the Parties do not agree on a single neutral arbitrator within ten (10) days after receipt of an arbitration notice[***].
- (d) The decision or award of the arbitrator(s) shall be final, binding, and incontestable and may be used as a basis for judgment thereon in any jurisdiction. [***].
- **14.4 Preliminary Injunctions.** Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction as provided in **Section 15.12 (Governing Law; Jurisdiction)** in order to prevent immediate and irreparable injury, loss, or damage [***].
- **14.5 Patent Disputes.** Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or Patent Application in a country within the Territory shall be determined in a court or other
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

governmental authority of competent jurisdiction under the applicable patent laws of such country, as provided in **Section 15.12 (Governing Law; Jurisdiction)**.

14.6 Confidentiality. All proceedings and decisions of the arbitrator(s) shall be deemed to be Confidential Information of each of the Parties, and shall be subject to Article 11 (CONFIDENTIALITY).

15. MISCELLANEOUS.

- **15.1 Agency.** Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer, or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.
- **15.2 Performance by Affiliates.** The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates; *provided, however*, that each Party shall remain responsible for the performance of its Affiliates and shall course its Affiliates to comply with the provisions of this Agreement in connection with such performance.
- 15.3 Assignment. Licensee shall not have the right to assign this Agreement or any obligation of Licensee hereunder without the prior written consent of BioGenerics, except the cases of (a) in whole or in part, to any of its Affiliates, (b) to any purchaser of all or substantially all of its assets to which this Agreement relates, or (c) to any successor corporation resulting from any merger, consolidation, share exchange, or other similar transaction. BioGenerics shall not have the right to assign this Agreement or any obligation of BioGenerics hereunder without the prior written consent of Licensee, which shall not be unreasonably withheld, delayed, or conditioned, except that BioGenerics may assign this Agreement and the rights, obligations, and interests of BioGenerics, (a) in whole or in part, to any of its Affiliates, (b) to any purchaser of all or substantially all of its assets to which this Agreement relates, or (c) to any successor corporation resulting from any merger, consolidation, share exchange, or other similar transaction. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 15.3 shall be void. Notwithstanding anything to the contrary in this Agreement, in the event of any such assignment, the intellectual property rights of the acquiring party (if other than one of the Parties to this Agreement) shall not be included in the intellectual property rights licensed to the other Party hereunder to the extent held by such acquirer prior to such transaction, or to the extent such intellectual property rights are developed outside the scope of activities conducted with respect to Products.
- **15.4 Further Actions.** Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

15.5 Non-Solicitation. While Licensee is performing Development and/or Commercialization activities under this Agreement and for a period of two (2) years thereafter, neither Party shall, without the express written consent of the other Party, recruit, solicit, or induce any employee of the other Party who has performed activities under this Agreement to terminate his or her employment with such other Party. The foregoing provision shall not, however, restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target the other Party or its Affiliates or from hiring any persons who respond to such generalized public advertisements.

15.6 Force Majeure. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by epidemic, earthquake, riot, civil commotion, rebellion, insurrection, invasion, fire, acts of God, war, terrorist acts, strike, storm, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the respective Party. The Party affected by such force majeure shall provide the other Party with all information relating thereto (including without limitation its best estimate of the likely extent and duration of the interference with its activities) as soon as reasonably and practically possible after its occurrence, and shall use commercially reasonable efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such event, including without limitation the possibility of the termination of this Agreement pursuant to Section 12.5 (Termination for Material Breach). Notwithstanding the foregoing, nothing in this Section 15.6 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

15.7 Notices. All notices and other communications hereunder shall be in writing and shall be deemed given (a) if delivered personally or by facsimile transmission (receipt verified), (b) five (5) days after mailed by registered or certified mail (return receipt requested), postage prepaid, or (c) three (3) days after sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; provided that notices of a change of address shall be effective only upon receipt thereof):

If to Licensee, addressed to:
Daiichi Sankyo Co., Ltd.
Nihonbashi Honcho 3-5-1, Chuo-ku, Tokyo 103-8426, Japan
Attn: [***]
Fax: [***]

If to BioGenerics, addressed to:

BioGenerics, Inc.

201 Redwood Shores Parkway, Suite 200

Redwood City, CA, USA 94065

Attn: Dennis M. Lanfear Fax: +1-866-491-7350

With copies to:

Latham & Watkins LLP 140 Scott Drive Menlo Park, CA 94062 Attn: Alan C. Mendelson

Fax: 650-463-2600

Latham & Watkins LLP 12636 High Bluff Drive, Suite 400

San Diego, CA 92130 Attn: John E. Wehrli Fax: 858-523-5450

15.8 Amendment. No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

15.9 Waiver. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

15.10 Counterparts; Electronic Delivery. This Agreement may be executed simultaneously in two counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.11 Construction. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders.

The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

- **15.12 Governing Law; Jurisdiction.** This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A., without regard to its or any other jurisdiction's choice of law rules. [***].
- 15.13 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but, if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.
- **15.14** Compliance with Applicable Laws. Each Party will comply with all Applicable Laws in performing its obligations and exercising its rights hereunder. Nothing in this Agreement shall be deemed to permit Licensee to export, re-export, or otherwise transfer any Information transferred hereunder or Product(s) without complying with Applicable Laws.
- 15.15 No Re-Importation. Licensee will ensure that reasonable safeguards are put in place so that Products sold in the Territory are not, directly or indirectly, exported, or marketed, distributed, or sold, outside of the Territory. Licensee shall not, directly or indirectly, offer Products to any Third Party in a country outside the Territory that Licensee knows is going to, directly or indirectly, export such Products, or market, distribute, or sell such Products, outside of the Territory. If Licensee becomes aware that any of its customers has, directly or indirectly, imported Products into, exported Products to, or marketed, distributed, or sold Products in, any country outside of the Territory, or has reason to believe that a customer intends to, directly or indirectly, import Products, export Products to, or market, distribute, or sell Products, outside of the Territory, Licensee shall take reasonable actions to cause such customer to cease such import, export, marketing, distribution, or sales activities; if such customer does not cease such activities, then Licensee shall immediately cease sale or distribution of any and all Products to such customer, unless prohibited by Applicable Law.

15.16 Entire Agreement of the Parties. This Agreement, including the exhibits attached hereto, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties, and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including without limitation the CDA, and neither Party shall be liable or bound to the other Party with respect to the subject matter of this Agreement in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon any party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall prevail.

[Signature Page Follows]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives as set forth below:

BIOGENERICS, INC.

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear

Title: Chief Executive Officer

DAIICHI SANKYO COMPANY, LIMITED

By: /s/ Joji Nakayama

Name: Joji Nakayama Title: President and CEO

[Signature Page to License Agreement]

BIOGENERICS PATENT RIGHTS

BIOGENERICS TRADEMARKS

BioGenerics

OPTION PRODUCTS

[***]: BioGenerics' biosimilar version of Enbrel (etanercept)

[***]: BioGenerics' biosimilar version of [***]

[***]: BioGenerics' biosimilar version of Rituxan (rituximab)

OPTION TERRITORY

[***]

PRODUCTS

[***]: BioGenerics' biosimilar version of Enbrel (etanercept)

[***]: BioGenerics' biosimilar version of Rituxan (rituximab)

TERRITORY

Japan

Taiwan

South Korea

EXHIBIT 2.1(e)

BIOGENERICS KNOW-HOW DISCLOSURE SCHEDULE

[***] (ETANERCEPT BIOSIMILAR):

Timeline:	Item(s) Disclosed:
[***] following the [***]	[***]
	[***] used for [***]
	[***] including [***] with [***], [***], [***], [***], and [***]
	[***] and [***]
[***] following the [***]	[***]
	[***]
	[***] including [***]
[***] following the [***]	[***]
	[***]
	[***]
	[***]
	[***]

[***] (RITUXIMAB BIOSIMILAR):

Timeline:	Item(s) Disclosed:
[***] following the [***]	[***] with [***]
	[***] and [***]
[***] following the [***]	[***]
	[***]
	[***]
	[***] including [***], [***], [***], and [***]
[***] following the [***]	[***]
	[***]
	[***]
	[***]
	[***]
	[***] including [***]

EXHIBIT 4.1

NON-CLINICAL STUDIES

[***] (ETANERCEPT BIOSIMILAR):

Study:

- (a) [***] study in [***] with [***]
- (b) [***] studies to [***] and [***] of [***]
- (c) Any other additional non-clinical studies to [***]

[***] (RITUXIMAB BIOSIMILAR):

Study:

- (a) [***] study in [***] with [***]
- (b) [***] studies to [***] and [***] of a [***]
- (c) Any other additional non-clinical studies to [***]

EXHIBIT 5.1

MANUFACTURING AND SUPPLY BY BIOGENERICS

- A. Supply for Regulatory Filings in the Territory. For any Clinical Trials conducted by Licensee, its Affiliate or Sublicensee under a Regulatory Filing:
 - BioGenerics will supply all required clinical materials, including placebo, for (a) bioequivalence trials and (b) Phase 1 Clinical Trials. In each case (a) and (b), BioGenerics will supply clinical Products at [***] for such trials for up to [***] patients to Licensee; provided, however, that Licensee will supply all innovator drug at [***]; and provided further, that Licensee will [***] for [***] required for such trials [***].
 - 2. BioGenerics will supply Product, as [***], and placebo for all other Clinical Trials conducted for Development purposes to Licensee at the [***] in connection with such supply of Product.
 - 3. BioGenerics shall supply Licensee with the Products and other materials described in Section A.1 and Section A.2 above as set forth below:

[***]: (etanercept): By [***]
[***]: (rituximab): By [***]

B. Commercial Supply in the Territory. BioGenerics will supply Product, as [***], and placebo for Commercialization purposes, if any, to Licensee at the [***] in connection with such supply of Product.

EXHIBIT 7.1

PAYMENT STRUCTURE

- A. Upfront License Payment. In partial consideration for the rights granted to Licensee under this Agreement, Licensee shall pay to BioGenerics a one-time, non-refundable, non-creditable payment of Ten Million Dollars (\$10,000,000) within one (1) day after the Effective Date by wire transfer of immediately available funds into an account designated in writing by BioGenerics.
- B. Equity Investment. Within one (1) day after the Effective Date, Licensee shall purchase Twenty Million Dollars (\$20,000,000) of Series B Preferred Stock of BioGenerics, pursuant to the terms and conditions of a stock purchase agreement substantially in the form attached hereto as Exhibit 7.1-B (Series B Preferred Stock Purchase Agreement) at Four Dollars and Eighteen and 41/100 Cents (\$4.1841) per share.
- C. Royalties on Net Sales. In partial consideration for the rights granted to Licensee under this Agreement, including without limitation Patent and know-how licenses and other proprietary rights, Licensee shall pay BioGenerics non-refundable and non-creditable royalties as set forth in this Section C.
 - 1. Licensee shall pay BioGenerics a royalty rate based on aggregate Net Sales in the Territory on a Product-by-Product basis each Calendar Year, as follows:

Aggregate Net Sales by Product in such Calendar Year	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]

For example, if the aggregate Net Sales for a Product in a Calendar Year is [***], then the royalty rate shall be [***].

2. If BioGenerics is Manufacturing Product pursuant to **Section 5.1 (Manufacturing by BioGenerics)**, Licensee shall pay BioGenerics [***], on a Product-by-Product basis.

D. Third Party Payments.

- 1. In partial consideration for the rights granted to Licensee under this Agreement, including without limitation Patent and know-how licenses and other proprietary rights, Licensee shall pay any royalty payments[***] to the extent such payments arise from activities of Licensee or its Affiliates or Sublicensees in the Territory pursuant to this Agreement. The Parties shall each pay [***] or [***] to any other Third Party in consideration for [***] (payments to other Third Parties shall be referred to as the "Third Party Payments") necessary to [***]; provided, however, that Licensee shall pay the Third Party Payments necessary to [***], unless [***].
- 2. If Licensee is Manufacturing Product pursuant to **Section 5.2 (Licensee Manufacturing Option)**, and the Parties mutually agree that BioGenerics will purchase Product Manufactured by Licensee [***] for sale in markets outside of the Territory, then [***].

EXHIBIT 7.1-B

SERIES B PREFERRED STOCK PURCHASE AGREEMENT

[To be added.]

LICENSEE OPT-OUT RIGHTS

A. Opt-Out Prior to Commercialization. Licensee shall have the right to terminate the Agreement on a Product-by-Product and country-by-country basis only during the period of time specified below following the occurrence of each milestone (i) through (vi) as set forth in the table below (each period of time, an "Opt-out Window"), and, except for the case of (vi) below, only (a) if Licensee concludes, in good faith, that the Development and/or Commercialization of such Product or in such country is not commercially viable, (b) if Licensee concludes, in good faith, that there are material safety, efficacy or patient tolerability issues with such Product that cannot be remedied or overcome, or (c) if Licensee concludes, in good faith, that it would be difficult to Develop and/or Commercialize the Product in a country in the Territory due to its internal/portfolio reason.

Milesto	one	
(i)	[***]	
ii)	[***]	
ii)	[***]	
v)	[***]	
v)	[***]	
vi)	[***]	

1. For the avoidance of doubt, in each of (i) through (vi), Licensee may [***], and [***].

- 2. The "Opt-out Date" with respect to this Section A shall be [***].
- **Opt-Out During Commercialization**. Licensee shall have the right to terminate the Agreement on a Product-by-Product and country-by-country basis [***] with [***] prior written notice to BioGenerics, and only if (a) Licensee concludes, in good faith, that Commercialization of such Product or in such country is not commercially viable, (b) if Licensee concludes, in good faith, that there are material safety, efficacy or patient tolerability issues with such Product that cannot be remedied or overcome, or (c) if Licensee concludes, in good faith, that it would be difficult to Develop and/or Commercialize the Product in a country in the Territory due to its internal/portfolio reason. The "**Opt-out Date**" with respect to this **Section B** [***].
- C. Additional Supply Periods. If Licensee is Manufacturing any Product (which Manufacturing for purposes of this Section C [***]) pursuant to Section 5.2 (Licensee Manufacturing Option) prior to the Opt-out Date for such Product, then Licensee shall utilize Commercially Reasonable Efforts to supply BioGenerics in a timely manner with BioGenerics' requirements for such Product for the country(ies) in the Territory as to which this Agreement terminates for the additional period of time following the Opt-out Date as set forth in the table below (such additional period of time, the "Additional Supply Period"). BioGenerics shall [***] in connection with such supply of Product. Any Manufacturing of Product for BioGenerics by Licensee during the Additional Supply Period shall be addressed in a manufacturing and supply agreement between the Parties, which the Parties shall negotiate in good faith following the Opt-out Date. Notwithstanding the foregoing, Licensee shall not be obliged to supply the Product to BioGenerics if [***].

Opt-out Trigger		Additional Supply Period
(i)	[***]	[***]
(ii)	[***]	[***]
(iii)	[***]	[***]

D. Additional Obligations.

- 1. For clarity, Licensee shall comply with the obligations set forth in Section 12.7(a) (Consequences of Expiration or Termination of this Agreement with Respect to One Product in a Country but Not in the Entire Territory) or Section 12.7(b) (Consequences of Expiration or Termination of this Agreement with Respect to One Product in the Entire Territory), as applicable. For the purposes of Section 12.7, the Opt-out Date [***].
- 2. For [***] following the Opt-out Date, Licensee may not Commercialize or Manufacture a product that is a biosimilar of the reference drug for the terminated Product(s) in the terminated country(ies).
- 3. Following the Opt-out Date, BioGenerics shall pay Licensee a royalty rate based on Net Sales of the applicable Product in the applicable country, as follows:

Time Period	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, the above royalties under this **Section D.3** are exclusive in the case of Licensee opt-out, and no royalty shall be due under **Exhibit 12.7(e)** (**Licensee Expiration or Termination Rights**) with respect to any Product or any country in the Territory under this **Section D.3** is due.

EXHIBIT 12.7(e)

LICENSEE EXPIRATION OR TERMINATION RIGHTS

1. Solely as provided by **Section 12.7(e)**, BioGenerics shall pay Licensee a royalty rate based on Net Sales of the applicable Product in the applicable country, as follows:

Time Period	Royalty Rate
[***]	[***]
[***]	[***]
[***]	[***]
[***]	[***]

For the avoidance of doubt, the above royalties under this **Exhibit 12.7(e)** are exclusive, and no royalty shall be due under **Exhibit 12.3(D)** (**Additional Obligations**) with respect to any Product or country in the Territory if a royalty with respect to such Product or country in the Territory under this **Exhibit 12.7(e)** is due.

EXECUTION VERSION

[***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

LICENSE AGREEMENT

by and among

COHERUS BIOSCIENCES, INC.,

BAXTER INTERNATIONAL INC.,

BAXTER HEALTHCARE CORPORATION,

AND

BAXTER HEALTHCARE SA

dated

August 30, 2013

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LICENSE AGREEMENT

THIS LICENSE AGREEMENT (the "Agreement") is made and entered into as of August , 2013 (the "Effective Date") among COHERUS BIOSCIENCES, INC., a Delaware corporation with a principal place of business at 201 Redwood Shores Parkway, Suite 200, Redwood City, California 94065, United States of America ("Coherus"), on the one hand, and BAXTER INTERNATIONAL, INC., a Delaware corporation with a principal place of business at 1 Baxter Parkway, Deerfield, IL 60015, United States of America ("BII"), BAXTER HEALTHCARE SA, a Swiss corporation with a principal place of business at Postfach 8010 Zurich, Switzerland ("BHSA") and BAXTER HEALTHCARE CORPORATION, a Delaware corporation with a principal place of business at 1 Baxter Parkway, Deerfield, IL 60015, United States of America ("BHC" and, together with BII and BHSA, "Licensee"), on the other hand. Coherus and Licensee are sometimes referred to herein individually as a "Party" and collectively as the "Parties".

RECITALS

WHEREAS, Coherus is a global biotechnology company that conducts research, development, manufacturing and commercialization and is developing various biosimilar products for the potential treatment of rheumatoid arthritis, psoriasis and other diseases and conditions;

WHEREAS, Licensee has existing development and commercialization capabilities in the Territory (as defined below); and

WHEREAS, Coherus and Licensee wish to collaborate for the development and commercialization of the Product (as defined below) in the Territory in accordance with the terms and conditions hereof.

AGREEMENT

NOW, THEREFORE, in consideration of the mutual promises contained herein, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, and intending to be legally bound, the Parties agree as follows:

- 1. **DEFINITIONS.** As used herein, the following terms shall have the following meanings:
 - 1.1 "Accounting Standards" shall mean GAAP or IFRS, as applicable, consistently applied.

- 1.2 "Affiliate" means a corporation, partnership, trust or other entity that directly, or indirectly through one or more intermediates, controls, is controlled by or is under common control with a specified Party but only for so long as such relationship exists. For such purposes, "control," "controlled by" and "under common control with" shall mean the possession of the power to direct or cause the direction of the management and policies of an entity, whether through the ownership of voting equity, voting member or partnership interests, control of a majority of the board of directors or other similar body, by contract or otherwise. In the case of a corporation, the direct or indirect ownership of fifty percent (50%) or more of its outstanding voting shares or the ability otherwise to elect a majority of the board of directors or other managing authority of the entity shall in any event be presumptively deemed to confer control, it being understood that the direct or indirect ownership of a lesser percentage of such shares shall not necessarily preclude the existence of control. Notwithstanding the preceding provisions, once an entity ceases to be an Affiliate of Licensee, then such entity shall, without any further action, cease to have any rights, including license and sublicense rights, under this Agreement that it has by reason of being an Affiliate and any and all Coherus Know-How or Confidential Information of Coherus transferred to such entity while it was an Affiliate under this Agreement shall be returned to Licensee within thirty (30) days of the time such entity ceases to be an Affiliate.
- 1.3 "Applicable Laws" means all applicable laws, rules, and regulations, including any rules (including stock exchange rules), regulations, guidelines or other requirements of the Regulatory Authorities or other governmental authorities, that may be in effect from time to time in any relevant legal jurisdiction.
 - 1.4 "[***] Opt-In" has the meaning set forth in Exhibit 1.4.
- 1.5 "Business Day" means a day other than Saturday, Sunday or any day on which commercial banks located in the State of New York, U.S.A. are authorized or obligated by Applicable Laws to close.
- **1.6 "Calendar Quarter"** means the respective periods of three (3) consecutive calendar months ending on March 31, June 30, September 30, and December 31; *provided, however*, that: (a) the first Calendar Quarter of the Term will extend from the Effective Date to the end of the first complete Calendar Quarter thereafter and (b) the last Calendar Quarter of the Term will end upon the expiration or termination of this Agreement.
 - 1.7 "Calendar Year" means each successive period of twelve (12) months commencing on January 1 and ending on December 31.
 - 1.8 "CDA" has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).
 - 1.9 "Chairperson" has the meaning set forth in Section 3.1(b) (Membership; Meetings).

