EX-10.35 15 dex1035.htm MANUFACTURING AND SUPPLY AGREEMENT  
Exhibit 10.35  
 \*\*\*Text Omitted and Filed Separately  
with the Securities and Exchange Commission.  
Confidential Treatment Requested  
Under 17 C.F.R. Sections 200.80(b)(4)  
and 230.406.  
MANUFACTURING AND SUPPLY AGREEMENT  
(HZT-501 LAUNCH STOCKS AND COMMERCIAL QUANTITIES)  
THIS MANUFACTURING AND SUPPLY AGREEMENT (the “Agreement”) is made as of May 25, 2011 (the “Effective Date”) between:  
HORIZON PHARMA USA, INC., a Delaware corporation with offices at 0000 Xxxxxx Xxxxxxxxx, Xxxxx 000, Xxxxxxxxxx, Xxxxxxxx 00000 (“Horizon”)  
AND  
SANOFI-AVENTIS U.S. LLC, a limited liability company duly organized and existing under the laws of the State of Delaware with offices at 00 Xxxxxxxxx Xxxxx, Xxxxxxxxxxx, Xxx Xxxxxx 00000 (“sanofi-aventis”).  
Horizon and sanofi-aventis are individually referred to herein as a “Party” and are collectively referred to herein as the “Parties”.  
BACKGROUND  
A. The Parties previously entered into the Technical Transfer Agreement, dated as of November 9, 2009 (the “Technical Transfer Agreement”), and the activities under the Technical Transfer Agreement have been substantially completed.  
B. Horizon wishes to engage sanofi-aventis to exclusively perform services for Horizon, as more specifically set forth herein, in connection with the manufacturing, labeling, packaging, laboratory testing, and supply of the Product (as defined below) in finished dosage form for human use. Sanofi-aventis is engaged in the manufacture, marketing, sales and distribution of pharmaceutical products and operates directly or through one or more Affiliates (as defined below) the Production Site (as defined below), and it is understood and agreed that sanofi-aventis is the principle representative and will be the key point of contact to represent all sanofi-aventis Affiliates with regards to the interpretation, terms and conditions associated with this Agreement, regardless of the Affiliate performing the services including non-US entities.  
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 C. Sanofi-aventis wishes to perform such services, all on the terms and conditions set forth in this Agreement.  
COVENANTS  
In consideration of the mutual covenants and promises set forth herein, and intending to be legally bound hereby, the Parties agree as follows:  
ARTICLE 1  
DEFINITIONS  
The following terms, whether used in the singular or plural, shall have the meanings assigned to them below for purposes of this Agreement:  
“Acquisition Cost” shall mean the […\*\*\*…] by sanofi-aventis to any Third Party for acquiring […\*\*\*…] required hereunder, including, but not limited to, […\*\*\*…] by sanofi-aventis to any Third Party in connection with the acquisition of […\*\*\*…], as the case may be.  
“Active Ingredients” or “Active Pharmaceutical Ingredients” or “API” shall mean the sanofi-aventis API and the Horizon API.  
“Additional Presses” shall have the meaning set forth in Section 11.1 hereof.  
“Affiliate” shall mean any corporation or non-corporate entity which controls, is controlled by, or is under common control with a Party. A corporation or non-corporate entity shall be regarded as in control of another corporation if it owns or directly or indirectly controls more than fifty percent (50%) of the voting stock of the other corporation or (a) in the absence of the ownership of more than fifty percent (50%) of the voting stock of a corporation or (b) in the case of a non-corporate entity, the power to direct or cause the direction of the management and policies of such corporation or non-corporate entity, as applicable. More specifically, with respect to sanofi-aventis, Affiliate refers to legal entities controlled by, controlling or under common control with sanofi-aventis that own or operate the Production Site.  
“Agreement” shall mean this Manufacturing and Supply Agreement, as it may hereafter be amended or supplemented from time to time.  
“Base Technology” shall have the meaning set forth in Section 12.1 hereof.  