- 1.10 "Clinical Trials" means human clinical trials conducted up through receipt of Regulatory Approval, including Phase 1 Clinical Trials, Phase 3 Clinical Trials, bioequivalence trials, and/or variations of such trials (for example, phase 2/3 studies). For clarity, the term 'Clinical Trials' shall not include Phase 4 Clinical Trials.
- **1.11 "Coherus Biosimilar Candidate(s)"** means: (a) [***] ([***] biosimilar), (b) [***] ([***] biosimilar), and (c) CHS-1701 (pegfilgrastim biosimilar); *provided, however*, a Rejected Biosimilar Candidate shall no longer be considered a Coherus Biosimilar Candidate for any purposes under this Agreement.
 - 1.12 "Coherus Indemnitees" has the meaning set forth in Section 10.1 (Coherus' Right to Indemnification).
- **1.13 "Coherus Inventions"** means all Inventions made, conceived, reduced to practice, authored or otherwise discovered solely by employees, independent contractors, or agents of Coherus, it Affiliates or sublicensees.
- **1.14 "Coherus Know-How"** means all Information that is: (a) Controlled by Coherus as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be known, and (b) useful or necessary to Develop, Manufacture and/or Commercialize the Product in the Field in the Territory. "Coherus Know-How" does not include Coherus Patent Rights.
 - 1.15 "Coherus-Owned Joint Inventions" has the meaning set forth in Section 8.3(a)(i).
 - 1.16 "Coherus-Owned Licensee Inventions" has the meaning set forth in Section 8.3(a)(i).
- 1.17 "Coherus Patent Rights" means any Patent and/or Patent Application that: (a) is Controlled by Coherus as of the Effective Date or during the Term (including Patents and Patent Applications covering Coherus Inventions, Coherus-Owned Licensee Inventions and Coherus-Owned Joint Inventions) and (b) claims a product, method, apparatus, material, manufacturing process, or other technology necessary or useful for Development, Process Development, Manufacture and/or Commercialization of the Product in the Field in the Territory. "Coherus Patent Rights" includes, but is not limited to, any of Coherus' interest in any Patents and Patent Applications covering Inventions. "Coherus Patent Rights" as of the Effective Date are set forth in Exhibit 1.17 (Coherus Patent Rights) which shall be updated from time to time.
- 1.18 "Coherus Trademarks" means the trademarks set forth in Exhibit 1.18 (Coherus Trademarks), which may be updated by Coherus from time to time during the Term by providing notice to Licensee.

- 1.19 "Commercially Reasonable Efforts" means the carrying out of obligations or tasks consistent with the reasonable practices of a company within the biopharmaceutical industry for the development, manufacture or marketing of a biopharmaceutical product having similar market potential or profit potential in the Territory as the Product, based on conditions then prevailing and taking into consideration issues of safety, efficacy, product profile, the competitiveness of the marketplace in the Territory, the regulatory structure involved and other relevant commercial factors. Commercially Reasonable Efforts requires that the Party, at a minimum: (a) determine the general industry practices in the Territory with respect to the applicable activities; (b) reasonably promptly assign responsibility for such obligations to specific employee(s) who are held accountable for progress and monitor such progress on an on-going basis; (c) set and consistently seek to achieve specific and meaningful objectives for carrying out such obligations; and (d) make and implement decisions and allocate resources designed to advance progress with respect to such objectives.
- **1.20 "Commercialization"** or "Commercialize" means any and all activities directed to the marketing, advertising, promotion, offering for sale, selling, distribution, importing and exporting (but not exporting to territories outside of the Territory) the Product for sale in the Territory, including costs associated with key opinion leaders engaged by or on behalf of Licensee.
- 1.21 "Commercialization Plan" means the plan for Commercialization of the Product in the Field in the Territory and the activities to be conducted by Licensee relating thereto (including the budget associated with such Commercialization activities), which includes the activities to be conducted prior to First Commercial Sale, planning for launch of the Product, and activities to be conducted after launch of the Product, as well as detailed near-term plans, for example detailed plans for sales and marketing after launch of the Product.
- **1.22 "Competitor"** means a Third Party that develops, manufactures, markets, distributes, or promotes, for itself or for others: (a) [***]; or (b) [***].
 - 1.23 "Confidential Information" has the meaning set forth in Section 11.1 (Confidentiality; Exceptions).
- **1.24 "Control"** means, with respect to any item of Information, Patent, Patent Application, or other intellectual property right, the right to grant a license or sublicense with respect thereto as provided for in this Agreement without violating the terms of any agreement or other arrangement with, or any legal rights of, any Third Party.
 - 1.25 "CRO" means a Third Party contract research organization, as that term is defined in 21 C.F.R. Part 312.3(b).

- **1.26 "CSR"** or "Clinical Study Report" means the final clinical study report generated in connection with a Clinical Trial containing all Information generated by the Clinical Trial, cleaned and statistically analyzed.
 - 1.27 "Damages" has the meaning set forth in Section 10.1 (Coherus' Right to Indemnification).
- **1.28 "Develop"** or **"Development"** means all pre-clinical, clinical, and regulatory activities relating to obtaining a Regulatory Approval in the Territory. Development includes, for example, [***]. For the avoidance of doubt, the term 'Development' specifically excludes [***] and [***].
- 1.29 "Development Budget" means the budget associated with Development activities with respect to the Product, on a Calendar Quarter basis, and includes the Global Studies Budget.
- 1.30 "Development Costs" means: (a) the costs invoiced by Third Parties to Coherus after the Effective Date in connection with enabling and supporting Development efforts for the Product in the Territory [***] as set forth in the Development Plan or otherwise approved by the JSC, and (b) any other costs and expenses [***] to Coherus after the Effective Date to enable or support the Development of the Product, as reasonably determined and required by the JDC and approved by the JSC. For the avoidance of doubt, the term 'Development Costs' shall exclude [***].
- **1.31 "Development Plan"** means the plan for conduct of Development activities with respect to the Product, including planning timelines, and the activities to be carried out by each Party relating thereto, and including a Development Budget as amended from time to time by the Parties and approved by the JSC pursuant to **Article 3**. The Development Plan shall include a multi-year plan for conducting anticipated Development activities, including the following anticipated activities or events: (a) [***], (b) [***], (c) [***], and (d) [***], if applicable.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.32 "Disputes" has the meaning set forth in Section 14.1 (Exclusive Dispute Resolution Mechanism).
- 1.33 "Dollar" means a U.S. dollar, and "\$" shall be interpreted accordingly.
- 1.34 "Enforcement Action" has the meaning set forth in Section 8.7(b) (Enforcement Actions Against Third Parties).
- 1.35 "Executive Officers" means the [***] of Coherus and the [***] of Licensee.
- 1.36 "FDA" means the United States Food and Drug Administration or any successor agency thereto.
- 1.37 "Field" means the treatment of human diseases and conditions.
- 1.38 "First Commercial Sale" means the first sale of the Product by Licensee, its Affiliates or Sublicensees to a Third Party end user (other than a Sublicensee) in a bona fide arm's length transaction for which payment has been received in any country in the Territory after all applicable Regulatory Approvals and Pricing and Reimbursement Approvals (if applicable) have been obtained for such country have been granted by the applicable Regulatory Authority in such country.
- **1.39 "GAAP"** means accounting principles generally accepted in the United States, consistently applied and employed by Licensee or its Affiliates or Sublicensees in the applicable country in the Territory.
 - 1.40 "Global Brand Trademark" has the meaning set forth in Section 6.3(b) (Global Brand Trademark).
 - 1.41 "Global Clinical Database" has the meaning set forth in Section 4.7 (Coherus Global Clinical Database).
- **1.42 "Global Psoriasis Study"** means the Phase 3 Clinical Trial of the Product in psoriasis conducted by or on behalf of Coherus directed toward obtaining Regulatory Approval for the Product with respect to psoriasis inside and outside the Territory.
- **1.43 "Global RA Study"** means the Phase 3 Clinical Trial of the Product in rheumatoid arthritis conducted by or on behalf of Coherus directed toward obtaining Regulatory Approval for the Product with respect to rheumatoid arthritis inside and outside the Territory.
 - 1.44 "Global Study Budget" means the overall budget for the Global Studies, included in the Development Budget.

- 1.45 "Global Study(ies)" means the Global Psoriasis Study and the Global RA Study.
- 1.46 "Grant-Back IP" means any [***], or other [***] and [***] covering [***]. For the avoidance of doubt, Grant-Back IP shall [***].
- **1.47 "IFRS"** shall mean International Financial Reporting Standards, consistently applied and employed by Licensee or its Affiliates or Sublicensees in the applicable country in the Territory.
- 1.48 "Illustrative Development Plan/Budget" means the documents attached to this Agreement as Exhibit 1.48 setting forth certain Development activities and the budget related thereto which are included for illustrative purposes for the JDC and JSC to review at their initial meetings in connection with its preparation of the actual Development Plan and related budget.
 - 1.49 "[***] Milestones" means [***]
 - 1.50 "Indemnification Claim" has the meaning set forth in Section 10.3 (Process for Indemnification).
 - 1.51 "Indemnitee" has the meaning set forth in Section 10.3 (Process for Indemnification).
 - 1.52 "Indemnitor" has the meaning set forth in Section 10.3 (Process for Indemnification).
- **1.53 "Initial Development Activities"** means the key development activities and related expenditures anticipated in the thirty (30) days following the Effective Date as set forth in **Exhibit 1.53 (Initial Development Activities)**, attached hereto.
- **1.54 "Information"** means ideas, Inventions, discoveries, concepts, formulas, practices, procedures, processes, methods, knowledge, know-how, trade secrets, technology, designs, drawings, computer programs, skill, experience, documents, results, clinical and regulatory strategies, test data, including pharmacological, toxicological and clinical and non-clinical data, analytical and quality control data, manufacturing data and descriptions, Patent and legal data, market data, financial data or descriptions, assay protocols, chemical formulas,
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

sequence listings, specifications, and the like, in written, electronic or other form, now known or hereafter developed, whether or not patentable, relating to the Product.

- **1.55 "Initial Review Period"** means a period of ninety (90) days following the Effective Date.
- 1.56 "Initiation" means:
- (a) with respect to the Global Psoriasis Study, the first dosing of a patient in such Global Psoriasis Study;
- (b) with respect to the Global RA Study, the first dosing of a patient in such Global RA Study; and
- (c) with respect to a Phase 3 Clinical Trial for the Product other than in the Global Psoriasis Study or the Global RA Study, the first dosing of a patient in such Phase 3 Clinical Trial.
 - **1.57 "Inventions"** means any and all inventions [***] by or on behalf of either Party, its Affiliates or Sublicensees in the course of activities performed under or contemplated by this Agreement.
 - 1.58 "Joint Commercialization Committee" or "JCC" has the meaning set forth in Section 3.4 (Joint Commercialization Committee).
 - 1.59 "Joint Development Committee" or "JDC" has the meaning set forth in Section 3.1(f) (Joint Development Committee).
 - **1.60 "Joint Inventions"** means all Inventions [***] by employees, independent contractors, or agents of both Licensee and Coherus (including their respective Affiliates or sublicensees).
 - 1.61 "Joint Patent Rights" has the meaning set forth in Section 8.5 (Joint Patent Filings).
 - 1.62 "Joint Process Development and Manufacturing Committee" or "JPDMC" has the meaning set forth in Section 3.3 (Joint Process Development and Manufacturing Committee).
 - 1.63 "Joint Steering Committee" or "JSC" has the meaning set forth in Section 3.1(a) (General).
 - 1.64 "Licensee Indemnitees" has the meaning set forth in Section 10.2 (Licensee's Right to Indemnification).

- **1.65 "Licensee Inventions"** means all Inventions [***] solely by employees, independent contractors, or agents of Licensee, it Affiliates or sublicensees.
- **1.66 "Licensee Know-How"** means all Information that is: (a) Controlled by Licensee or its Affiliates as of the Effective Date or during the Term that is not publicly known, even though parts thereof may be known, and (b) necessary to develop, make, have made, use, sell, offer to sell, have sold, import or export the Product. "Licensee Know-How" does not include Licensee Patent Rights.
- 1.67 "Licensee Patent Rights" means any Patent and/or Patent Application that is: (a) Controlled by Licensee or its Affiliates as of the Effective Date or during the Term (including Patents and Patent Applications covering Licensee Inventions that are owned by Licensee pursuant to Section 8.3(a)(ii)) and (b) claims a product, method, apparatus, material, manufacturing process, or other technology necessary to develop, make, have made, use, sell, offer to sell, have sold, import or export the Product. "Licensee Patent Rights" includes, but is not limited to, any of Licensee's interest in any Patents and Patent Applications covering Inventions.
- **1.68 "Licensee Trademarks"** means any trademark, other than a Product Trademark, that is: (a) Controlled by Licensee or its Affiliates and (b) used in the Commercialization.
 - 1.69 "Major EU Country(ies)" means the [***].
- 1.70 "Manufacture" or "Manufacturing" means all manufacturing activities, undertaken with respect to the Product in support of clinical and commercial supply of the Product, as applicable, including manufacture of formulated bulk, fill and finish operations, sterilization, lyophilization, packaging, labeling, storing, transporting (with respect to the Product used in the Global Trials) quality control, quality assurance, and release but specifically excluding Process Development activities.
 - 1.71 "Manufacturing and Supply Agreement" has the meaning set forth in Section 5.1 (Manufacturing and Supply Agreement).
- 1.72 "Manufacturing Cost" means the costs of Manufacturing bulk drug substance or Units (including Product contained in such Unit). Manufacturing Costs shall include the cost of [***] ([***]), costs associated with [***], [***]. For the avoidance of doubt, the term 'Manufacturing Cost' shall [***].
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

1.73 "Manufacturing Regulatory Filings" means any and all regulatory applications, filings, approvals and associated correspondence required to Manufacture the Product in the country in which it is Manufactured as well as to import the Product into each country or jurisdiction in the Territory.

1.74 "Net Sales" means, on a country-by-country basis, the gross revenues invoiced by Licensee, its Affiliates and Sublicensees in connection with the sale, lease or other transfer for value of Product in a bona fide arm's-length transaction with unaffiliated Third Parties; less the following items to the extent actually incurred or accrued in accordance with the Accounting Standards and to the extent not already deducted in the amount invoiced: (a) trade and quantity and/or cash discounts actually allowed or taken; (b) governmental customs, duties, sales, withholding and similar taxes (including, for the avoidance of doubt value added or import/export taxes, sales taxes and excise taxes but excluding taxes based on income), if any, imposed on the Product, to the extent directly related to such sale; (c) amounts actually allowed or credited by reason of rejections, return of goods (including as a result of recalls), any retroactive price reductions or allowances specifically identifiable as relating to the Product (including those resulting from inventory management or similar agreements with wholesalers); (d) amounts incurred resulting from government-mandated rebate programs, including programs mandated by any agency thereof; (e) rebates actually given to a Third Party specifically for Product; (f) freight, postage, shipping and applicable insurance charges, to the extent same are separately itemized in the invoice price and charged to the buyer; (g) patient discount programs, administrative fees and chargebacks or similar price concessions related to the sale of the Product; and (h) [***].

Net Sales shall not include a sale or transfer of Product to an Affiliate or Sublicensee or if done for clinical, regulatory or governmental purposes where no consideration is received, but resale by such Affiliate or Sublicensee to a Third Party end user shall be included in Net Sales.

If any Product is sold in combination with one or more other products (*e.g.* a delivery device) or active ingredients which are not the subject of this Agreement (as used in this definition of Net Sales, a "Combination"), then the gross amount invoiced for that Product shall be calculated by multiplying the gross amount invoiced for such Combination by the fraction A/(A+B), where "A" is the gross amount invoiced for the Product sold separately and "B" is the gross amount invoiced for the other active ingredient(s) sold separately. In the event that the other active ingredient is not sold separately, then the gross amount invoiced for that Product shall be calculated by multiplying the gross amount invoiced for the Combination by the fraction A/C, where "A" is the gross invoice amount for the Product, if sold separately, and "C" is the gross invoice amount for the Combination. In the event that no such separate sales are made, Net Sales for royalty determination shall be determined by the Parties in good faith.

- **1.75 "Non-Negative Central Scientific Advice"** means receipt of guidance from the central Regulatory Authority in the European Union as part of the central scientific advice response [***] the Development Plan as approved by the JSC.
 - 1.76 "Opting-In Party" has the meaning set forth in Section 8.4(b) (Opt-In Rights).
 - 1.77 "Opting-Out Party" has the meaning set forth in Section 8.4(b) (Opt-In Rights).
- 1.78 "Patent" means: (a) letters patent (or other equivalent legal instrument), including utility and design patents, and including any extension, substitution, registration, confirmation, reissue, re-examination or renewal thereof, and (b) all foreign or international equivalents of any of the foregoing in any country.
- 1.79 "Patent Application" means: (a) an application for letters patent, including a provisional patent application, a reissue application, a re-examination application, a continuation application, a continuation application, a continuation application, a divisional application or any equivalent thereof that is pending at any time during the Term before a government patent agency and (b) all foreign or international equivalents of any of the foregoing in any country.
- **1.80 "Phase 1 Clinical Trial"** means a human clinical trial of the Product, the principal purpose of which is a preliminary determination of safety in healthy individuals or patients, as described in 21 C.F.R. 312.21(a), or a similar clinical study prescribed by the Regulatory Authorities in a foreign country.
 - **1.81 "Phase 1 Results"** means: (a) [***]; (b) [***] and [***]; (c) [***]; and (d) [***].
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.82 "Phase 3 Clinical Trial" means a confirmatory safety and efficacy human clinical trial of the Product performed after evidence suggesting effectiveness of the compound has been obtained pursuant to [***]: (a) that portion of an FDA submission and approval process which provides for the continued trials of a product on sufficient numbers of human patients to confirm with statistical significance the safety and efficacy of a product sufficient to support a Regulatory Approval for the proposed indication, as more fully described in 21 C.F.R. 312.21(c), or (b) equivalent Regulatory Filings with similar requirements in a country other than the United States, or a similar human clinical study prescribed by the Regulatory Authorities in a foreign country. For clarity, 'Phase 3 Clinical Trial' includes [***].
- **1.83 "Phase 4 Clinical Trial"** means a human clinical trial of the Product in the Territory commenced following receipt of Regulatory Approval in the Territory not for the purpose of satisfying a condition imposed by a Regulatory Authority to obtain Regulatory Approval or receipt of Pricing and Reimbursement Approvals in the Territory, but only to support the marketing of the Product.
- **1.84 "Post-Regulatory Approval Activities"** means the following activities conducted following receipt of Regulatory Approval: (a) any clinical trials required to receive or maintain Regulatory Approvals or receipt of Pricing and Reimbursement Approvals in the Territory; (b) open label extension studies; (c) any Phase 4 Clinical Trial; (d) studies required to support pharmacovigilance activities in the Territory; and (e) the equivalent in any country within the Territory of U.S. post-approval commitment studies and risk evaluation and mitigation strategies ("REMS") programs.
- **1.85 "Pricing and Reimbursement Approval"** means any approval received from a Regulatory Authority in a country or region relating to (a) the price that may be charged to a third party for the sale of a medical product or (b) the amount to be reimbursed (directly or indirectly) to the seller of such a medical product pursuant to the Applicable Laws in such country or region.
- 1.86 "Process Development" means all process development activities undertaken with respect to the Product, including activities related to [***].
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.87 "Process Development Costs" means all costs invoiced by Third Parties to Coherus and/or its Affiliates for Process Development activities after the Effective Date directly resulting from any Process Development efforts as set forth in the Process Development Plan or otherwise approved by the JSC. Process Development Costs shall include [***], such as [***]. For the avoidance of doubt, the term 'Process Development Costs' shall include [***].
- **1.88 "Process Development Plan"** means the plan for conduct of Process Development activities with respect to the Product, and the activities to be carried out by each Party relating thereto, including the budget therefor.
- **1.89 "Product"** means Coherus' product known as CHS-0214 that is intended to be a "biosimilar medicine" product of Enbrel (etanercept) pursuant to the EMEA guidance document 837805 dated 27th of September 2012.
 - 1.90 "Product Trademark" has the meaning set forth in Section 6.3(a) (Product Trademark; Licensee Trademark).
- **1.91 "Regulatory Approval"** means approval by the Regulatory Authority having jurisdiction in the applicable country of a Regulatory Approval Application and satisfaction of all related applicable regulatory and notification requirements and such other approvals that are necessary to Commercialize the Product in such country. [***].
- **1.92 "Regulatory Approval Application"** means: (a) the application or set of applications in the applicable country that is comparable to a Biologic License Application, as defined by the FDA in 21 CFR Part 601, or other applicable filing for a biological product to commercialize such product in the applicable country and (b) any related registrations with or notifications to such Regulatory Authority, and any amendments or supplements to either of the foregoing and any substitutes therefor.
- 1.93 "Regulatory Authority" means any applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other government entities regulating or otherwise exercising authority with respect to the Product in the Territory, including the equivalent in the Territory to the FDA.
- 1.94 "Regulatory Filings" means any and all Regulatory Approval Applications and other regulatory applications, filings and associated correspondence required to obtain Regulatory Approval or receipt of Pricing and Reimbursement Approvals to Develop, Commercialize, import the Product in, or into, or export the Product from the applicable country or jurisdiction.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 1.95 "Reimbursable Costs" means (subject to Section 4.1 (Development Activities; Process Development Activities and Funding)): (a) [***], (b) [***], (c) the [***], or (d) [***]; but, in each case, excluding, for the avoidance of doubt, any costs and expenses solely related to [***].
- - 1.96 "Renewal Period" has the meaning set forth in Section 12.2 (Extension of Term).
 - 1.97 "Responsible Party" has the meaning set forth in Section 8.5 (Joint Patent Filings).
- 1.98 "ROFR Agreement" means a definitive agreement entered into by Coherus and Licensee related to either a Coherus Biosimilar Candidate or Product X pursuant to Section 2.4 (Licensee Rights of First Refusal).
 - 1.99 "Rules" has the meaning set forth in Section 14.3(b) (Arbitration).
 - 1.100 "Second Review Period" has the meaning set forth in Section 2.4(e) (Product Opt-Out).
- 1.101 "Sublicensee" means any person or entity to which Licensee grants a sublicense to the extent permitted under Section 2.2 (Sublicense Rights) (other than Coherus or Affiliates of Coherus).
 - 1.102 "Term" has the meaning set forth in Section 12.1 (Term).
- 1.103 "Territory" means worldwide, excluding the following countries: Japan, the United States (including its territories and protectorates), [***].
 - 1.104 "Third Party" means any person or entity other than Licensee, Coherus, or an Affiliate of either of them.
 - 1.105 "Third Party Payments" has the meaning set forth in Exhibit 7.1(D) (Royalties on Net Sales; Third Party Payments).
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- **1.106 "Trademark"** means any word, name, symbol, color, designation or device or any combination thereof, whether registered or unregistered, including any trademark, trade dress, service mark, service name, brand mark, trade name, logo or business symbol.
- 1.107 "Unit" means one (1) filled, finished, labeled, and released dosage form comprised of one of the following: (a) [***] Product, or (b) [***] Product, or (c) [***] Product, or (d) another mutually agreed upon [***].