“Batch” shall mean […\*\*\*…] tablets of Product for the Xxxxx, Xxxxxx, Xxxxxx Production Site and […\*\*\*…] tablets of Product for the Compiegne, France Production Site, or such other number of tablets of Product as may be mutually agreed by the Parties, in each case to be manufactured by sanofi-aventis in accordance  
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 with the Product Specifications under cGMPs.  
“cGMPs” shall mean current Good Manufacturing Practices for medicinal products established by applicable laws, rules and regulations, including 21 CFR (Parts 210 and 211), as the same may be amended and any successor regulations thereto, each as in effect from time to time.  
“Certificate of Analysis” shall mean a document, signed by an authorized representative of sanofi-aventis, certifying the Specifications for, and testing methods applied to, the Product, and the results thereof, and which includes the Product date of manufacture, date of release, and date for re-testing or expiry.  
“Certificate of GMP Compliance” shall mean a document, signed by an authorized representative of sanofi-aventis, certifying that the Product being delivered to Horizon has been manufactured in conformity with cGMPs.  
“Contract Year” shall mean a calendar year during the Term, beginning with January 1 and ending on December 31 of such year; provided, however, that the initial Contract Year hereunder shall commence on the Effective Date of this Agreement and end on December 31 of such year and the final Contract Year hereunder shall commence on January 1 of the applicable calendar year and end on the last day of the Term.  
“Coordinators” shall have the meaning set forth in Article 3 hereof.  
“Excipients” shall mean all raw materials, other than the Active Ingredient required to manufacture the Product in accordance with the Product Specifications.  
“FDA” shall mean the United States Food and Drug Administration or any successor entity thereto.  
“First Commercial Sale” shall mean the date of the first sale of a Product in the Territory.  
“Force Majeure Event” shall have the meaning set forth in Section 22.1 hereof.  
“Horizon Equipment” shall mean the equipment listed in Exhibit 6, including any modifications to such equipment purchased by Horizon pursuant to the second paragraph of Section 11.1.  
“Horizon API” shall mean Ibuprofen DC-85.  
“Horizon IP” shall mean all Base Technology made available to sanofi-aventis or its Affiliates by Horizon or its Affiliates pursuant to this Agreement or the Technical Transfer Agreement that is required for sanofi-aventis or its designated Affiliate to perform sanofi-aventis’ obligations under this Agreement.  
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 “ICH Guidelines” shall mean those guidelines endorsed by the International Conference on Harmonization of Technical Requirements for Registrations of Pharmaceuticals for human use as in effect from time to time.  
“Information” shall mean any and all information relating to the Product, manufacture of the Product or the business of either Party, owned and/or disclosed by one Party to the other in written, electronic or any other form, including, but not limited to, Know-How, operational methods, formulae, samples, Specifications, analytical methods as well as any details of a commercial, technical, pharmaceutical, scientific and industrial nature whether disclosure of such information occurred prior to or after the Effective Date, including any such information disclosed pursuant to the Technical Transfer Agreement.  
“Initial Term” shall have the meaning set forth in Section 15.1 hereof.  
“Intellectual Property Rights” shall mean patents and patent applications, Know-How, utility models, trademarks, design rights, copyrights and any other proprietary rights.  
“Investigation” shall mean a detailed and thorough review of any atypical manufacturing deviation (or any other matter requiring review pursuant to the terms of this Agreement) that is documented in a written report and approved at a senior management level, as further described in the Quality Agreement.  
“Know-How” shall mean all confidential and identified technical and scientific information and data, irrespective of its subject-matter and form, including, but not limited to, processes, formulae, designs and data as well as inventions and improvements whether patentable or not.  
“Latent Defect” shall mean a defect that causes Product to fail to conform to the Specifications or to the warranties provided by sanofi-aventis hereunder, which defect is not discoverable upon reasonable physical inspection and testing but is discovered at a later time.  