1.108 "Vendors" means [***].

2. LICENSES; LICENSEE RIGHT OF FIRST REFUSAL.

2.1 License Grants.

- (a) Development and Commercialization License to Licensee. Subject to the terms and conditions of this Agreement including Sections 2.1(b) (Licenses to Coherus) and Section 2.3 (No Implied Rights or Licenses; Retained Rights), Coherus hereby grants to Licensee and its Affiliates an exclusive, royalty-bearing license, under the Coherus Know-How and Coherus Patent Rights, to Develop, Commercialize and use the Product in the Field in the Territory. The foregoing license does not include the right to Manufacture, or have Manufactured, the Product, or to conduct, or have conducted, any Process Development activities.
- (b) Licenses to Coherus. Subject to the terms and conditions of this Agreement, Licensee hereby grants to Coherus and its Affiliates: (i) a fully-paid, non-exclusive license, under the Licensee Know-How and Licensee Patent Rights, to perform Coherus' obligations under this Agreement; (ii) a fully-paid, non-exclusive, perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP, to develop, make, have made, use, sell, offer to sell, have sold and import the Product outside of the Territory; and (iii) a fully-paid, non-exclusive, perpetual, irrevocable license (with full rights to grant sublicenses through multiple tiers) under any Licensee Inventions owned by Licensee pursuant to Section 8.3(a)(ii) (Generally) solely to the extent necessary to make, have made, use, sell, offer to sell, have sold and import the Product (whether inside and outside the Territory).

2.2 Sublicense Rights. Licensee shall not have the right to grant sublicenses under the licenses granted to it under Section 2.1(a) (Development and Commercialization License to Licensee) and Section 6.3(d) (Use of Coherus Trademark), without the prior written consent of Coherus, which consent may be withheld [***], except with respect to [***], in which case [***]. For the avoidance of doubt, it shall be [***] with respect to [***]. If Coherus consents in writing to allow Licensee to grant a sublicense, then Licensee may grant such sublicense, through [***], subject to the following: (a) each Sublicensee shall agree to be bound by all of the applicable terms and conditions of this Agreement; (b) the terms of each sublicense granted by Licensee shall provide that the Sublicensee shall be subject to the terms and conditions of this Agreement; (c) Licensee's grant of any sublicensee shall not relieve Licensee from any of its obligations under this Agreement; (d) Licensee shall be liable for any breach of a sublicensee to the extent that such breach would constitute a breach of this Agreement, and any breach of the sublicensee by such Sublicensee shall be deemed a breach of this Agreement by Licensee to the extent that such breach would constitute a breach of this Agreement as if Licensee had committed such breach; provided, however, that in each instance of any breach, Licensee and/or Sublicensee, and the territory in which it has granted such sublicense, promptly after entering into any sublicense. Notwithstanding anything to the contrary in this Agreement, for clarity, Licensee shall not have the right to grant sublicenses under Section 2.1 (License Grants) to any Third Party to Manufacture Products or to conduct Process Development.

2.3 No Implied Rights or Licenses; Retained Rights. Neither Coherus nor Licensee grants to the other Party any rights or licenses in or to any Patent, Information, Trademark, or other intellectual property right, whether by implication, estoppel or otherwise, except to the extent expressly set forth in this Agreement. All rights not expressly granted to Coherus or Licensee (as applicable) in this Agreement are hereby retained by the Party that owns such rights. Notwithstanding the foregoing, Licensee expressly acknowledges that Coherus will use the Regulatory Filings (including any Regulatory Approvals in the Territory) in Manufacturing, obtaining Regulatory Approvals outside the Territory and selling the Product outside the Territory.

2.4 Licensee Rights of First Refusal.

(a) Right of First Refusal for Coherus Biosimilar Candidates. During the Initial Review Period, Licensee will be granted [***] to [***]. Within forty-five (45) days of the commencement of the Initial Review Period, Licensee shall provide written notice (the "Rejection Notice") of one (1) Coherus Biosimilar Candidate in which it has no interest in developing and/or commercializing with Coherus (a "Rejected Biosimilar Candidate") and such Rejected Biosimilar Candidate shall no longer be subject to the rights set forth in this Section 2.4(a). In addition, during the Initial Review Period, Licensee may elect, by providing written notice of such election (the "Election Notice") to Coherus during the Initial Review Period, to enter into an agreement with Coherus for the development and commercialization of one (1) of the remaining Coherus Biosimilar Candidates in the Field in a territory which is not, as of the Effective Date, subject to a development and/or commercialization license from Coherus to a Third Party [***]. Alternatively, Licensee may elect, by providing an Election Notice to Coherus during the Initial Review Period, to enter into a joint venture or other commercial arrangement with Coherus for the development and commercialization of a biosimilar compound ("Product X"); provided, however; that, at the time of such election by Licensee, [***]. If Product X is the product selected in the Election Notice, the identity of Product X, and Licensee's election to proceed with a joint venture or other commercial arrangement, must be made within the Initial Review Period; Coherus [***]. The Coherus Biosimilar Candidate or Product X which Licensee selects during the Initial Review Period shall be known as the "ROFR Candidate." For clarity, Licensee is not obligated to select a ROFR Candidate during the Initial Review Period unless the provisions set forth in Section 2.4(e) (Product Opt-Out) are operative.

(b) Coherus/Licensee Product X Compounds as of Effective Date. As of the Effective Date [***] the following compounds which shall be eligible to be named as a Product X during the Initial Review Period (each, an "Available Product X"): [***]. Between the Effective Date and the expiration of the Initial Review Period, [***]. For clarity, the list of Available Product Xs set forth in this Section 2.4(b) is [***] named by Licensee and [***] Licensee may [***].

(c) [***] After the Initial Review Period. After the Initial Review Period, Coherus may permit Third Parties to [***] with respect to any such Coherus Biosimilar Candidates until at least thirty (30) days following the end of the Initial Review Period. Following receipt of the Rejection Notice, Coherus may permit Third Parties to [***].

(d) Negotiation Periods.

- (i) If the Election Notice identifies one of the Coherus Biosimilar Candidates as the ROFR Candidate, the Parties shall enter into a period of [***] negotiations of thirty (30) days which shall commence on the date that Licensee delivers to Coherus the applicable Election Notice, with the goal of [***] by Coherus [***]. If a [***] during such thirty (30)-day period, the Parties shall promptly enter into a period of [***] negotiations of not more than sixty (60) days following the [***] mutually acceptable financial and other terms under which Coherus would [***] license to Licensee such intellectual property rights.
- (ii) If the Election Notice identifies a Product X as the ROFR Candidate, the Parties shall enter into a period of [***] negotiations of not more than six (6) months following the receipt by Coherus of the applicable Election Notice with the goal of executing a definitive license agreement setting forth the mutually acceptable financial and other terms under which Coherus would exclusively license to Licensee the intellectual property rights related to Product X that are Controlled by Coherus.

- (e) Product Opt-Out. Licensee shall have a period of forty-five (45) days (which shall be extended by Coherus by an additional fifteen (15) days upon the reasonable request of Licensee) following [***] "Product Opt-Out Period") to make a decision not to proceed with Development solely based on: (i) the failure of the Phase 1 Results to demonstrate pharmacokinetic bio-equivalence [***]; (ii) material safety issues with the Product which are evident in the Phase 1 Results and which issues cannot be remedied or overcome; or (iii) quality audits of the Vendors conducted between the Effective Date and the expiration of the Product Opt-Out Period ([***]) that provide findings identifying violations of applicable GXP of such a severity or number that they would, in the aggregate, preclude the ability of one or both of the Vendors to qualify under Licensee's standard vendor qualification policies and procedures taking into account the performance of reasonable remediation efforts in a timely manner. The Parties will work together in good faith to remediate any such findings. The Parties will share any reports generated in connection with the quality audits under subsection (iii) above, to the extent not otherwise prohibited by any Third Party consultants utilized in such quality audits. If Licensee makes a decision not to proceed with Development pursuant to this Section 2.4(e), it shall, prior to the expiration of the Product Opt-Out Period, provide written notice of such decision to Coherus (an "Opt-Out Notice"), setting forth in reasonable detail the basis on which it has made its decision. If Licensee delivers an Opt-Out Notice during the Product Opt-Out Period, Licensee shall have an additional sixty (60)-day period following delivery of the Opt-Out Notice (the "Second Review Period") to elect to enter into one or more [***] term sheets and/or ROFR Agreements (as contemplated below) with Coherus for the development and commercialization of additional product candidates as follows:
 - (i) Coherus shall promptly [***];
 - (ii) If Licensee selected a ROFR Candidate within the Initial Review Period, Licensee may, during the Second Review Period, select [***], such that, [***], Licensee may [***]; whereas if [***], Licensee must [***];
 - (iii) If Licensee did not select a ROFR Candidate within the Initial Review Period, Licensee may, during the Second Review Period, select [***]; provided, however, that [***];
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (iv) The identity of Product X, and Licensee's election to proceed with [***] must be made within the Product Opt-Out Period;
- (v) For clarity, the expiration of the Initial Review Period shall not impact Licensee's ability to select one or more Coherus Biosimilar Candidates or Product X during the Second Review Period following delivery by Licensee of an Opt-Out Notice during the Product Opt-Out Period; and
- (vi) [***] of the Upfront Payment paid to Coherus pursuant to Exhibit 7.1 Section A (Upfront License Payment) shall be [***] under the definitive ROFR Agreement(s) to be negotiated pursuant to this Section 2.4(e) (Product Opt-Out); provided, however, that: (A) [***], (B) [***]; and (C) [***]. For clarity, this [***] is only applicable in the event of Product Opt-Out by Licensee.
- (f) [***] Term Sheet and/or Definitive Agreements to be Negotiated. Any [***] term sheet or ROFR Agreement between Coherus and Licensee related to either a Coherus Biosimilar Candidate or Product X will be negotiated in good faith, within the timeframes for completing negotiations set forth in Section 2.4 (Licensee Rights of First Refusal), subject to extension by mutual agreement of the Parties, and will provide for mutually acceptable financial and other terms; provided, however, that it is anticipated that any ROFR Agreement(s) for Product X shall [***]; provided, however, that, [***]:
 - (i) with respect to any ROFR Agreement for the first Coherus Biosimilar Candidate, Coherus shall [***]; and
 - (ii) with respect to any ROFR Agreement for [***], Coherus shall not bear any internal or external development costs.

3. GOVERNANCE.

3.1 Joint Steering Committee.

- (a) Generally. As soon as practicable after the Effective Date, but in any event within fifteen (15) days of the Effective Date, the Parties shall establish a joint steering committee (the "Joint Steering Committee" or "JSC") to oversee the Development, Process Development, Manufacturing, Process Development and Commercialization activities of the Parties with respect to Product in the Territory during the Term as further detailed in this Article 3 (GOVERNANCE). The JSC shall have review and coordination responsibilities for Development, Manufacturing, Process Development and Commercialization activities and in connection therewith shall review and provide advice regarding the overall progress thereof. The JSC shall also provide a forum for sharing advice, progress, and results relating to such activities and shall attempt to facilitate the resolution of any disputes between the Parties, as described in Section 3.1(d) (Decision-Making; Deciding Vote).
- (b) Membership; Meetings. The JSC shall be composed of three (3) representatives of Licensee and three (3) representatives of Coherus or such other number as the Parties may agree. During the Term, the JSC shall meet at least [***] per [***], or more often as the JSC shall determine, in person, by teleconference, or by video-teleconference. There will be an annually rotating chairperson (the "Chairperson") with the first Chairperson to be designated by Licensee. In-person meetings shall alternate between Coherus and Licensee locations whenever possible unless otherwise agreed by the Parties. The first such meeting shall be held within ninety (90) days after the Effective Date. Any member of the JSC may designate a substitute to attend with prior written notice to the other Party. Ad hoc guests who are employees of neither Licensee nor Coherus but who are subject to written confidentiality obligations commensurate in scope to the provisions in Article 11 (CONFIDENTIALITY) may, subject to the other Party's consent (not to be unreasonably withheld, conditioned or delayed), attend the JSC meetings. Each Party may replace its JSC members with other of its employees, at any time, upon prior written notice to the other Party.
- (c) Sub-Committees. No later than its initial meeting, the JSC shall agree upon the formation of certain sub-committees to address specific issues in greater detail (each, a "Sub-Committee") including the JDC, JPDMC and JCC (each, as hereinafter defined) with each Sub-Committee consisting of an equal number of representatives from Coherus and Licensee. In connection therewith, the JSC shall establish and appoint members to the Sub-Committees and each such Sub-Committee shall hold its first meeting in person as set forth in the applicable sections below at such location designated by the JSC. [***]. For clarity, either Party may, as appropriate and reasonable, invite additional employees or other ad-hoc guests who are subject to written confidentiality obligations commensurate in scope to the provisions in Article 11 (CONFIDENTIALITY) to the meetings of the Sub-Committees.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (d) Decision-Making; Deciding Vote. Except as otherwise expressly set forth in this Section 3.1(d), decisions of the JSC and each Sub-Committee shall be made by consensus, with each Party having, collectively, one (1) vote in all decisions. In the event that the JSC or any Sub-Committee is unable to reach a consensus decision on a matter that is within its decision-making authority within fifteen (15) day after it has met and attempted to reach such decision, then either Party may submit such matter for resolution to the Executive Officers in accordance with Section 14.2 (Resolution by Executive Officers), and, except as set forth below in this Section 3.1(d), the dispute resolution procedure set forth in Article 14 (DISPUTE RESOLUTION) shall apply.
 - (i) The JDC will report to the JSC. Any disagreement between the Parties' members on the JDC will be submitted for resolution to the JSC. If the JSC is unable to resolve such disagreement, such disagreement will be escalated to the Executive Officers for their resolution in accordance with Section 14.2 (Resolution by Executive Officers); provided, however, that if the disagreement that is escalated to the Executive Officers relates to [***], then the Executive Officers shall [***]; provided further, [***].
 - (ii) The JPDMC will report to the JSC, and any disagreement between the Parties' members on the JPDMC will be submitted for resolution to the JSC and, if necessary, for subsequent escalation to and resolution by the Executive Officers in accordance with Section 14.2 (Resolution by Executive Officers); provided, however, that if the Executive Officers are unable to reach resolution in accordance with Section 14.2 (Resolution by Executive Officers), then no further escalation of dispute resolution under Article 14 (DISPUTE RESOLUTION) shall apply and [***] shall have the final deciding vote.
 - (iii) The JCC will report to the JSC, and any disagreement between the Parties' members on the JCC will be submitted for resolution to the JSC and, if necessary, for subsequent escalation to and resolution by the Executive Officers in accordance with Section 14.2 (Resolution by Executive Officers); provided, however, that if the Executive Officers are unable to reach resolution in accordance with Section 14.2 (Resolution by Executive Officers), then no further escalation of dispute resolution under Article 14 (DISPUTE RESOLUTION) shall apply and [***] shall have the final deciding vote.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- **(e)** Limitations on JSC and Sub-Committees. The JSC and each Sub-Committee shall have only such powers as are specifically delegated to it in this Agreement and such powers shall be subject to the terms and conditions set forth in this Agreement. Without limiting the generality of the foregoing, neither the JSC nor any Sub-Committee thereof shall have any power to amend, modify or waive compliance with this Agreement though the JSC or any Sub-Committee may make recommendations to the Parties regarding any such amendments, modifications or waivers.
- (f) Secretary; Minutes. The Chairperson of the JSC and the chairperson of each Sub-Committee shall designate a secretary who will be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting, and preparing and circulating minutes within fifteen (15) days after each meeting of the JSC setting forth, among other things, a description, in reasonable detail, of the discussions at the meeting and a list of any actions, decisions, or determinations approved by the JSC or the applicable Sub-Committee. Definitive minutes of all meetings shall be finalized no later than thirty (30) days after the meeting to which the minutes pertain. Such minutes shall be effective only after being approved by both Parties.

3.2 Joint Development Committee.

- (a) No later than its initial meeting, the JSC shall establish a joint Development committee (the "Joint Development Committee" or "JDC") which shall hold its initial meeting within fifteen (15) days of its establishment. At its first meeting, the JDC shall: (i) [***], and (ii) review, modify as necessary and recommend for approval to the JSC a Development Plan (including the Development Budget). The Illustrative Development Plan/Budget is an illustrative indication of the activities and the budget to be considered and addressed in the first Development Plan and shall not be binding on the Parties, the JSC or the JDC. Following its initial meeting, the JDC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to [***].
- (b) Without limiting the foregoing, the JDC shall be responsible for: (i) reviewing, consulting with the Parties on and modifying (as appropriate) the Development Plan including the Development Budget; (ii) recommending the Development Plan including the Development Budget (as modified) for approval by the JSC; (iii) communicating with the JCC regarding the interrelationship between Development activities and potential Commercialization; (iv) reviewing and monitoring the activities and progress against the Development Plan; (v) reviewing and monitoring the costs and expenses of Development against the Development Budget; (vi) finalizing the Product specifications for inclusion in the Regulatory Filings for the Territory and Regulatory Approvals and Pricing and Reimbursement Approvals for the Territory; and (vii) communicating with the Parties regarding all of the foregoing. For the avoidance of doubt, the CRO used for Clinical Trials shall be selected by Coherus, and such selection shall not be subject to the dispute escalation process under Section 3.1(d) (Decision-Making; Deciding Vote).

3.3 Joint Process Development and Manufacturing Committee. At its initial meeting, the JSC shall establish a joint Process Development and Manufacturing committee (the "Joint Process Development and Manufacturing Committee" or "JPDMC") which shall, as noted above, hold its initial meeting within fifteen (15) days of its establishment. Following its initial meeting, the JPDMC will meet in person, by teleconference or by videoteleconference at least [***] per [***] to review and discuss material decisions and key activities that relate to the matters set forth below. The JPDMC will be responsible for reviewing Process Development, progress and development of analytical methods and analysis, Product formulations, coordination of Process Development and Manufacturing related activities and the review, modification as necessary and recommendation for approval to the JSC of a Process Development Plan. For the avoidance of doubt, the Third Party contract manufacturer for clinical and commercial supplies of Product in the Territory shall be selected by Coherus, and such selection shall not be subject to the dispute escalation process under Section 3.1(d) (Decision-Making; Deciding Vote).

3.4 Joint Commercialization Committee. Upon a decision by the JSC to activate the joint Commercialization committee, but in no case later than eighteen (18) months prior to the projected First Commercial Sale (the "Joint Commercialization Committee" or "JCC"), the Parties shall establish the JCC. The JCC shall hold its initial meeting within thirty (30) days of its establishment. Following its initial meeting, the JCC will meet in person, by teleconference or by video-teleconference at least [***] per [***] to review and discuss material decisions and key activities that relate to the matters set forth below. The JCC will be responsible for the communication, review and discussion of the Commercialization Plan and other Commercialization matters, including marketing strategy and planning, pricing, commercial manufacture, and [***], in each case in the Territory. Without limiting the foregoing, the JCC shall be responsible for: (a) reviewing and consulting with Coherus on the Commercialization Plan prior to adoption of the Commercialization Plan or changes by Licensee; (b) recommending the Commercialization Plan for approval by the JSC prior to adoption of the Commercialization Plan; (c) communicating with the JDC regarding the interrelationship between Development activities and potential Commercialization activities; (d) reviewing and monitoring the activities and progress against the Commercialization Plan; (e) monitoring and reporting on the competitive landscape for the Product in the Territory; (f) establishing appropriate processes for coordinating review of promotional materials for the Territory to ensure compliance with Applicable Laws and industry best practices; (g) overseeing the trademark and publication strategies for the Territory; and (h) communicating with the Parties regarding all of the foregoing.

4. DEVELOPMENT AND REGULATORY MATTERS.

4.1 Development Activities; Process Development Activities and Funding.

- (a) Coherus Responsibilities. Subject to the oversight of the JDC, the JPDMC and the JSC ([***]), Coherus shall be solely responsible for carrying out all activities set forth in the Development Plan and the Process Development Plan. Coherus shall use Commercially Reasonable Efforts to conduct all Development and Process Development activities in accordance with the Development Plan or the Process Development Plan (as applicable) and the terms of this Agreement. Without limiting the generality of the foregoing, Coherus' responsibility with respect to Development shall include:
 (a) preparing Regulatory Approval Applications for submission in the Territory by and in the name of Licensee to the relevant Regulatory Authorities in the Territory; (b) carrying out all major Development tasks to be conducted prior to submission of filings for such Regulatory Approvals; (c) identifying key Development objectives, expected associated resources, risk factors, timelines, decision points and relevant decision criteria; (d) carrying out all aspects of all Clinical Trials (including bioequivalence Clinical Trials) necessary to obtain Regulatory Approval and receipt of Pricing and Reimbursement Approvals in the Territory including: (i) designing study protocols, developing [***], (ii) establishing and contracting with Clinical Trial sites, investigators and CROs, (iii) enrolling Clinical Trial subjects, (iv) organizing investigator meetings, scientific meetings, advisory panel workshops and regulatory meetings, and (v) analyzing and summarizing Clinical Trial results; (e) performing any other additional clinical research in support of the Development; (f) [***]; (g) reporting on study design, study outcome, other communications and Regulatory Filings in the Territory to the appropriate Regulatory Authority in the Territory; and (h) submitting all Clinical Trial results and any other clinical data to the Global Clinical Database pursuant to Section 4.7 (Coherus Global Clinical Database). For clarity, any Post-Regulatory Approva
- **(b)** Clinical Trials in the Territory. Except as contemplated by the Global Studies and such other Phase 3 Clinical Trials being conducted by or on behalf of Coherus in support of Regulatory Approvals or Pricing and Reimbursement Approvals in the Territory, [***].
- (c) Expense Reports for Reimbursable Costs. Coherus shall deliver to Licensee, within thirty (30) days of the end of each Calendar Quarter, a report setting forth in reasonable detail the Reimbursable Costs for such Calendar Quarter. Licensee shall promptly notify Coherus of any good faith dispute regarding an invoice submitted pursuant to this Section 4.1, and the Parties shall work in good faith to exchange information to resolve such dispute; provided, however, [***].

(d) Cost Reimbursement. [***]:

(i) Global RA Study. [***] of:

- (1) the Development Costs for the Global RA Study; and
- (2) the Manufacturing Cost for Units (including Product contained therein) and bulk drug substance Manufactured for use in such Global RA Study; and
- (3) the cost of comparator drug to be used in such Global RA Study.

(ii) Other Clinical Trials. [***] of:

- (1) the Development Costs for any Clinical Trial(s) (including a Global Psoriasis Study) under the Development Plan other than the trials referenced in **Section 4.1(d)(i)(1) (Global RA Study)** above; and
- (2) the Manufacturing Cost for Units (including Product contained therein) and bulk drug substance Manufactured for use in such Clinical Trial(s); and
- (3) the cost of comparator drug to be used in such Clinical Trial(s).

(iii) Process Development and Manufacture Supporting Clinical Trials and Launch. [***] of:

(1) Process Development Costs, including those incurred by Coherus with respect to: (A) [***], (B) [***] and (C) [***]; and [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (2) the Manufacturing Cost for all Units (including Product contained therein) and bulk drug substance Manufactured to enable or support Development (including in connection with Process Development activities) [***].
 - (e) For the avoidance of doubt, Subsection 4.1(d)(ii)(3) is not intended to nor shall it include [***] and [***].
- **(f) Cost Reimbursement Limitations; Cost Caps.** Notwithstanding anything else contained in this Agreement and in this **Section 4.1** in particular, the Parties agree as follows:
 - (i) Licensee [***].
 - (ii) [***]. All Reimbursable Costs for such Global Studies in excess of the Global Study Reimbursement Cap shall be shared by the Parties with Licensee being responsible for [***] percent ([***]%) of such incremental costs and Coherus being responsible for [***] percent ([***]%) of such incremental costs; provided, however, that any Reimbursable Costs associated with Clinical Trials in addition to the Global Studies that are requested by Licensee or any Regulatory Authority within the Territory or Licensee's request or such Regulatory Authority's request to expand the scope, numbers of patients, or otherwise to expand the Global Studies beyond their scope as of the Effective Date (inclusive of pharmacoeconomic or other clinical endpoints required to support Pricing and Reimbursement Approvals after receipt of Regulatory Approval) shall not be included for purposes of calculating whether the Global Study Reimbursement Cap has been reached or exceeded. Licensee shall [***].
 - (iii) [***]. All Reimbursable Costs for Process Development and Manufacturing in excess of the Process Development Cap shall be shared by the Parties with Licensee being responsible for [***] percent ([***]%) of such incremental costs and Coherus being responsible for [***] percent ([***]%) of such incremental costs.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (iv) Licensee shall pay all Reimbursable Costs in excess of the Global Study Reimbursement Cap and/or Process Development Cap (as applicable) for which it is responsible pursuant to this **Section 4.1(f)(ii)** or (iii) within thirty (30) days of receipt of an invoice from Coherus, setting forth in reasonable detail the costs and expenses to be reimbursed by Licensee (including any reasonably requested supporting materials). Licensee shall promptly notify Coherus of any dispute regarding an invoice submitted pursuant to this **Section 4.1(d)** and the Parties shall work in good faith to exchange information to resolve such dispute; *provided, however*, that [***].
 - (v) Licensee [***].
- (vi) For clarity, all Reimbursable Costs incurred by Coherus directly resulting from Coherus' preparation of: (A) the Regulatory Filing for the EU Regulatory Approval and (B) Regulatory Filings for the [***] countries within the Territory other than the EU for which Regulatory Approval is sought, shall be included as Reimbursable Costs which are subject to the cap described in this Section 4.1(f). Except as set forth in the immediately preceding sentence, Licensee shall be responsible for and shall pay all Reimbursable Costs incurred by Coherus directly resulting from Coherus' preparation of Regulatory Filings for all other countries in the Territory that are approved by the JSC and such Reimbursable Costs shall not be subject to the cap described in this Section 4.1(f).
- (g) Coherus Reimbursement of Licensee Development Costs and Expenses. If the Product is commercialized in the United States other than by entering into a commercial arrangement therefor with Licensee, Coherus shall reimburse Licensee for [***] percent ([***]%) of the sum of all Reimbursable Costs ([***]) actually paid to Coherus, whether Coherus commercializes the Product in the United States with a Third Party or Coherus commercializes the Product without a Third Party. In either case, reimbursement to the Licensee shall be due forty five (45) days after the first commercial sale of the Product in the United States whether for Coherus' own account or by a Third Party.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

4.2 Development Plans. Coherus shall provide to the JDC, in advance of its first meeting, a draft Development Plan. The draft Development Plan may [***]. If modifications or changes to the draft Development Plan are proposed by either Party, the JDC shall review and recommend any modifications or changes thereto and shall make its recommendation to the JSC for review and approval of the draft Development Plan (as modified by the JDC). For clarity, the Illustrative Development Plan/Budget is illustrative of the activities and the budget to be considered and addressed in the draft Development Plan to be provided by Coherus to the JDC. Following approval by the JSC, the Development Plan shall be updated and/or amended by the JDC no less frequently than [***], with any such updates and amendments being subject to the approval of the JSC. The Development Plan shall be consistent with and shall not contradict the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Development Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Laws requires a change to a Development Plan, the JDC shall, subject to the approval of the JSC, revise the Development Plan. For the avoidance of doubt, no Development Plan shall be binding on the Parties unless and until it has been approved by the JSC.

4.3 Efforts. Coherus shall use Commercially Reasonable Efforts to Develop the Product in the Territory in accordance with the Development Plan and the terms of this Agreement, including the preparation, for Licensee's subsequent submission to Regulatory Authorities in the Territory, of all Regulatory Filings (including Regulatory Approval Applications) covering the Product in the Territory.

4.4 Regulatory Filings.

(a) Responsibilities. Coherus shall, subject to the oversight of the JDC and approval of the JSC, have primary responsibility for preparing each Regulatory Filing in the Territory, and shall also be responsible for establishing and managing timelines for completion of each such Regulatory Filing (including drafting of responses to Regulatory Authority questions during the Regulatory Approval Application review period) until receipt of the applicable Regulatory Approval for the applicable country or region in the Territory. With respect to the Territory, and notwithstanding Coherus' obligation to prepare such filings pursuant to the preceding sentence: (i) all Regulatory Filings in the Territory shall be prepared in the name of Licensee or an Affiliate of Licensee, (ii) Licensee shall be the owner of all Regulatory Filings and all Regulatory Approvals and Pricing and Reimbursement Approvals relating thereto, and (iii) Licensee shall be responsible for submitting the Regulatory Approval Applications in the Territory to the Regulatory Authorities for approval within the timing set forth in subsection (b) below.

(b) Review and Submission of Regulatory Approval Applications.

- (i) European Union. Coherus shall deliver to Licensee the Regulatory Approval Application [***] for initial review. Licensee shall promptly review and provide comments to the initial draft in a time-frame that is consistent with the document review and development plan. Subsequently, Coherus will develop a final draft of the Regulatory Approval Application and shall deliver to the Licensee for final review and approval. Within thirty (30) days of delivery of such Regulatory Approval Application, Licensee shall provide any comments for Coherus' reasonable consideration of inclusion in such Regulatory Approval Application. Failure to provide any comments within such thirty (30)-day period shall be deemed Licensee's consent to the filing of such Regulatory Approval Application, as previously delivered to Licensee, with the Regulatory Authorities in the European Union. Coherus and Licensee shall work in good faith to resolve any comments provided by Licensee within such thirty (30)-day period. If Coherus and Licensee are unable to resolve any Licensee comments within such thirty (30)-day period, any delay involved in the filing beyond the initial thirty (30)-day period shall be credited to Coherus, on a day-for-day basis, in determining the order of entrance to market for the EU Regulatory Approval Milestone. If Coherus and Licensee have resolved any such comments, but it takes longer than such thirty (30)-day period for the Parties to revise the Regulatory Approval Application for submission to the Regulatory Authorities in the European Union, [***].
- (ii) All Other Countries. All other Regulatory Filings for the Product in the Territory shall be subject to [***] prior to submission to Regulatory Authorities in the Territory.

(c) Responsible Party.

(i) Prior to submission of a Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or jurisdiction in the Territory, Coherus shall be the responsible Party for all interactions concerning the Product with Regulatory Authorities in such country or jurisdiction, including relating to Regulatory Filings for the Global Studies and for interactions related to the design and conduct of the Global Studies and Regulatory Authority inspections of the manufacturing facilities and/or Clinical Trial sites. Coherus will be responsible for the inspection(s) findings and resulting commitments to Regulatory Authorities. Coherus shall keep Licensee reasonably informed of all communications received from Regulatory Authorities in the Territory.

- (ii) After submission of a Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or jurisdiction in the Territory, Licensee shall be the responsible Party for all interactions concerning the Product with Regulatory Authorities in such country or jurisdiction except for Regulatory Authority inspections related to the Clinical Studies and manufacturing facilities. Licensee shall keep Coherus reasonably informed of all communications received from Regulatory Authorities in the Territory.
- (iii) Parties shall consult and cooperate to maximize the possibility of receipt of the Full Label in the period after filing of a Regulatory Approval Application and prior to receipt of Regulatory Approval in each country or jurisdiction in the Territory.

(d) Face-to-Face Meetings.

- (i) Prior to submission of the Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or region in the Territory, Licensee shall, at its sole cost and expense, have the right to send one (1) representative to attend all face-to-face meetings relating to the Product with any Regulatory Authority in the Territory. After submission of the Regulatory Approval Application in the name of Licensee or its Affiliate in the applicable country or region in the Territory, Coherus shall have the right to send one (1) representative to all face-to-face meetings relating to the Product with any Regulatory Authority in the Territory.
- (ii) Licensee shall, at its sole cost and expense, have the right to send one (1) representative to attend all face-to-face meetings relating to the Product, solely as an observer, with Regulatory Authorities for unpartnered territories for the Product. In addition, Coherus will request that each Third Party partner of Coherus for the Product permit the participation of one (1) Licensee representative in such meetings within such partner's territories.
- **(e)** Manufacturing Facility and/or Clinical Site Inspections. Prior to and following Regulatory Approval of the Product, Licensee shall, at its sole cost and expense, have the right to send one (1) representative to attend all Regulatory Authority inspections of manufacturing facility(ies) and/or Clinical Trial sites.
 - (f) Regulatory Communications.

- (i) Except as otherwise provided for in this Section 4.4(f), each Party shall provide summaries for each Calendar Quarter to the other Party of any oral or any substantive written communications to or from Regulatory Authorities on matters relating to the Product in the Territory. Notwithstanding the foregoing, each Party shall notify the other Party of any oral communications with, and provide such other Party with copies of any written communications to or from, Regulatory Authorities on matters which may reasonably be deemed to impact Development, Manufacture, Process Development, Commercialization or Regulatory Approval and Pricing and Reimbursement Approvals as soon as reasonably practicable (but in all events within seventy two (72) hours of receipt of such communication, or such earlier date as required by Applicable Laws). Moreover, in each such case, each Party shall give the other Party reasonable opportunity to review and comment on any proposed response to any such oral or written communications relating to the Product to or from Regulatory Authorities prior to submitting any response thereto, and provide such other Party with a copy of the final response as specified herein.
- (ii) Coherus shall promptly notify Licensee of all communications received by Coherus from Regulatory Authorities [***] and Coherus shall [***].
- (g) Regulatory Reports. Each Party shall provide the other Party, at such other Party's request and expense, with summary documents related to the Product in the Territory for Regulatory Filings, Regulatory Approvals and Pricing and Reimbursement Approvals and key interactions with Regulatory Authorities relating thereto for which it is the responsible Party. In addition, each Party shall keep the other Party informed on a regular basis ([***]) of Regulatory Filings in the Territory.
- 4.5 Development Reports. At least [***] per [***], Coherus will provide the JDC with written Development reports or presentations. Each report or presentation shall include, but not be limited to, the Development activities accomplished by or on behalf of Coherus since the previous JDC meeting, including a summary of significant results and Information generated, significant challenges anticipated and [***]. Upon request by Licensee, Coherus shall provide Licensee additional information with respect to the material experimental data underlying such summary, summaries of available clinical protocols, investigator brochures, regulatory submissions and correspondence from Regulatory Authorities with respect to the Product. Upon request of either Party, the other Party's JDC members shall meet with the requesting Party's JDC members to discuss any aspects of such reports within a reasonable time period after such request. Coherus shall keep, and shall require its Affiliates, agents and Third Party service providers to keep (all in accordance with the Accounting Standards), accurate records in sufficient detail to allow Reimbursable Costs to be determined for a period of at least three (3) Calendar Years to facilitate the audits contemplated under Section 7.8 (Audit Request).

4.6 Right of Reference.

- (a) Coherus hereby grants to Licensee, its Affiliates and Sublicensees a right of reference (including the right to inspect) to any Regulatory Filings for the Product [***].
- (b) Licensee hereby grants to Coherus, its Affiliates and licensees a right of reference (including the right to inspect) to any Regulatory Filings for the Product [***].

4.7 Coherus Global Clinical Database.

- (a) Subject to Section 4.8 (Pharmacovigilance), Coherus shall create a global database for all Clinical Trial results and clinical data related to the Product submitted by Coherus and/or its licensees throughout the world to applicable Regulatory Authorities (the "Global Clinical Database"). The purpose of the Global Clinical Database will be for Coherus and its exclusive licensees who submit data to the Global Clinical Database to share such data in support of their Regulatory Filings, and, in the case of Coherus, for any purpose generally related to enhancing Coherus' understanding of, or to improving, the Product.
 - (b) Coherus shall have the right to submit all clinical data pertaining to the Product in the Territory [***].
- (c) Coherus shall be responsible for managing, maintaining, and updating the Global Clinical Database in accordance with Applicable Laws and shall have the right to share any and all de-identified information received from Licensee under this **Section 4.7** with Coherus' Affiliates, and with all licensees of Coherus outside the Territory relating to the Product who submit data to the Global Clinical Database.
- (d) Licensee shall have reasonable access to the Global Clinical Database in connection with the activities contemplated by this Agreement including for use in its Regulatory Filings, without cost (other than any cost charged by the Third Party database provider associated with the transfer of data from the Global Clinical Database to Licensee for its use in connection with Regulatory Filings), and shall have the right to share any and all Information in the Global Clinical Database with Licensee's Affiliates and Sublicensees in the Territory.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 4.8 Pharmacovigilance. Ninety days prior to the submission of a Regulatory Approval Application in any country in the Territory but in no event later than twelve (12) months after the Effective Date, the Parties shall enter into a pharmacovigilance agreement concerning all matters relating to the pharmacovigilance and the exchange of all relevant Information that relates to the safety of the Product worldwide and especially all adverse events. Generally, (a) Licensee shall be responsible for reporting all adverse drug reactions required to be reported to the Regulatory Authorities in the applicable countries in the Territory, in accordance with Applicable Laws; and (b) Coherus, its Affiliates or licensees or sublicensees shall be responsible for submitting all Regulatory Filings and for reporting of all adverse drug reactions, relating to the Product required to be reported to the appropriate Regulatory Authorities outside of the Territory in accordance with the Applicable Laws of the relevant countries. Coherus shall have the right to share any and all information received from Licensee under this Section 4.8 with Coherus' Affiliates and licensees and sublicensees outside the Territory. Licensee shall have the right to share any and all information received from Coherus under this Section 4.8 with Licensee's Affiliates and Sublicensees in the Territory. The JSC shall review from time to time Licensee's pharmacovigilance policies and procedures.
- **4.9 Formulation Development.** Coherus shall be responsible for [***] development of Product formulations and performance of stability analyses on such formulations.
- **4.10 Initial Development Activities.** The Parties acknowledge that during the thirty (30)-day period immediately following the Effective Date, Coherus will undertake the activities set forth in **Exhibit 1.29 (Initial Development Activities)**, pursuant to which Coherus will incur the Reimbursable Costs included therein.
- **4.11 Development Partners**. To the extent that Coherus is not, as of the Effective Date, contractually obligated to use a specific Third Party for any Development activities contemplated by this Agreement, the Parties shall discuss and consider in good faith the Third Parties to be used for such activities at meetings of the JDC.

5. MANUFACTURING.

- 5.1 Manufacturing and Supply of Product. Within one hundred eighty (180) days following completion of enrollment in the Global RA Study, the Parties shall negotiate in good faith and enter into a definitive written commercial supply agreement (the "Manufacturing and Supply Agreement" or "MSA") and a quality agreement related thereto, pursuant to which Coherus, either directly or through its designee, shall Manufacture and supply to Licensee, its Affiliates and Sublicensees (as applicable) all of Licensee's, its Affiliates' and Sublicensees' requirements of Units for Commercialization in the Territory. The MSA will provide, among other things, that all Product supplied thereunder will meet the Product specifications set forth in the applicable Regulatory Filings and Regulatory Approvals and any Pricing and Reimbursement Approvals in the Territory and shall contain customary terms and conditions including: [***] and shall otherwise be consistent with the terms and conditions in this Article 5. The Manufacturing and Supply Agreement shall provide that Coherus shall have the right to supply Product or Units produced at facilities licensed under Licensee's Regulatory Approval to its ex-Territory licensees of Product. The MSA shall also include [***].
- **5.2 Manufacturing Regulatory Filings.** Coherus shall be solely responsible for the preparation and submission of all Manufacturing Regulatory Filings, including with respect to the use of any Third Party to Manufacture and supply the Product. Licensee shall provide Coherus such reasonable cooperation as may be requested by Coherus in connection with any such Manufacturing Regulatory Filings, and Coherus shall [***]. In addition, upon the written request of Coherus, Licensee shall provide to Coherus one (1) complete copy of each Regulatory Filing and each Regulatory Approval for Coherus', its Affiliates' or licensees' use in Manufacturing the Product for sale or use outside the Territory, and Licensee hereby grants to Coherus, its Affiliates and licensees the right to provide each such Regulatory Filing and Regulatory Approval to Regulatory Authorities outside the Territory.

5.3 Process Development and Capital Expenditures.

- (a) Process Development. Coherus, through the JPDMC, shall develop a Process Development Plan (as well as the anticipated associated budget) for review by the JPDMC and subsequent approval by the JSC. The Process Development Plan shall include the plan for implementing Process Developments [***] and such Process Development Plan shall include provisions for [***]. Any amendment or update to an approved Process Development Plan is subject to review by the JPDMC and approval by the JSC. The Process Development Plan shall be consistent with and shall not contradict the terms of this Agreement without the written consent of the Parties, and in the event of any inconsistency between the Process Development Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Laws requires a change to a Process Development Plan, the JPDMC shall revise the Process Development Plan to the extent necessary to comply with such requirement and shall promptly submit the revised Process Development Plan to the JSC for approval. Licensee shall bear all costs and expenses for the activities contemplated in the Process Development Plan pursuant to Section 4.1(d)(iii)(1).
- **(b) Process Development Plan.** Coherus shall retain sole responsibility for performing any activities under an approved Process Development Plan[***].
- (c) Capital Expenditures for Post Launch Expansion. [***] associated with the construction of all Manufacturing facilities necessary to satisfy Licensee's, its Affiliates' and Sublicensees' requirements for Product pursuant to Section 5.1 and the MSA. For clarity, the [***] are separate and distinct from, and shall not include, the costs and expenses for Process Development borne by Licensee pursuant to Section 4.1(d)(iii)(1) above.
- **5.4 Records.** Each Party shall, and shall require its Affiliates, subcontractors and sublicensees to, maintain records of all work conducted by such Party in connection with the Process Development activities and the Manufacture of Product or Units and all results, Information, and developments made in conducting such activities in accordance with Applicable Laws. Such records shall be complete and accurate and shall fully and properly reflect all such work done and all results achieved in sufficient detail and in good scientific manner appropriate for patent and regulatory purposes.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

5.5 [***] Technology Transfer. The Parties shall agree on a process for, and shall prepare appropriate documentation pertaining to, the implementation of a technology transfer of all know-how (including all Coherus Know-How) necessary for a Third Party to Manufacture or have Manufactured the Product for Commercialization in [***], and the Parties shall execute an agreement thereon (the "Technology Transfer Agreement"). The Technology Transfer Agreement shall specify, among other items: (i) the composition of the technology transfer teams, and (ii) a timeline for technology transfer and (iii) the responsibilities of the Parties with respect thereto. The costs and expenses of executing the technology transfer pursuant to the Technology Transfer Agreement shall be borne solely by Licensee[***].

6. COMMERCIALIZATION.

6.1 Efforts. Licensee shall be responsible for Commercialization of the Product in the Territory, and, as between the Parties, shall book all sales of the Product in the Territory. Licensee shall use Commercially Reasonable Efforts to Commercialize the Product in each of the Major EU Countries, [***] in accordance with the Commercialization Plan and the terms of this Agreement. Without limiting the obligation set forth in the immediately preceding sentence, Licensee shall initiate Commercialization activities within each of the Major EU Countries within three (3) months following [***] for the Product in the applicable Major EU Country.

6.2 Commercialization Plan.

- (a) Initial Commercialization Plan. No later than eighteen (18) months prior to the anticipated commercial launch of the Product in the Territory, Licensee will provide to the JCC for review its initial Commercialization Plan for the Territory. Such initial Commercialization Plan will describe Licensee's plans for activities to be conducted for the Territory on a country-by-country basis. The Commercialization Plan shall include the details of activities to be performed by Licensee, its Affiliates and/or Sublicensees relative to the applicable stage of Commercialization (*e.g.*, pre-launch, launch planning, launch, or post-launch) during the time period covered by such Commercialization Plan and subsequent time periods.
- **(b) Updated Commercialization Plan Prior to First Commercial Sale.** Prior to the First Commercial Sale in the Territory, Licensee will provide to the JCC for review and subsequent review and approval by the JSC, an updated Commercialization Plan for the Territory on a country-by-country basis. Such updated Commercialization Plan will include Licensee's updated plans for activities to be conducted for the Territory, on a country-by-country basis, prior to launch as well as activities to be conducted in connection with such launch.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- **(c) Updated Commercialization Plan After First Commercial Sale.** Promptly after the first anniversary of the First Commercial Sale in the Territory and thereafter on each subsequent anniversary during the Term, Licensee will provide to the JCC for review an updated Commercialization Plan for the Territory on a country-by-country basis. Such updated Commercialization Plan will include, but not be limited to, Licensee's plans for Commercialization activities for the Territory, on a country-by-country basis, for the twelve (12) month period following the date of delivery of such Commercialization Plan.
- (d) General. Each Commercialization Plan shall be consistent with and shall not contradict the terms of this Agreement [***], and in the event of any inconsistency between the Commercialization Plan and this Agreement, the terms of this Agreement shall prevail. Notwithstanding the foregoing, if a Regulatory Authority or Applicable Laws requires a change to the Commercialization Plan, the JSC shall revise the Commercialization Plan to the extent necessary to comply with such requirement and shall promptly provide the revised Commercialization Plan to the JSC for approval.

6.3 Trademarks.

- (a) Product Trademark; Licensee Trademark. Subject to Section 6.3(d) (Use of Coherus Trademarks), all Product, including all packaging, promotional materials, package inserts, and labeling for the Product, shall bear one or more Trademark(s) that pertain specifically to the Product in the Territory, to be determined by the JSC and owned by Licensee ("Product Trademark"). Further, to the extent allowed by Applicable Laws, the Licensee may include on such packaging, promotional materials, package inserts, and labeling for the Product additional Licensee Trademarks.
- (b) Global Brand Trademark. Licensee shall have the option[***] to use one or more Trademark(s) Controlled by Coherus that pertain specifically to the Product outside of the Territory for the Product in the Territory (the "Global Brand Trademark") in place of using the Product Trademark under Section 6.3(a) (Product Trademark; Licensee Trademark). Such Global Brand Trademark may be used in the Territory including on all packaging, promotional materials, package inserts, and labeling for the Product.
- (c) Trademark Prosecution and Maintenance. Licensee shall [***] be responsible for filing, prosecuting and maintaining (including searching and policing) any and all Product Trademarks and Licensee Trademarks, and conducting litigation with respect thereto. Coherus shall [***] be responsible for filing, prosecuting and maintaining (including searching and policing) any and all Global Brand Trademarks and Coherus Trademarks, and conducting litigation with respect thereto.

(d) Use of Coherus Trademark. To the extent permitted by Applicable Laws [***] (but subject to the remainder of this Section 6.3), Licensee may include on the packaging, promotional materials, package inserts, and labeling for the Product, the Coherus Trademark. In connection therewith and subject to the terms and conditions of this Agreement, Coherus hereby grants to Licensee a non-exclusive, royalty-free license, under the Coherus Trademarks and, subject to Licensee's option under Section 6.3 (Global Brand Trademark), under the Global Brand Trademarks, with the right to grant sublicenses in accordance with Section 2.2 (Sublicense Rights), throughout the Territory, to use and display the Coherus Trademarks in connection with the Commercialization throughout the Territory, as provided under and in accordance with this Section 6.3. All representations of the Coherus Trademark(s) that Licensee so uses, if intended to be disclosed to Third Parties and not previously approved by Coherus, will first be submitted to Coherus for approval[***], and Coherus will have fifteen (15) Business Days to review and approve each such representation of the Coherus Trademark(s). [***]. Licensee shall not use any Coherus Trademark outside the scope of this Agreement, and shall not knowingly take any action that would materially adversely affect the value of any Coherus Trademark. Coherus shall retain the right to monitor the quality of the goods on or with which any Coherus Trademark is used solely to the extent necessary to maintain Coherus' Trademark rights. For clarity, should Applicable Laws only permit one Trademark (i.e. Licensee Trademark or Coherus Trademark) on the Product, the Licensee Trademark shall be the Trademark used.

7. PAYMENT OBLIGATIONS.

- **7.1 Payment Structure.** In consideration for the rights granted to Licensee under this Agreement, Licensee shall pay Coherus the amounts set forth in **Exhibit 7.1 (Payment Structure)**.
- 7.2 Coherus Reports. During the Term following the First Commercial Sale, within forty five (45) days after the end of each Calendar Quarter, Coherus shall provide a report showing the Manufacturing Cost per Unit for each configuration of Units supplied to Licensee for the immediately preceding Calendar Quarter
- **7.3** Licensee Reports and Payments. During the Term following the First Commercial Sale, within sixty (60) days after the end of each Calendar Quarter, Licensee shall pay to Coherus the Coherus Royalty (as such term is defined in **Exhibit 7.1**) and shall provide a report showing, on a country-by-country basis, the items set forth below in this **Section 7.3**. If no Coherus Royalty is due for any period hereunder, Licensee shall so report, otherwise the report shall set forth:
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (a) the gross amount invoiced for and the Net Sales during such Calendar Quarter reporting period, including the specific deductions applied in the calculation of such Net Sales amounts;
 - (b) the Manufacturing Cost per Unit (as provided by Coherus in its quarterly report);
 - (c) the related Coherus Royalty in Dollars which shall have accrued hereunder with respect to such Net Sales; and
 - (d) the rate of exchange used by Licensee in determining the amounts payable hereunder in Dollars.
- **7.4 Sublicensing.** In the event Licensee grants one or more sublicenses under **Section 2.2 (Sublicense Rights)** to a Sublicensee to offer to sell or sell Product in the Territory each sublicense agreement shall require the applicable Sublicensee to account for and report its net sales of the Product on the same basis as if such sales were Net Sales by Licensee, and Licensee shall pay a Coherus Royalty on such sales as if the net sales of the Sublicensees were Net Sales of Licensee.
- **7.5 Currency of Payment.** All payments to be made under this Agreement shall be made in Dollars. Net Sales made in foreign currencies shall be converted into Dollars using [***] for each of the three calendar months included in the Calendar Quarter in which such Net Sales were made.

7.6 Records; Accounting.

(a) Licensee shall keep, and shall require its Affiliates and Sublicensees to keep (all in accordance with the Accounting Standards and Licensee's applicable policies and practices as such may be modified from time to time), complete and accurate records in sufficient detail to properly reflect the Net Sales and to enable the Coherus Royalty payable hereunder (if any) to be determined for a period of at least [***] Years or as otherwise necessary to facilitate the audits contemplated under Section 7.8 (Audit Request).

- (b) Licensee shall determine Net Sales consistent with the Accounting Standards and Licensee's applicable policies and practices as such may be modified from time to time. In the case of amounts to be determined by Third Parties (for example, net sales by Sublicensees), such amounts shall be determined in accordance with the Accounting Standards in effect in the country in which such Third Party is engaged. Licensee retains the right to modify its policies and practices to comply with specific changes in the Accounting Standards and as otherwise deemed necessary or appropriate by Licensee but shall not do so solely to reduce the amount of payments due to Coherus hereunder. Where Coherus notifies Licensee that the change is material to Coherus, Licensee shall provide an explanation of the change and an accounting of the effect of the change on the relevant revenue, cost, or expense category.
- (c) In the event of the payment or receipt of non-cash consideration in connection with the performance of activities under this Agreement, Licensee shall advise Coherus of such transaction, including Licensee's assessment of the fair market value of such non-cash consideration and the basis therefor. Such transaction shall be accounted for on a cash equivalent basis, as mutually agreed by the Parties in good faith.
- **7.7 Withholding Tax.** Licensee shall bear any and all taxes required to be paid on amounts due to Coherus, and Licensee shall not be entitled to deduct such payments from such amounts payable to Coherus under **Section 7.1 (Payment Structure)**. For clarity, amounts due to Coherus under **Section 7.1** shall be based on amounts due to Coherus prior to any deduction as a result of taxes payable by Licensee. Coherus shall reasonably cooperate with Licensee to facilitate appropriate proceedings required by tax authorities in the Territory relating to the payments hereunder.

7.8 Audit Request. Each Party shall, at its sole cost and expense (except as provided below), have the right one (1) time each Calendar Year to audit, during regular business hours and upon not less than fifteen (15) days prior written notice to the other Party, the books and records maintained by such other Party to determine with respect to any Calendar Year, the accuracy of any report or payment made or expense charged by one Party to the other under this Agreement in the [***] Calendar Years. If a Party desires to audit such records, it shall engage an independent, certified public accountant reasonably acceptable to the other Party, to examine such records under conditions of confidentiality. Such accountant shall be instructed to provide to the auditing Party are report verifying any report made or payment submitted or expense charged by the other Party during such period, but shall not disclose to the auditing Party any Confidential Information of the other Party not necessary to be disclosed. The expense of such audit shall be borne by the auditing Party; provided, however, that, if an error of more than five percent (5%) is discovered, then such expenses shall be paid by the other Party. If such accountant concludes that additional payment amounts were owed or additional expenses were charged to the auditing Party during any period, the other Party shall pay such payment amount (including interest thereon pursuant to Section 7.9 (Interest) from the date such amounts were payable) within thirty (30) days after the date the auditing Party delivers to the other Party such accountant's written report so concluding, unless such other Party notifies the auditing Party of any dispute regarding the audit and commences proceedings under Article 14 (DISPUTE RESOLUTION) within thirty (30) days after delivery of the accountant's report (in which case the payment shall be delayed until conclusion of the proceeding). Such auditors shall not be paid on a contingency basis.

7.9 Interest. Interest shall be payable: (a) on any payments that are not paid on or before the date such payments are due under this Agreement calculated based on the total number of days payment is delinquent and (b) on any errors identified pursuant to the audit conducted pursuant to Section 7.8 (Audit Request) calculated from the date such payments were originally made at [***], or the maximum applicable legal rate, if less.

8. INTELLECTUAL PROPERTY AND INVENTIONS.

- **8.1 Intellectual Property.** Except as otherwise expressly set forth in this Agreement, neither Party grants to the other Party any right, title, or interest in any Patent, Patent Application, Information, Trademark, or other intellectual property right Controlled by such Party.
- **8.2 Disclosure.** Each Party shall promptly disclose to the other Party any Inventions that it or its employees, sublicensees, Affiliates, independent contractors or agents solely or jointly make, conceive, reduce to practice, author, or otherwise discover in the course of activities performed under or contemplated by this Agreement.

8.3 Ownership of Inventions.

(a) Generally.

- (i) Subject to the license granted in Section 2.1(a) (Development and Commercialization License to Licensee), and as between Coherus and Licensee, Coherus owns: (a) all Coherus Inventions (b) any Joint Inventions to the extent such Joint Inventions relate [***] (the "Coherus-Owned Joint Inventions") and (c) any Licensee Inventions to the extent such Licensee Inventions relate [***] (the "Coherus-Owned Licensee Inventions").
- (ii) Subject to the license granted in Section 2.1(b) (Licenses to Coherus), and as between Coherus and Licensee, Licensee owns all Licensee Inventions (excluding Coherus-Owned Licensee Inventions).
- (iii) Each Party owns an undivided one half (1/2) interest in: (a) all Joint Inventions (excluding the Coherus-Owned Joint Inventions) and (b) all Patents and Patent Applications claiming all Joint Inventions (excluding those Patents and Patent Applications for the Coherus-Owned Joint Inventions). Coherus' interest in any Patents and Patent Applications covering Joint Inventions shall be included in the Coherus Patent Rights, and Licensee's interest in any Patents and Patent Applications covering Joint Inventions shall be included in the Licensee Patent Rights.
- **(b) Ownership Disputes.** The [***] shall attempt in good faith to resolve any disputes arising hereunder regarding ownership of Inventions, Patents and any other intellectual property. In the event the [***] is unable to resolve such dispute within thirty (30) days after its receipt of notice of the dispute, the dispute resolution procedure set forth in Article 14 (Dispute Resolution) shall apply.
- (c) Assignment and Perfection of Interests. Without additional consideration, each Party hereby assigns to the other Party such of its right, title, and interest in and to any Inventions, Patents, and Patent Applications claiming them, and all other intellectual property rights therein, and shall require its sublicensees and Affiliates, and all independent contractors, employees, or agents of such Party, its Affiliates, or its sublicensees to so assign to the other Party such of their right, title, and interest in and to Inventions as set forth in this Section 8.3. Each Party shall, and shall cause its sublicensees and Affiliates, and all independent contractors, employees, and agents of such Party, its Affiliates, or its sublicensees to, cooperate with the other Party and take all reasonable additional actions and execute such agreements, instruments, and documents as may be reasonably required to perfect the other Party's right, title, and interest in and to Inventions, Patents, and Patent Applications and other intellectual property rights thereon or therein as such other Party has pursuant to this Section 8.3. If a Party is unwilling or unable to execute any such agreements, instruments, and documents, it hereby appoints the other Party as its attorney-in-fact, which shall be coupled with an interest, to execute the same on its behalf. Each Party shall also include provisions in its relevant agreements with Third Parties that effect the intent of this Section 8.3(c).

- **8.4 Individual Patent Filings.** Each Party will, to the maximum extent practicable, strive to separate any claims within Patents and Patent Applications that claim Inventions into separate Patents and Patent Applications consisting of claims that claim solely Coherus Inventions, solely Licensee Inventions, or solely Joint Inventions.
- (a) Solely Owned Inventions. Coherus shall have sole discretion and responsibility to prepare, file, prosecute, and maintain any and all Patents and Patent Applications within the Coherus Patent Rights. Licensee shall have sole discretion and responsibility to prepare, file, prosecute, and maintain any and all Patents and Patent Applications within the Licensee Patent Rights. At least sixty (60) days prior to the contemplated filing date of any Patent Application in the Territory claiming a Party's solely-owned Invention, such Party [***], [***], and [***], and shall [***] with respect to such Patent Application. Licensee shall [***] pursuant to this Section 8.4(a) for Patents and Patent Applications within the Licensee Patent Rights, and Coherus shall [***] pursuant to this Section 8.4(a) for Patents and Patent Applications Patent Rights.
- (b) Opt-In Rights. If a Party elects, in any country of the Territory, not to file or not to continue to prosecute and thereby abandon a Patent or Patent Application within the patent rights licensed to the other Party under this Agreement, or not to maintain and thereby abandon such a Patent or Patent Application, without the intent to file a continuing or divisional filing or an equivalent thereof or upon advice of patent counsel to optimize the overall patent protection on the Product or Process Development, such Party (the "Opting-Out Party") shall notify the other Party (the "Opting-In Party") not less than thirty (30) days before any relevant deadline, and thereafter such Opting-In Party shall have the right, but not the obligation, to pursue, [***] preparation, filing, prosecution, and maintenance of such Patent or Patent Application; provided, however, that the Opting-In Party provides the Opting-Out Party with [***] at least thirty (30) days prior to the proposed submission date and such Opting-Out Party determines [***] that any such submission will not prejudice any other Patents and Patent Applications of such Opting-Out Party.

8.5 Joint Patent Filings. With respect to all Patents and Patent Applications claiming Joint Inventions, but not Coherus Inventions (the "Joint Patent Rights"), Coherus shall have the first right, but not the obligation, to file, prosecute, maintain, and defend such Joint Patent Rights on behalf of both Parties (the "Responsible Party"). At least sixty (60) days prior to the contemplated filing of any Joint Patent Right, Coherus shall submit a substantially completed draft of such Joint Patent Right to Licensee for its approval, which shall not be unreasonably withheld, delayed, or conditioned. Except as set forth in this Section 8.5, below, the Parties shall [***], pursuant to [***] ([***]). If Coherus does not wish to file, prosecute, or maintain any Joint Patent Right or maintain or defend such a Joint Patent Right in a particular country, it shall grant Licensee any necessary authority to file, prosecute, and maintain such Joint Patent Right or maintain or defend such Joint Patent Right in the name of both Parties if Licensee so requests. If either Party elects [***], it shall so notify the other Party, in which case the other Party may proceed with respect to such Joint Patent Right in its own name [***]. In such case, the [***] shall [***] such Joint Patent Right [***].

8.6 Defense of Infringement Claims by Third Parties.

(a) In the event of the institution or threatened institution of any suit by a Third Party against Licensee for infringement involving Commercialization, Licensee shall have the right to defend such suit at its own expense and shall be responsible for all damages (including lost profits) incurred as a result thereof. Coherus hereby agrees to assist and cooperate with Licensee, at Licensee's reasonable request, and Licensee shall reimburse Coherus any reasonable, documented, out-of-pocket costs incurred in connection therewith. Licensee shall solely control the defense of such a claim and shall also have the right to control settlement of such claim; *provided, however*, that any such settlement shall not adversely affect Coherus' rights or interests without Coherus' prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. Subject to such control, Coherus may join any defense and settlement pursuant to this **Section 8.6 with its own counsel at its sole cost.**

- **(b)** In the event of the institution or threatened institution of any suit by a Third Party against Coherus for infringement involving the development, Manufacture, or Commercialization of the Product in the Territory, Coherus shall have the right to defend such suit at its own expense and shall be responsible for all damages incurred as a result thereof. Licensee hereby agrees to assist and cooperate with Coherus, at Coherus' reasonable request, and Coherus shall reimburse Licensee any reasonable, documented, out-of-pocket costs incurred in connection therewith. Coherus shall solely control the defense of such a claim and shall also have the right to control settlement of such claim; *provided, however*, that any such settlement shall not adversely affect Licensee's rights or interests without Licensee's prior written consent, which shall not be unreasonably withheld, delayed, or conditioned. Subject to such control, Licensee may join any defense and settlement pursuant to this **Section 8.6** with its own counsel at its sole cost.
- (c) If such Third Party asserts that a patent or other intellectual property right owned by it is infringed by the Development, Manufacture or Commercialization of the Product in the Territory by both of the Parties, then the Parties shall meet and confer, and both Parties shall have the sole right to defend against any such assertions with respect to its activities at its respective sole cost. Regardless of which Party is the defending Party (or if both Parties are a defending Party), the defending Party shall seek and reasonably consider the other Party's comments before determining the strategy for such matter. Without limiting the foregoing, the defending Party shall keep the other Party advised of all material communications and actual and prospective filings or submissions regarding such action, and shall provide the other Party copies of and an opportunity to review and comment on any such communications, filings and submissions before delivered or filed. Each Party shall keep the other reasonably informed of all claims and actions governed by this Section 8.6.
- (d) In the event the Parties mutually agree that a settlement of any suit involving payment of prospective royalties is reasonable and necessary for continued Commercialization of Product in the Territory, the Parties shall consult in good faith and discuss a mutually satisfactory basis for sharing responsibility for such prospective royalties. In the absence of such agreement, the Parties shall share responsibility for such royalties as described in Exhibit 7.1 (Payment Structure).
- (e) In the event Licensee is required to pay damages and/or lost profits pursuant to paragraph (a) above, Licensee shall be entitled to deduct from Coherus Royalty payments up to [***] of the amount of such damages and/or lost profits; *provided, however*, the amount of such deduction applied by Licensee when added to any Third Party Payments in any given Calendar Quarter shall not reduce the Coherus Royalty payment by more than [***] in such Calendar Quarter.

8.7 Enforcement Actions Against Third Parties.

- (a) If either Party learns of an infringement, unauthorized use, misappropriation, ownership claim, threatened infringement, or other similar claim by a Third Party with respect to the Coherus Patent Rights or Coherus Know-How in the Territory, such Party shall promptly notify the other Party in writing and shall promptly provide such other Party with available evidence of such infringement or other such claim.
- (b) Coherus shall have the first right, but not the obligation, to institute an infringement suit or take other appropriate action against such Third Party in the Territory. If Coherus does not secure actual cessation of such infringement, misappropriation or institute a proceeding (which may include sending a cease and desist letter if appropriate) against an offending Third Party with respect to infringement of such Coherus Patent Rights or misappropriation of such Coherus Know-How as a result of the development, manufacture, commercialization or use of a product that is competitive with the Product in the Territory ("Enforcement Action"), Coherus shall notify Licensee as soon as reasonably practicable but in any case no later than sixty (60) days of learning of such infringement. Upon receipt of such notice or absent such notice within such sixty (60) days, Licensee shall have the right at its sole discretion to institute an Enforcement Action in the name of either or both Parties. Each Party shall execute all necessary and proper documents, take such actions as shall be appropriate to allow the other Party to institute and prosecute such infringement actions and shall otherwise cooperate in the institution and prosecution of such actions (including consenting to being named as a nominal party thereto).
 - (c) The costs and expenses of any such Enforcement Action (including fees of attorneys and other professionals) shall be borne [***].

9. REPRESENTATIONS, WARRANTIES, AND COVENANTS.

- 9.1 Mutual Representations and Warranties. Each Party represents and warrants to the other, as of the Effective Date, as follows:
- (a) such Party is a corporation duly organized, validly existing and in good standing under the laws of the jurisdiction of its organization, and has all requisite power and authority, corporate or otherwise, to execute, deliver and perform this Agreement;
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (b) the execution and delivery of this Agreement and the performance by such Party of the transactions contemplated hereby have been duly authorized by all necessary corporate action and will not violate: (i) such Party's certificate of incorporation or bylaws, (ii) any agreement, instrument or contractual obligation to which such Party is bound in any material respect, (iii) any requirement of any Applicable Laws, or (iv) any order, writ, judgment, injunction, decree, determination or award of any court or governmental agency presently in effect applicable to such Party;
- (c) this Agreement is a legal, valid and binding obligation of such Party enforceable against such Party in accordance with its terms and conditions:
- (d) such Party is not under any obligation, contractual or otherwise, to any person or entity that conflicts with or is inconsistent in any respect with the terms of this Agreement or that would impede the diligent and complete fulfillment of its obligations hereunder;
- (e) to such Party's knowledge, all of its employees, officers, contractors, and consultants have executed agreements requiring assignment to such Party of all Inventions made during the course of and as a result of their association with such Party and obligating each such employee, officer, contractor, and consultant to maintain as confidential the Confidential Information of such Party; and
- (f) neither such Party, nor any of its employees, officers, subcontractors or consultants who have rendered or will render services relating to the Product: (i) has ever been debarred (or is subject to debarment) or convicted of a crime for which an entity or person could be debarred under 21 U.S.C. Section 335a or its foreign equivalent or (ii) has ever been under indictment for a crime for which a person or entity could be debarred under any such provision.
 - 9.2 Additional Representations, Warranties, and Covenants of Coherus. Coherus hereby represents, warrants, and covenants to Licensee that:
 - (a) as of the Effective Date, Coherus is entitled to grant the rights and licenses granted to Licensee as set forth in this Agreement;
- **(b)** Coherus has not granted in the Territory as of the Effective Date, and will not grant during the Term, any right or license in or to any of the Coherus Patent Rights in the Territory that is in conflict with the rights or licenses granted to Licensee under this Agreement;
- (c) Coherus has not granted in the Territory as of the Effective Date, and will not knowingly grant during the Term, any right or license in or to any of the Coherus Know-How in the Territory that is in conflict with the rights or licenses granted to Licensee under this Agreement;

- (d) Coherus has not granted any liens or security interests to the Coherus Know-How or Coherus Patent Rights other than under any licenses or sublicenses;
- (e) there are no existing or, to the knowledge of Coherus, threatened, actions, suits or claims pending with respect to the right of Coherus to enter into and perform its obligations under this Agreement;
- **(f)** Coherus has not received, with respect to the Coherus Know-How or Coherus Patent Rights, any written notice of infringement or misappropriation or any other written communication relating to an alleged infringement or misappropriation of any patent rights or any know-how Controlled by a Third Party; and

(g) [***].

- 9.3 Additional Representations, Warranties, and Covenants of Licensee. Licensee hereby represents, warrants, and covenants to Coherus that:
 - (a) as of the Effective Date, Licensee is entitled to grant the rights and licenses granted to Coherus as set forth in this Agreement;
- **(b)** Licensee has not granted in the Territory as of the Effective Date, and will not grant during the Term, any right or license in or to any of the Licensee Patent Rights or Grant-Back IP that is in conflict with the rights or licenses granted to Coherus under this Agreement;
- (c) Licensee has in place policies related to ensuring that its business operations and practices are compliant with all Applicable Laws in the United States and the Territory relating to anti-corruption, including the Foreign Corrupt Practices Act of 1977, as amended, and those enacted to implement the OECD Convention on Combating Bribery of Foreign Officials in International Business Transactions. Coherus acknowledges that Licensee has provided to Coherus prior to the Effective Date copies of the following Licensee policies: (a) International Anticorruption Policy, (b) International Anticorruption Third Party Policy and (c) Code of Conduct (collectively, as such may be amended from time to time in accordance with Licensee's customary practices, the "Policies and Codes");
- (d) Licensee will use best efforts to ensure that, throughout the Term, it, its Affiliates, Sublicensees and agents comply with the Policies and Codes;
- (e) At Coherus' reasonable request (including to permit Coherus to respond to inquiries regarding compliance with Applicable Laws), Licensee shall promptly provide to Coherus then-current copies of the Policies and Codes; and
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

(f) Licensee shall use best efforts to ensure that any Third Party who represents Licensee or its Affiliates in connection with, or who will be involved in performing, this Agreement or any related activity, shall certify to compliance with all applicable anti-corruption laws and the obligations set forth in the Policies and Codes prior to any involvement in this Agreement or any related activity.

9.4 Additional Covenants of the Parties. Each Party hereby covenants to the other Party that:

- (a) if, during the Term, such Party has reason to believe that it or any of its employees, officers, subcontractors, or consultants rendering services relating to the Product: (a) is or will be debarred, excluded under any United States federal healthcare programs or convicted of a crime under 21 U.S.C. Section 335a or the foreign equivalent thereof, or (b) is or will be under indictment under any such provision, then such Party shall immediately notify the other Party in writing;
- (b) all of such Party's employees and officers involved in development of the Product shall be obligated to assign to such Party all Inventions and to maintain as confidential any and all Confidential Information; and
- (c) it shall, in performing the activities contemplated to be performed by it under this Agreement, including those in connection with the Development, Process Development, Manufacturing and Commercialization, and shall ensure that each of its Affiliates, subcontractors and agents shall, comply with all Applicable Laws.
- **9.5 Covenant Not to Challenge Patents.** Licensee hereby covenants: (a) not to challenge the validity, scope, or enforceability of or otherwise oppose any Patent or Patent Application included in the Coherus Patent Rights or any foreign counterparts thereof; (b) that it shall include in all of its sublicense agreements relating to the Product the obligation binding on the Sublicensee under such sublicense agreement not to challenge the validity, scope, or enforceability of or otherwise oppose any such Patent or Patent Application; (c) that it shall include provisions in all sublicense agreements relating to the Product providing that, if the Sublicensee challenges the validity, scope, or enforceability of or otherwise opposes any such Patent or Patent Application, Licensee shall have the right to terminate such sublicense agreement, and such Sublicensee shall no longer have any rights under any such Patent or Patent Application. In the event that all or any portion of this **Section 9.5** is determined to be invalid, illegal, or unenforceable, then the Parties will use their best efforts to replace the invalid, illegal, or unenforceable provision(s) with valid, legal, and enforceable provision(s).

10. INDEMNIFICATION AND INSURANCE.

10.1 Coherus' Right to Indemnification. Licensee shall indemnify, defend, and hold harmless Coherus and its Affiliates, and their respective officers, directors, employees, agents, and their respective successors, heirs and assigns and representatives (the "Coherus Indemnitees"), from and against any and all damages, losses, suits, proceedings, liabilities, costs (including reasonable legal expenses, costs of litigation and reasonable attorney's fees), or judgments, whether for money or equitable relief, of any kind ("Damages") resulting from Third Party claims or actions, to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness, or wrongful intentional acts or omissions of Licensee, its Affiliates, and/or its Sublicensees and its or their respective directors, officers, employees, and agents, in connection with Licensee's performance of its obligations or exercise of its rights under this Agreement; (b) any breach by Licensee of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) the Development, Commercialization, transfer, importation or exportation, labeling, handling or storage, or use of, or exposure to, the Product by or for Licensee or any of its Affiliates, Sublicensees, agents, and contractors in the Territory; and (d) the failure by Licensee, or any of its Affiliates, Sublicensees, agents, or subcontractors to comply with Applicable Laws or the failure of Licensee, or any of its Affiliates, Sublicensees, agents, or subcontractors to materially comply with Policies and Codes then in effect; except in any such case for Damages to the extent reasonably attributable to any Coherus Indemnitee:

(i) having committed an act or acts of negligence, recklessness, or willful misconduct; (ii) having failed to materially comply with Applicable Laws;

(iii) having materially breached this Agreement; or (iv) to the extent such Damages result from or arise out of any act or omission for which Coherus is found to have an indemnity obligat

10.2 Licensee's Right to Indemnification. Coherus shall indemnify, defend, and hold harmless Licensee and its Affiliates, and their respective officers, directors, employees, agents, licensors, and their respective successors, heirs and assigns and representatives (the "Licensee Indemnitees"), from and against any and all Damages resulting from Third Party claims or actions, to the extent arising out of or relating to, directly or indirectly: (a) the negligence, recklessness, or wrongful intentional acts or omissions of Coherus and its Affiliates and its or their respective directors, officers, employees, and agents, in connection with Coherus' performance of its obligations or exercise of its rights under this Agreement; (b) any breach by Coherus of any obligation, representation, warranty, or covenant set forth in this Agreement; (c) the development (including Development), commercialization, transfer, importation or exportation, Manufacture, labeling, handling or storage, or use of, or exposure to, the Product by Coherus or any of its Affiliates, Sublicensees, agents, and contractors outside of the Territory; (d) [***] by Coherus or any of its Affiliates, sublicensees, agents, and contractors inside or outside of the Territory, and (e) the failure to comply with Applicable Laws by Coherus, or any of its Affiliates, agents, or subcontractors; except in any such case for Damages to the extent reasonably attributable to any Licensee Indemnitee (i) having committed an act or acts of negligence, recklessness or willful misconduct; (ii) having failed to materially comply with Applicable Laws; (iii) having materially breached this Agreement; or (iv) to the extent such Damages result from or arise out of any act or omission for which Licensee is found to have an indemnity obligation under Section 10.1 (Coherus' Right to Indemnification).

10.3 Process for Indemnification. A claim to which indemnification applies under Section 10.1 (Coherus' Right to Indemnification) or Section 10.2 (Licensee's Right to Indemnification) shall be referred to herein as an "Indemnification Claim". If a party intends to claim indemnification under Section 10.1 or Section 10.2, such Party (the "Indemnitee") shall notify the other Party (the "Indemnitor") in writing promptly upon becoming aware of any claim that may be an Indemnification Claim (it being understood and agreed, however, that the failure by an Indemnitee to give such notice shall not relieve the Indemnitor of its indemnification obligation under this Agreement except and only to the extent that the Indemnitor is actually prejudiced as a result of such failure to give notice). The Indemnitor shall have the right to assume and control the defense of the Indemnification Claim at its own expense with counsel selected by the Indemnitor and reasonably acceptable to the Indemnitee; provided, however, that the Indemnitee shall have the right to retain its own counsel, with the fees and expenses to be paid by the Indemnitee, if representation of such Indemnitee by the counsel retained by the Indemnitor would be inappropriate due to actual or potential differing interests between such Indemnitee and any other party represented by such counsel in such proceedings. If the Indemnitor does not assume the defense of the Indemnification Claim as described in this Section 10.3 above, the Indemnitee may defend the Indemnification Claim but shall have no obligation to do so. The Indemnitee shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitor, and the Indemnitor shall not settle or compromise the Indemnification Claim without the prior written consent of the Indemnitee's interests, without the prior written consent of the Indemnitee shall reasonably cooperate with the Indemnitor at the Indemnitor's expense and shall make available to the Indemnitor all pertinent informa

10.4 Insurance. During the Term and for five (5) years thereafter, each Party shall maintain, at its sole expense, such types of insurance coverage as is appropriate and customary in the biopharmaceutical industry in light of the nature of the activities to be performed by such Party hereunder; *provided*, *however*; that Licensee shall have the right to self-insure. Such insurance shall be in such amounts and subject to such deductibles as are prevailing in the biosimilar industry from time to time, provided that, each Party shall maintain a minimum of an aggregate of [***] and [***] in general comprehensive liability insurance and an aggregate of: (a) [***] in product liability insurance until receipt of the first Regulatory Approval in a country in the Territory; and (b) [***] in product liability insurance (or such other amount as is mutually agreed upon by the Parties) no later than thirty (30) days following receipt of the first Regulatory Approval in a country in the Territory.

11. CONFIDENTIALITY.

- 11.1 Confidentiality; Exceptions. Except to the extent expressly authorized by this Article 11 or otherwise agreed in writing, each Party hereby agrees that, during the Term and for five (5) years thereafter, it shall keep confidential and shall not publish or otherwise disclose or use for any purpose other than as explicitly provided for in this Agreement any confidential and proprietary information or materials, patentable or otherwise, in any form (written, oral, photographic, electronic, magnetic, or otherwise) which is disclosed to it by the other Party or otherwise received or accessed by a Party under this Agreement [***], including any trade secrets, know-how, Product specifications, formulae, processes, techniques and information relating to a Party's past, present and future marketing, financial, and research and development activities for any product of the other Party and the pricing thereof (collectively, "Confidential Information"). Notwithstanding the foregoing, any Confidential Information that constitutes a trade secret shall not be subject to such five (5) year term, but shall continue to be subject to the obligations of confidentiality and non-use set forth in this Agreement for as long as such Confidential Information remains a trade secret under New York law (including New York's version of the Uniform Trade Secrets Act if and when adopted). The terms and conditions of this Agreement shall be deemed to be Confidential Information of each Party. In addition, and notwithstanding the foregoing, if, under Article 8 (INTELLECTUAL PROPERTY AND INVENTIONS), Information relating specifically to Inventions and discoveries are to be owned by one Party, such Information shall be deemed to be Confidential Information of such Party, even if such Information or materials that a Party can demonstrate by contemporaneous written records:
- (a) is already lawfully known to such Party, other than under an obligation of confidentiality at the time of disclosure by the other Party as evidenced by written records kept in the ordinary course of business, or other documentary proof of actual use by such Party;
 - (b) is generally available to the public or otherwise part of the public domain at the time of its disclosure to such Party;
- (c) becomes generally available to the public or otherwise part of the public domain after its disclosure to such Party and other than through any act or omission of such Party or its Affiliates in violation of this Agreement;
- (d) is independently developed by such Party as demonstrated by documented evidence prepared contemporaneously with such independent development; or
- (e) is lawfully disclosed to such Party, other than under an obligation of confidentiality, by a Third Party who had no obligation not to disclose such information to others.
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- 11.2 Degree of Care; Permitted Use. Each Party shall take reasonable steps to maintain the confidentiality of the Confidential Information of the other Party, which steps shall be no less protective than those steps that such Party takes to protect its own Information and materials of a similar nature, but in no event less than a reasonable degree of care. Neither Party shall use or permit the use of any Confidential Information of the other Party except for the purposes of carrying out its obligations or exercising its rights under this Agreement, and neither Party shall copy any Confidential Information of the other Party except as may be reasonably useful or necessary for such purposes. All Confidential Information of a Party, including all copies and derivations thereof, is and shall remain the sole and exclusive property of the disclosing Party and subject to the restrictions provided for herein. Neither Party shall disclose any Confidential Information of the other Party other than to [***].
- 11.3 Authorized Disclosure. Notwithstanding Section 11.1 (Confidentiality; Exceptions) and Section 11.2 (Degree of Care; Permitted Use), each Party may disclose Confidential Information of other Party:
 - (a) in its publicly-filed financial statements or other public statements to the extent required by Applicable Laws; provided, however, that: [***];
 - (b) to the extent it is required to be disclosed in response to a valid order by a court or other governmental body and provided that [***];
- (c) to the extent it is required to be disclosed in connection with any legal or regulatory requirements or obligations, including SEC filings or Regulatory Filings inside or outside the Territory; *provided, however,* [***];
- [***] Certain information in this document has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.

- (d) to Regulatory Authorities to facilitate the issuance of Regulatory Approvals or receipt of Pricing and Reimbursement Approvals inside or outside the Territory; provided, however, that reasonable measures shall be taken to assure confidential treatment of such Confidential Information;
 - (e) [***]
 - (f) to Third Parties in connection with such Party's efforts to secure financing or enter into strategic partnerships; provided, however, [***].

11.4 Publications.

- (a) In the event either Party proposes a publication or presentation to a Third Party that includes Confidential Information of the other Party relating to the Product in the Territory, or which otherwise includes Confidential Information of the other Party, such Party shall first submit to [***] an early draft of such publication or presentation, whether they are to be presented orally or in written form, prior to submission for publication or presentation. [***] shall review such proposed publication or presentation in order to avoid the unauthorized disclosure of its Confidential Information and to preserve the patentability of Inventions and shall, as soon as reasonably possible, inform such Party if its proposed publication or presentation:
- (i) contains Confidential Information of the other Party, in which case such Party shall delete such Confidential Information from its proposed publication or presentation; or
- (ii) could be expected to have a material adverse effect on any Patent or Information of the other Party, then such Party shall delay such proposed publication or presentation sufficiently long to permit the timely preparation and first filing of Patent Application(s) on the Information involved.
 - (b) This Section 11.4 shall not apply to any disclosures pursuant to Section 11.3 (Authorized Disclosure).

11.5 Press Releases; Publicity. Except with respect to (i) the press release which will be attached hereto as Exhibit 11.5 (which shall be issued by the Parties at a mutually agreed upon time following execution of this Agreement), and (ii) the matters listed in Exhibit 11.5A which Coherus may disclose to potential investors, collaboration partners, and underwriters on a non-confidential basis, no press release or public announcement shall be made by either Party concerning the execution of this Agreement or the terms and conditions hereof without [***]. Notwithstanding the foregoing, either Party may disclose the existence of this Agreement and the terms and conditions hereof without the prior written consent of the other in connection with a due diligence process associated with any future financing by either Party or the negotiation or exploration of a possible strategic transaction involving such Party; provided that such disclosure is made in the course of such diligence, negotiation or exploration pursuant to confidentiality obligations consistent with those set forth in this Agreement. Each Party may issue a press release or public announcement concerning the development of the Product, provided that such Party shall provide the other Party with a copy of such press release or public announcement at least ten (10) days in advance of its intended publication or release thereof and shall consider in good faith the comments of the other Party which comments shall be provided as promptly as reasonably practicable following receipt of the press release or public announcement from the Party desiring to make the disclosure. Further, each Party agrees that it shall cooperate fully and in a timely manner with the other Party with respect to all disclosures required by the Securities and Exchange Commission of the United States and any other Regulatory Authority, including requests for confidential treatment of Confidential Information of either Party included in any such disclosure. Notwithstanding the foregoing, either Party may issue any public announcement that it is advised by legal counsel is required under applicable Laws, provided that such Party provides to the other Party a copy of such press release or public announcement not less than two (2) business days in advance of its release if legally permissible. In the event [***] wishes to disclose information in its non-confidential discussions with potential investors, partners and underwriters which is not [***], [***] shall seek [***] written consent for such disclosure and [***] shall consider [***] request in good faith, such consent not to be unreasonably withheld, conditioned or delayed.

11.6 Irreparable Injury. The Parties acknowledge that either Party's breach of this Article 11 would cause the other Party irreparable injury for which it would not have an adequate remedy at law. In the event of a breach, the nonbreaching Party may seek injunctive relief, whether preliminary or permanent, in addition to any other remedies it may have at law or in equity, without necessity of posting a bond.

12. TERM AND TERMINATION.

12.1 Term. The term of this Agreement shall commence on the Effective Date and, unless sooner terminated or extended as specifically provided in this Article 12, shall continue in effect until the tenth (10th) anniversary of the Effective Date (the "Initial Term").

12.2 Extension of Term. If this Agreement has not been earlier terminated with respect to a particular country in the Territory during the Term (including any renewal Periods), the Term for each such non-terminated country shall, at Licensee's discretion, be extended for an additional period of three (3) years (each, a "Renewal Period" and, together with the Initial Term, the "Term"); provided, however, that the JSC has approved the Commercialization Plan for the applicable country/ies in the six (6) months immediately preceding the tenth (10th) anniversary of the Effective Date or in the six (6) months immediately preceding the last day of the third year of a Renewal Period.

12.3 Termination by Licensee.

- (a) Opt Out Termination. Licensee shall have the right to terminate this Agreement (in its entirety or on a country-by-country basis as set forth below) by providing written notice to Coherus during the applicable window noted below if Licensee concludes in good faith that: (1) the Development and/or Commercialization in the Territory or such country in the Territory, as applicable, is not commercially viable, and/or (2) there are material safety, efficacy or patient tolerability issues with the Product that cannot be remedied or overcome as follows:
 - (i) Solely with respect to the entire Territory, within the Product Opt-Out Period; or
 - (ii) Solely with respect to the entire Territory, within three (3) months following the later to occur of receipt by Licensee of the Clinical Study Report for (A) the Global RA Study and (B) the Global Psoriasis Study; or
 - (iii) With respect to one or more countries in the Territory, within one (1) month following submission by Licensee of the Regulatory Approval Application for the Product in such country/ies; or
 - (iv) With respect to one or more countries in the Territory, within ten (10) days following the later to occur of: (A) receipt of Regulatory Approval (if such approval does not include Pricing and Reimbursement Approvals) or (B) receipt of Pricing and Reimbursement Approvals of the Product in such country/ies; or
 - (v) Licensee shall have the right to terminate this Agreement (in its entirety or with respect to a country within the Territory, as applicable) following the occurrence of each milestone.

For the avoidance of doubt, the provisions of **Section 2.4** allowing Licensee to consider alternative programs during the Initial and/or Second Review Periods shall survive termination of this Agreement.

(b) Other Licensee Termination. Licensee shall also have the right to terminate this Agreement in its entirety, in its sole discretion, as follows:

- (i) After First Commercial Sale in the Territory, without cause upon eighteen (18) months prior written notice to Coherus; or
- (ii) At any time if the aggregate expenses for which Licensee is responsible pursuant to Section 4.1(d)(i) (Global RA Study) and Section 4.1(d)(ii) (Clinical Trials) are reasonably expected to exceed [***]; or
- (iii) At any time if the aggregate expenses for which Licensee is responsible pursuant to Section 4.1(d)(ii)(3) (Process Development and Manufacture Supporting Clinical Trials and Launch) are reasonably expected to exceed [***]; or
- (iv) If by [***], the Manufacturing Cost exceeds [***] for one (1) filled, finished, released, labeled dosage form [***]; provided, however, such Manufacturing Cost shall be adjusted each January 1 occurring after the Effective Date [***]; or
- (v) If by [***], the Manufacturing Cost exceeds [***] for one (1) filled, finished, released, labeled dosage form [***]; provided, however, such Manufacturing Cost shall be adjusted each January 1 occurring after the Effective Date [***].
- 12.4 Termination by Coherus. Coherus shall have the right to terminate this Agreement immediately upon written notice to Licensee in the event that Licensee or any of its Affiliates challenges in a court of competent jurisdiction, the validity, scope or enforceability of, or otherwise opposes, any Patent included in the Coherus Patent Rights. If a Sublicensee of Licensee or its Affiliate challenges the validity, scope or enforceability of or otherwise opposes any Patent included in the Coherus Patent Rights under which such Sublicensee is sublicensed, then Licensee or its Affiliate, as applicable, shall provide written notice to Coherus and shall promptly terminate the sublicense agreement but, for the avoidance of doubt, such challenge by a Sublicensee, unless directed by Licensee, shall not be grounds for termination of this Agreement by Coherus.

- 12.5 Termination for Material Breach. If either Party believes the other Party is in material breach of this Agreement (which shall include any breach of any payment obligation hereunder), it shall give notice of such breach to such other Party, and such other Party shall have ninety (90) days in which to remedy any such material breach, or ten (10) Business Days in the case of breach (whether material or not) of any payment obligation hereunder. If such alleged breach is not remedied in the time period set forth above, the nonbreaching Party shall be entitled, without prejudice to any of its other rights conferred on it by this Agreement, and in addition to any other remedies available to it by law or in equity, to terminate this Agreement upon written notice to the other Party. In the event of a dispute regarding any payments due and owing hereunder, all undisputed amounts shall be paid when due, and the balance, if any, shall be paid promptly after settlement of the dispute, including any accrued interest thereon pursuant to Section 7.9. Subject to foregoing (including the right to cure), if Licensee does not materially comply with the obligations set forth in Section 6.1 (Efforts) with respect to Commercialization in each of the Major EU Countries, Canada, Brazil, China and Australia, Coherus shall have the right to terminate the Agreement with respect to such country, and Section 12.7 (Consequences of Expiration or Termination) shall apply with respect to the Product in such terminated country.
- 12.6 Termination Upon Insolvency. To the extent permitted under Applicable Laws, either Party may terminate this Agreement if, at any time, the other Party: (a) files in any court or agency pursuant to any statute or regulation of any state or country, a petition in bankruptcy or insolvency or for reorganization or for an arrangement or for the appointment of a receiver or trustee of such other Party or of its assets, (b) proposes a written agreement of composition or extension of its debts, (c) is served with an involuntary petition against it, filed in any insolvency proceeding, and such petition shall not be dismissed within forty-five (45) days after the filing thereof, (d) proposes or is a party to any dissolution or liquidation, or (e) makes an assignment for the benefit of its creditors.

12.7 Consequences of Expiration or Termination.

- (a) Consequences of Termination of this Agreement with Respect to One or More Country(ies) but Not in the Entire Territory. Upon early termination of this Agreement by Licensee pursuant to Section 12.3 (Termination by Licensee) or by Coherus pursuant to Section 12.5 (Termination for Material Breach) with respect to a country (but not all countries in a Territory):
 - (i) the licenses granted to Licensee pursuant to Section 2.1 (License Grants) and Section 6.3 (Trademarks) with respect to the Product shall terminate in such terminated country, except as otherwise necessary to conduct the activities expressly set forth in Section 12.7(a)(ii);
 - (ii) promptly after the effective date of such termination, Licensee shall commence winding down its Development and Commercialization activities for such country under the oversight of the JSC, and shall complete any and all such wind-down Development and Commercialization activities within three (3) months after the effective date of such termination;

- (iii) Licensee shall and hereby does grant to Coherus, effective as of the effective date of such termination, the exclusive, perpetual, royalty-free, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP to develop, make, have made, use, sell, offer to sell, have sold and import the Product in such country;
- (iv) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to Coherus, effective as of the effective date of such termination, all of Licensee's (or its Affiliate's) rights, title and interests in and to the Product Trademark and all relevant trademark applications and registrations with respect thereto in such terminated country. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this Section 12.7(a)(iv);
- (v) Licensee shall assign to Coherus or Coherus' designee its entire right in all clinical and related study data based on use or research on such Product and all Regulatory Filings and Regulatory Approvals relating to such Product in the terminated country, and shall provide reasonable assistance to Coherus or its designee to allow such party to become the holder of such Regulatory Approvals; and
- (vi) Licensee shall promptly notify Coherus of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities for any and all countries terminated. At Coherus' request, which request shall be made within three (3) months after the termination of this Agreement with respect to a country, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to Coherus, and Coherus shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities in such terminated country, including agreements with CROs, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals in such country(ies), unless such agreement: (A) expressly prohibits such assignment, (B) covers clinical trials for products in addition to the Product, or (C) covers the Product in a country or countries in respect of which this Agreement has not been terminated. In all cases (A)–(C), Licensee shall cooperate with Coherus in all reasonable respects to facilitate the execution of a new agreement between the Coherus and the Third Party.
- (b) Consequences of Expiration or Certain Terminations of this Agreement in its Entirety. Upon expiration of this Agreement under Section 12.1 (Term), or early termination of this Agreement in its entirety by Licensee pursuant to Section 12.3 (Termination by Licensee), by Coherus pursuant to Section 12.4 (Termination by Coherus), by Coherus pursuant to Section 12.5 (Termination for Material Breach), or by Coherus pursuant to Section 12.6 (Termination upon Insolvency):

- (i) the licenses granted to Licensee pursuant to Section 2.1 (License Grants) and Section 6.3 (Trademarks) shall terminate, except as otherwise necessary to conduct the activities expressly set forth in this Section 12.7(b);
- (ii) Licensee shall return to Coherus within three (3) months of the effective date of such expiration or termination (or certify the destruction of) any and all Coherus Know-How or Confidential Information of Coherus transferred to Licensee under this Agreement;
- (iii) promptly after the effective date of such termination or expiration, Licensee shall commence winding down its Development and Commercialization activities under the oversight of the JSC, and shall use best efforts to complete any and all such Development and Commercialization activities within three (3) months after the effective date of such termination or expiration;
- (iv) Licensee shall and hereby does grant to Coherus, effective as of the effective date of such termination or expiration, the exclusive, worldwide, perpetual, royalty-free, irrevocable license (with full rights to grant sublicenses through multiple tiers), under any Grant-Back IP, to develop, make, have made, use, sell, offer to sell, have sold and import the Product in or for the Territory;
- (v) Licensee shall and hereby does assign, at its cost, and shall cause its Affiliates (as applicable) to assign, to Coherus, effective as of the effective date of such termination or expiration, all of Licensee's (or its Affiliate's) rights, title and interests in and to any and all Product Trademarks and all relevant trademark applications and registrations with respect thereto. Each Party shall execute and deliver or shall cause its Affiliates (as applicable) to execute and deliver to the other Party all documents that are necessary to fulfill the obligations set forth in this Section 12.7(b)(v);
- (vi) Licensee shall assign to Coherus or Coherus' designee its entire right in all clinical and related study data based on use or research on the Product and all Regulatory Filings and Regulatory Approvals, and shall provide reasonable assistance to Coherus or its designee to allow such party to become the holder of such Regulatory Filings or Regulatory Approvals; and

(vii) Licensee shall promptly notify Coherus of any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities. At Coherus' request, which request shall be made within three (3) months after the expiration or termination of this Agreement, Licensee shall utilize Commercially Reasonable Efforts to assign (or cause its Affiliates to assign) to Coherus, and Coherus shall have the right, but not the obligation, to assume, any and all agreements between Licensee (and/or its Affiliates) and Third Parties with respect to the conduct of Development and/or Commercialization activities, including agreements with CROs, clinical sites and investigators, that relate to Clinical Trials in support of Regulatory Approvals, unless such agreement: (A) expressly prohibits such assignment, or (B) covers clinical trials for products in addition to the Product. In both cases (A) and (B), Licensee shall cooperate with Coherus in all reasonable respects to facilitate the execution of a new agreement between the Coherus and the Third Party.

- (c) Consequences of Certain Terminations of this Agreement in its Entirety by Licensee. Upon early termination of this Agreement by Licensee pursuant to Section 12.5 (Termination for Material Breach), or by Licensee pursuant to Section 12.6 (Termination upon Insolvency).
 - (i) the licenses granted to Coherus pursuant to Section 2.1 (License Grants) shall terminate;
 - (ii) Coherus shall return to Licensee within three (3) months of the effective date of such termination (or certify the destruction of) any and all Licensee Know-How or Confidential Information of Licensee transferred to Coherus under this Agreement; and
 - (iii) Coherus shall promptly notify Licensee of any and all agreements between Coherus (and/or its Affiliates) and Third Parties to whom any sublicenses were granted and shall confirm to Licensee that all such sublicenses were terminated as of the effective date of such termination.
- (d) For eighteen (18) months following early termination of this Agreement, whether in its entirety or as to one or more countries in the Territory, Licensee may not commercialize in the terminated country(ies) any product that is a biosimilar (or biobetter) of the reference drug for the Product; *provided, however*; this Section 12.7(c) shall not apply if Licensee terminates this Agreement under Section 12.5 (Termination for Material Breach).

(e) Expiration or termination of this Agreement for any reason shall not: (i) release any Party from any obligation that has accrued prior to the effective date of such expiration or termination (including the obligation to pay amounts accrued and due under this Agreement prior to the effective date of such expiration or termination but that are unpaid or become payable thereafter (including any payments then accrued because the event has occurred but the payment is not yet due)), (ii) preclude any Party from claiming any other damages, compensation, or relief that it may be entitled to upon such expiration or termination, or (iii) terminate any right to obtain performance of any obligation provided for in this Agreement that shall survive expiration or termination

12.8 General Surviving Obligations. The rights and obligations set forth in this Agreement shall extend beyond the expiration or termination of this Agreement only to the extent expressly provided for herein, or to the extent that the survival of such rights or obligations are necessary to permit their complete fulfillment or discharge. In the event of expiration or termination of this Agreement for any reason, the following provisions shall survive in addition to others specified in this Agreement to survive in such event: <a href="https://example.com/Articles 1.9.10.13 and 14 and Sections 8.3, 8.4, 8.5, 8.6, 8.7., 11.1, 11.2, 11.3, 12.7, 12.8, 15.5, 15.7, 15.11 15.13 and 15.16.

13. LIMITATION OF LIABILITY; DISCLAIMER OF WARRANTY.

13.1 LIMITATION OF LIABILITY. EXCEPT IN THE CASE OF A BREACH OF ARTICLE 11 (CONFIDENTIALITY), AND WITHOUT LIMITING THE PARTIES' OBLIGATIONS UNDER ARTICLE 10 (INDEMNIFICATION AND INSURANCE), NEITHER PARTY SHALL BE LIABLE TO THE OTHER PARTY FOR SPECIAL, INDIRECT, INCIDENTAL, PUNITIVE OR CONSEQUENTIAL DAMAGES (INCLUDING DAMAGES RESULTING FROM LOSS OF USE, LOSS OF PROFITS, INTERRUPTION OR LOSS OF BUSINESS, OR OTHER ECONOMIC LOSS) ARISING OUT OF THIS AGREEMENT OR WITH RESPECT TO A PARTY'S PERFORMANCE OR NON-PERFORMANCE HEREUNDER.

13.2 DISCLAIMER OF WARRANTY. EXCEPT AS EXPRESSLY PROVIDED IN THIS AGREEMENT, NEITHER PARTY PROVIDES ANY WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS OR IMPLIED, REGARDING PRODUCT USED IN PRECLINICAL STUDIES OR CLINICAL TRIALS OR FOR COMMERCIAL USE, AND EACH PARTY HEREBY DISCLAIMS ALL OTHER WARRANTIES, WHETHER WRITTEN OR ORAL, EXPRESS AND IMPLIED, INCLUDING THE IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE AND FREEDOM FROM INFRINGEMENT OF THIRD PARTY RIGHTS.

14. DISPUTE RESOLUTION.

- 14.1 Exclusive Dispute Resolution Mechanism. In the event that the Parties cannot reach agreement on a matter arising out of or in connection with this Agreement and any other agreement entered into pursuant hereto or in connection herewith (including matters relating to any Party's rights and/or obligations hereunder and/or regarding the construction, interpretation, and enforceability of such agreements), the procedures set forth in this Article 14 shall be the exclusive mechanism for resolving any dispute, controversy, or claim in connection with this Agreement, the construction hereof, or the rights, duties or liabilities of either Party under this Agreement (collectively, "Disputes") between the Parties or the JSC that may arise from time to time that cannot be resolved through good faith negotiation between the Parties, except as set forth in Section 14.4 (Preliminary Injunctions) and/or Section 14.5 (Patent Disputes) or unless otherwise set forth herein.
- 14.2 Resolution by Executive Officers. Except as otherwise provided in this Agreement, in the event of any Dispute, the Parties shall first attempt in good faith to resolve such Dispute by negotiation and consultation between themselves. In the event that such Dispute is not resolved on an informal basis within ten (10) Business Days after one Party provides notice to the other Party of such Dispute, either Party may, by written notice to the other Party, refer such Dispute to the Executive Officers for attempted resolution by good faith negotiation within thirty (30) days after such notice is received. In the event that any Dispute is not resolved under the foregoing provisions, each Party may, at its sole discretion, seek resolution of such Dispute in accordance with Article 3 (GOVERNANCE) or Section 14.3 (Arbitration), as applicable.

14.3 Mediation; Arbitration.

- (a) Except as set forth in Section 14.4 (Preliminary Injunctions) and/or Section 14.5 (Patent Disputes), or unless otherwise set forth herein, any Dispute that is not resolved pursuant to Section 14.2 (Resolution by Executive Officers) shall be submitted to the International Institute for Conflict Prevention & Resolution ("CPR") for mediation, and if the matter is not resolved through mediation, then it shall be submitted to CPR for exclusive, final and binding arbitration pursuant to this Section 14.3.
- **(b)** Any such mediation or arbitration shall be conducted in New York, New York, United States of America, unless otherwise agreed to by the Parties in writing. Each and any arbitration shall be administered by CPR pursuant to its Arbitration Rules and Procedures (the "Rules"), as such Rules may be amended from time to time, or modified by this Section 14.3 or by agreement of the Parties. At any applicable hearing, the Parties may present testimony (either by live witness or deposition) and documentary evidence and have the right to be represented by counsel. The U.S. Federal Rules of Evidence will apply to any and all matters submitted to final and binding arbitration under this Agreement.

- (c) Within ten (10) days after receipt of an arbitration notice from a Party, the Parties shall attempt in good faith to agree on a single neutral arbitrator with relevant industry experience to conduct such arbitration. If the Parties do not agree on a single neutral arbitrator within ten (10) days after receipt of an arbitration notice, each Party shall select one (1) arbitrator and the two (2) Party-selected arbitrators shall select a third arbitrator with relevant industry experience to constitute a panel of three (3) arbitrators to conduct the arbitration in accordance with the Rules. In the event that only one of the Parties selects an arbitrator, then such arbitrator shall be entitled to act as the sole arbitrator to resolve the Dispute or any and all unresolved issues subject to such arbitration. Each and every arbitrator of the arbitration panel conducting the arbitration must and shall agree to render an opinion within thirty (30) days after the final hearing before the panel.
- (d) The decision or award of the arbitrator(s) shall be final, binding, and incontestable and may be used as a basis for judgment thereon in any jurisdiction. The arbitrator(s) shall, upon the request of any Party, issue a written opinion of the findings of fact and conclusions of law and shall deliver a copy to each of the Parties. Each Party shall bear its own costs and attorney's fees, and the Parties shall equally bear the fees, costs, and expenses of the arbitrator(s) and the arbitration proceedings; provided, however, that the arbitrator(s) may exercise discretion to award costs, including attorney's fees, to the prevailing Party. Without limiting any other remedies that may be available under Applicable Laws, the arbitrator(s) shall have no authority to award provisional remedies of any nature whatsoever, or special, indirect, incidental, punitive, consequential, or any other similar form of damages (including damages resulting from loss of use, loss of profits, interruption or loss of business, or other economic loss).
- **14.4 Preliminary Injunctions.** Notwithstanding anything in this Agreement to the contrary, a Party may seek a temporary restraining order or a preliminary injunction from any court of competent jurisdiction as provided in **Section 15.12 (Governing Law; Jurisdiction)** in order to prevent immediate and irreparable injury, loss, or damage on a provisional basis, pending the decision of the arbitrator(s) on the ultimate merits of any Dispute.
- 14.5 Patent Disputes. Notwithstanding anything in this Agreement to the contrary, any and all issues regarding the scope, construction, validity, and enforceability of any Patent or Patent Application in a country within the Territory shall be determined in a court or other governmental authority of competent jurisdiction under the applicable patent laws of such country, as provided in Section 15.12 (Governing Law; Jurisdiction).
- **14.6 Confidentiality.** All proceedings and decisions of the arbitrator(s) shall be deemed to be Confidential Information of each of the Parties, and shall be subject to **Article 11 (CONFIDENTIALITY)**.

15. MISCELLANEOUS.

- **15.1 Agency.** Neither Party is, nor shall be deemed to be, an employee, agent, co-venturer, or legal representative of the other Party for any purpose. Neither Party shall be entitled to enter into any contracts in the name of, or on behalf of the other Party, nor shall either Party be entitled to pledge the credit of the other Party in any way or hold itself out as having the authority to do so.
- **15.2 Performance by Affiliates.** The Parties recognize that each Party may perform some or all of its obligations under this Agreement through Affiliates; *provided, however*, that each Party shall remain responsible for the performance of its Affiliates and shall course its Affiliates to comply with the provisions of this Agreement in connection with such performance.
- 15.3 Assignment. Neither Party shall have the right to assign this Agreement or any obligation of such Party hereunder without the prior written consent of the other Party, which shall not be unreasonably withheld, delayed, or conditioned, except that a Party may assign this Agreement and the rights, obligations, and interests of such Party: (a) in whole or in part, to any of its Affiliates, (b) to any purchaser of all or substantially all of its assets to which this Agreement relates, or (c) to any successor corporation resulting from any merger, consolidation, share exchange, or other similar transaction. This Agreement shall be binding upon and inure to the successors and permitted assignees of the Parties and the name of a Party appearing herein shall be deemed to include the names of such Party's successors and permitted assigns to the extent necessary to carry out the intent of this Agreement. Any assignment not in accordance with this Section 15.3 shall be void. Notwithstanding anything to the contrary in this Agreement, in the event of any such assignment, the intellectual property rights of the acquiring party (if other than one of the Parties to this Agreement) shall not be included in the intellectual property rights licensed to the other Party hereunder to the extent held by such acquirer prior to such transaction, or to the extent such intellectual property rights are developed outside the scope of activities conducted with respect to the Product.
- **15.4 Further Actions.** Each Party agrees to execute, acknowledge, and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.
- 15.5 Non-Solicitation. While the Parties are performing Development and/or Commercialization activities under this Agreement and for a period of eighteen (18) months thereafter, neither Party shall, without the express written consent of the other Party, recruit, solicit, or induce any employee of the other Party who has performed activities under this Agreement to terminate his or her employment with such other Party. The foregoing provision shall not, however, restrict either Party or its Affiliates from advertising employment opportunities in any manner that does not directly target the other Party or its Affiliates or from hiring any persons who respond to such generalized public advertisements.

15.6 Force Majeure. Neither Party shall be liable to the other for failure or delay in the performance of any of its obligations under this Agreement for the time and to the extent such failure or delay is caused by epidemic, earthquake, riot, civil commotion, rebellion, insurrection, invasion, fire, acts of God, war, terrorist acts, strike, storm, flood, or governmental acts or restriction, or other cause that is beyond the reasonable control of the respective Party. The Party affected by such force majeure shall provide the other Party with all information relating thereto (including its best estimate of the likely extent and duration of the interference with its activities) as soon as reasonably and practically possible after its occurrence, and shall use Commercially Reasonable Efforts to overcome the difficulties created thereby and to resume performance of its obligations as soon as practicable. In such event, the Parties shall meet promptly to determine an equitable solution to the effects of any such event, including the possibility of the termination of this Agreement pursuant to Section 12.5 (Termination for Material Breach). Notwithstanding the foregoing, nothing in this Section 15.6 shall excuse or suspend the obligation to make any payment due hereunder in the manner and at the time provided.

15.7 Notices. All notices and other communications hereunder shall be in writing and shall be deemed given: (a) if delivered personally or by facsimile transmission (receipt verified), (b) five (5) days after mailed by registered or certified mail (return receipt requested), postage prepaid, or (c) three (3) days after sent by express courier service, to the Parties at the following addresses (or at such other address for a Party as shall be specified by like notice; *provided, however*; that notices of a change of address shall be effective only upon receipt thereof):

If to Licensee, addressed to:

Baxter Healthcare SA Postfach 8010 Zurich Switzerland

Attn: Legal Department Fax: +41 44 878 6520

and

Baxter Healthcare Corporation 1 Baxter Parkway Deerfield, IL 60015 Attn: General Counsel

Attn: General Counse Fax: (224) 948-3441

If to Coherus, addressed to:

Coherus Biosciences, Inc. 201 Redwood Shores Parkway, Suite 200 Redwood City, CA, USA 94065

Attn: Dennis M. Lanfear Fax: (866) 491-7350

With copies to:

Latham & Watkins LLP 140 Scott Drive Menlo Park, CA 94062 Attn: Alan C. Mendelson Fax: 650-463-2600

Latham & Watkins LLP 12636 High Bluff Drive, Suite 400 San Diego, CA 92130

Attn: Faye H. Russell Fax: 858-523-5450

15.8 Amendment. No amendment, modification, or supplement of any provision of this Agreement shall be valid or effective unless made in writing and signed by a duly authorized officer of each Party.

15.9 Waiver. The waiver by either Party of any right hereunder or the failure to perform or of a breach by the other Party shall not be deemed a waiver of any other right hereunder or of any other breach or failure by such other Party whether of a similar nature or otherwise.

15.10 Counterparts; Electronic Delivery. This Agreement may be executed simultaneously in two counterparts, either one of which need not contain the signature of more than one Party but both such counterparts taken together shall constitute one and the same agreement. Signatures to this Agreement transmitted by facsimile, by email in "portable document format" (".pdf"), or by any other electronic means intended to preserve the original graphic and pictorial appearance of this Agreement shall have the same effect as physical delivery of the paper document bearing original signature.

15.11 Construction. The descriptive headings of this Agreement are for convenience only, and shall be of no force or effect in construing or interpreting any of the provisions of this Agreement. Except where the context otherwise requires, wherever used the singular shall include the plural, the plural the singular, the use of any gender shall be applicable to all genders. The term "including" or "includes" means "including without limitation" or "includes without limitation." The language of this Agreement shall be deemed to be the language mutually chosen by the Parties and no rule of strict construction shall be applied against either Party.

- 15.12 Governing Law; Jurisdiction. This Agreement shall be governed by and interpreted in accordance with the substantive laws of the State of New York, U.S.A., without regard to its or any other jurisdiction's choice of law rules. Any Disputes not subject to Section 14.3 (Mediation; Arbitration) shall be brought in the state or federal courts located in the State of New York, U.S.A., and the Parties irrevocably accept the exclusive jurisdiction of such courts solely and specifically for the purpose of adjudicating such Disputes, and in no event shall any Party be deemed to have consented to such jurisdiction for any other purpose. Each Party further agrees that such courts provide a convenient forum for any such action, and waives any objections or challenges to venue with respect to such courts.
- 15.13 Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under Applicable Laws, but, if any provision of this Agreement is held to be prohibited by or invalid under Applicable Laws, such provision shall be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of this Agreement. In the event of such invalidity, the Parties shall seek to agree on an alternative enforceable provision that preserves the original purpose of this Agreement.
- **15.14 Compliance with Applicable Laws.** Each Party will comply with all Applicable Laws in performing its obligations and exercising its rights hereunder. Nothing in this Agreement shall be deemed to permit Licensee to export, re-export, or otherwise transfer any Information transferred hereunder or Product without complying with Applicable Laws.

15.15 No Re-Importation.

(a) Licensee will ensure that reasonable safeguards are put in place so that Product sold in the Territory is not, directly or indirectly, exported, or marketed, distributed, or sold, outside of the Territory. Licensee shall not, directly or indirectly, offer Product to any Third Party in a country within the Territory that Licensee knows is going to, directly or indirectly, export such Product, or market, distribute, or sell such Product, outside of the Territory. If Licensee becomes aware that any of its customers has, directly or indirectly, imported Product into, exported Product to, or marketed, distributed, or sold Product in, any country outside of the Territory, or has reason to believe that a customer intends to, directly or indirectly, import Product, export Product to, or market, distribute, or sell Product, outside of the Territory, Licensee shall take prompt and reasonable actions to cause such customer to cease such import, export, marketing, distribution, or sales activities; if such customer does not cease such activities, then Licensee shall immediately cease sale or distribution of any and all Product to such customer, unless prohibited by Applicable Laws.

(b) Coherus will ensure that reasonable safeguards are put in place so that Product sold outside the Territory is not, directly or indirectly, exported, or marketed, distributed, or sold, within the Territory. Coherus shall not, directly or indirectly, offer Product to any Third Party in a country outside the Territory that Coherus knows is going to, directly or indirectly, import such Product, or market, distribute, or sell such Product, within the Territory. If Coherus becomes aware that any of its customers or commercial partners has, directly or indirectly, imported Product into, exported Product to, or marketed, distributed, or sold Product in, any country in the Territory, or has reason to believe that a customer intends to, directly or indirectly, import Product, export Product to, or market, distribute, or sell Product, in the Territory, Coherus shall take prompt and reasonable actions to cause such customer or commercial partner to cease such import, export, marketing, distribution, or sales activities; if such customer does not cease such activities, then Coherus shall immediately cease sale or distribution of any and all Product to such customer or commercial partner, unless prohibited by Applicable Laws.

15.16 Entire Agreement of the Parties. This Agreement, including the exhibits attached hereto, constitutes and contains the complete, final and exclusive understanding and agreement of the Parties, and cancels and supersedes any and all prior or contemporaneous negotiations, correspondence, understandings, and agreements, whether oral or written, between the Parties respecting the subject matter hereof, including the CDA, and neither Party shall be liable or bound to the other Party with respect to the subject matter of this Agreement in any manner by any representations, warranties, covenants, or agreements except as specifically set forth herein or therein. Nothing in this Agreement, express or implied, is intended to confer upon any party, other than the Parties and their respective successors and assigns, any rights, remedies, obligations, or liabilities under or by reason of this Agreement. To the extent that anything set forth in an exhibit attached hereto conflicts with the terms of this Agreement, the terms of this Agreement shall prevail.

[Signature Page Follows]

[Signature Page to License Agreement]

IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed as of the Effective Date by their duly authorized representatives as set forth below:

COHERUS BIOSCIENCES, INC.

By: /s/ Dennis M. Lanfear
Name: Dennis M. Lanfear
Title: Chief Executive Officer

BAXTER INTERNATIONAL INC.

By: /s/ Ludwig N. Hantson
Name: Ludwig N. Hantson
Title: CVP/President BioScience

BAXTER HEALTHCARE CORPORATION

By: /s/ Ludwig N. Hantson
Name: Ludwig N. Hantson
Title: CVP/President BioScience

BAXTER HEALTHCARE SA

By: /s/ Piero Novello
Name: Piero Novello
Title: Commercial Director
Emerging Markets EMEA

By: /s/ Steven Martin
Name: Steven Martin
Title: VP Quality EMEA

EXHIBIT 1.4

[***] OPT-IN

For a period of [***] from the Effective Date, Licensee shall have the exclusive right to negotiate and enter into a definitive agreement with a Third Party relating to Commercialization of the Product in [***] in which a technology transfer of Coherus Know-How or other intellectual property rights of Coherus is contemplated (the "[***] Agreement").

If, after such [***] period, Licensee has not entered into a [***] Agreement, Licensee and Coherus shall each have the right to pursue such a [***] Agreement.

In any case, during the period of time that Licensee is selling finished Product directly (or through an Affiliate or Sublicensee) in [***] such that Licensee (or such Affiliate) is booking sales of the Product, the Coherus Royalty for Net Sales in [***] shall be as set forth in **Exhibit 7.1 (Payment Structure)**.

If either Party enters into a [***] Agreement, it shall provide written notice to the other Party within [***] thereafter. Coherus shall have [***] following delivery or receipt of such notice to elect to be responsible for a portion of the costs incurred in connection with the associated technology transfer as set forth below (the "[***] Opt-In") by providing written notice to Licensee.

If Coherus notifies Licensee of its election of the [***] Opt-In, the Parties shall share both the costs incurred in connection with executing the technology transfer under the [***] Agreement and the financial payments received under the [***] Agreement in the following proportions:

- (a) Licensee, [***] percent ([***]%); and (b) Coherus, [***] percent ([***]%).
- .,

Following a [***] Opt-In, no Coherus Royalties shall be due on Net Sales in [***].

If Coherus does not notify Licensee of its election of the [***] Opt-In within the required period, Coherus shall receive [***] percent ([***]%) of any financial payments received by Licensee under the [***] Agreement and Licensee shall bear all costs incurred in connection with executing the technology transfer under the [***] Agreement.

For the avoidance of doubt, if Licensee enters into a [***] Agreement, Coherus shall be obligated to grant Licensee (or its designee or sublicensee) a license to all Coherus Know-How and Coherus Patent Rights that are necessary or useful to enable Licensee (whether by itself or through an Affiliate or sublicensee) to develop, make, have made, use, sell, offer to sell, have sold or import the Product in [***] (including the right to grant sublicenses therefor). Such license may be set forth in the MSA or in an amendment to this Agreement.

EXHIBIT 1.17

COHERUS PATENT RIGHTS

1. Patent Filings Owned by Coherus

[***

Coherus Patent Rights (Cont'd)

2. Patents Owned by [***], Licensed To Coherus.

(Note: [***] patents listed below are included within Coherus Patent Rights)

[***]

[***]

[***]

EXHIBIT 1.18

COHERUS TRADEMARKS

Coherus

EXHIBIT 1.48

ILLUSTRATIVE DEVELOPMENT PLAN/BUDGET

[***]

EXHIBIT 1.53

INITIAL DEVELOPMENT ACTIVITIES

[***]

EXHIBIT 5

MANUFACTURING AND SUPPLY BY COHERUS

Coherus will use Commercially Reasonable Efforts to execute a definitive agreement for the Manufacture and supply of Product for the Global Studies within ninety (90) days of the Effective Date.

Coherus will provide a draft of the Manufacturing and Supply Agreement to Licensee prior to execution and will reasonably consider Licensee's comments thereto.

Coherus will use Commercially Reasonable Efforts to supply Units, for Commercialization purposes to Licensee at Coherus' documented Manufacturing Cost [***]. Licensee will also be responsible for [***].

Coherus may Manufacture Units for commercialization outside the Territory using the Third Party manufacturer and/or Manufacturing facility licensed under Licensee's Regulatory Approval in the Territory, [***].

Contemporaneously with the execution of the Manufacturing and Supply Agreement, the Parties will execute a quality agreement in a mutually acceptable form.

The term of the Manufacturing and Supply Agreement shall be coincident with this Agreement.

EXHIBIT 7.1

PAYMENT STRUCTURE

A. Upfront Payment.

- 1. In partial consideration for the rights granted to Licensee under this Agreement, Licensee shall pay to Coherus a one-time, non-refundable payment of Thirty Million Dollars (\$30,000,000) within one (1) Business Day after the Effective Date by wire transfer of immediately available funds into an account designated in writing by Coherus. A portion of this Upfront Payment [***] as set forth in Section 2.4(e)(v) (Product Optout).
- 2. Following delivery of an Opt-Out Notice, [***] the Upfront Payment [***].
- 3. Following delivery of an Opt-Out Notice, if Licensee does not elect to enter into a ROFR Agreement within the Second Review Period, [***] the Upfront Payment [***].
- B. Milestone Payments. In partial consideration for the rights granted to Licensee under this Agreement, the following one-time, non-refundable, non-creditable payments shall be due and payable upon the occurrence of the applicable event ("Milestone Payment(s)"), with each such payment to occur within fifteen (15) days of the occurrence of the applicable event by wire transfer of immediately available funds into an account designated in writing by Coherus:

[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	
[***]	[***]	[***]	

[***] [***]

[***]. Such Milestone Payments shall be paid by Licensee to Coherus within fifteen (15) days of the occurrence of the applicable event by wire transfer of immediately available funds into an account designated in writing by Coherus.

C. EU Regulatory Approval Payments. In partial consideration for the rights granted to Licensee under this Agreement, the following one-time, non-refundable, non-creditable payments shall be due and payable upon receipt of Regulatory Approval in the European Union ("EU Regulatory Approval"), as follows:

[***]

- [***].
- [***]
- [***].
- [***].

By way of example, if the Product is [***], Coherus would receive [***]. If[***] the Product [***], Coherus would receive [***]. If[***], Coherus would receive [***].

Such EU Regulatory Approval Payments shall be paid by Licensee to Coherus within fifteen (15) days of the occurrence of the applicable event by wire transfer of immediately available funds into an account designated in writing by Coherus.

- D. Royalties on Net Sales; Third Party Payments. In partial consideration for the rights granted to Licensee under this Agreement, including Patent and know-how licenses and other proprietary rights, Licensee shall pay Coherus non-refundable and non-creditable royalties as set forth in this Section D.
 - 1. Licensee shall pay Coherus a royalty rate of [***] Net Sales in the Territory, on a country-by-country basis each Calendar Year, calculated in [***] on a country-by-country basis, in the applicable Calendar Quarter, as follows (the "Coherus Royalty"):
 - (a) [***]; and
 - (b) [***]; and
 - (c) [***].
 - 2. Notwithstanding the foregoing, except in connection with the exercise by Coherus of the [***] Opt-In, Licensee shall pay Coherus a Coherus Royalty equal to [***] of Net Sales in [***].

3. In partial consideration for the rights granted to Licensee under this Agreement, including Patent and know-how licenses and other proprietary rights, Licensee shall [***]. In addition, Licensee may reduce the Coherus Royalty by an amount [***] or [***] to any other Third Party in consideration for [***] (payments to other Third Parties shall be referred to as the "Third Party Payments") which [***] is either necessary or commercially reasonable to Develop, Manufacture, or Commercialize; *provided, however*; that in no case shall such reduction (or the aggregate reduction if multiple Third Party licenses are required) for Third Party Payments exceed the greater of:

(a) [***] or (b) [***].

EXHIBIT 11.5

PRESS RELEASE

(See attached.)

EXHIBIT 11.5A

CERTAIN PUBLICITY MATTERS

The following general matters related to the subject matter of this Agreement may be disclosed by Coherus to potential investors, collaboration partners and underwriters, on a non-confidential basis and without the prior written consent of Licensee:

- 1. That the size of the overall market that the Product addresses is approximately \$3 billion or is a multi-billion market.
- 2. That the transaction has up fronts and milestones worth approximately \$150 million payable between signing and issuance of regulatory approval.
- 3. That the transaction includes royalties that Coherus expects will be in the double digits.
- 4. That Coherus will be responsible for manufacturing with its CMO partner, such partner also being a Coherus shareholder.
- 5. That the transaction has the potential for additional products, and we hope to be able to expand the collaboration.
- 6. That Licensee will cover 100% of anticipated development costs not covered by other partners and therefore Coherus expects 100% of the development costs for Product to be covered by its partners.