“NDA” shall mean a new drug application, marketing authorization application or equivalent application, and all amendments and supplements thereto, filed with the applicable regulatory authority in a country or jurisdiction in the Territory (including the FDA in the United States) with respect to such Product.  
“Organizational Change” shall have the meaning set forth in Section 6.1 hereof.  
“Packaging Components” shall mean primary and secondary packaging materials used in the production of the Product.  
“Packaging Specifications” shall mean the packaging and labeling specifications for the Product attached hereto as Exhibit 2 and made a part hereof, as such specifications may be amended from time to time by mutual written agreement of the Parties in accordance with the terms and conditions of the Quality Agreement.  
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 “Product” shall mean tablets containing the Active Ingredients in finished packaged form, marketed by Horizon, currently known as HZT-501.  
“Product Price” shall have the meaning set forth in Section 9.1 hereof.  
“Product Specifications” shall mean the specifications for the Product attached hereto as Exhibit 3 and made a part hereof, as determined in accordance with the analytical methodology set forth therein, as such specifications may be amended from time to time by mutual written agreement of the Parties in accordance with the terms and conditions of the Quality Agreement.  
“Production Site” shall mean any or all of the facilities of sanofi-aventis or its Affiliates located in Laval, Quebec, Canada, St Louis, Missouri, USA, and Compiegne, France, and such other facilities approved by Horizon as Production Sites pursuant to Section 24.3 of this Agreement.  
“Quality Agreement” shall have the meaning set forth in Section 2.2 hereof.  
“QC Laboratory Methods Raw Material Specifications” shall mean the validated test methods communicated to sanofi-aventis and those listed in the NDA for the Product, which are used to test and evaluate for suitability all incoming materials for their intended use in the manufacturing process.  
“Recall” shall have the meaning set forth in Section 16.2(a) hereof.  
“Regulatory Change” shall have the meaning set forth in Section 22.2 hereof.  
“Renewal Term” shall have the meaning set forth in Section 15.1 hereof.  
“Replacement Cost” shall mean (i) with respect to a product produced by a Party, the total cost of replacing in-kind the APIs being replaced and used in the process and the manufacture of such product plus the actual cost, if any, of delivering such product to the location of its intended use and (ii) with respect to a product produced by a Third Party, the total out-of-pocket cost incurred by a Party to have such product manufactured and delivered to the location of its intended use.  
“Sanofi-aventis API” shall mean Famotidine.  
“Sanofi-aventis Equipment” shall have the meaning set forth in Section 11.1 hereof.  
“SAUS IP” shall mean all Base Technology provided by sanofi-aventis or its Affiliates to Horizon or its Affiliates pursuant to this Agreement or the Technical Transfer Agreement which may be required for sanofi-aventis or its designated Affiliate to perform sanofi-aventis’ obligations under this Agreement.  
“SKU” shall mean a sanofi-aventis stock keeping unit reference. Each packaging configuration of the Product shall have its own SKU.  
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 “Specifications” shall mean the quality standards, the Product Specifications and the Packaging Specifications, including, without limitation, tests, analytical procedures and acceptance criteria that are established to confirm the quality of Product which are listed in the applicable NDA and mutually agreed to in writing by sanofi-aventis and Horizon and are contained or referenced in the master batch record for Product or as otherwise mutually agreed to in writing by the Parties.  
“Term” shall have the meaning set forth in Section 15.1 hereof.  
“Territory” shall mean, at the time of commercial launch of the Product, the territories listed in Exhibit 7.  
“Third Party” shall mean any person or entity other than Horizon, sanofi-aventis and their respective Affiliates.  
ARTICLE 2  
MANUFACTURE, SALE AND PURCHASE OF PRODUCT  
2.1 Generally. Subject to the terms and conditions of this Agreement, Horizon shall exclusively purchase from sanofi-aventis all of Horizon’s requirements for quantities of Product for commercial use in the Territory. Sanofi-aventis shall order all APIs and Excipients from Horizon designated producers in sufficient quantities to manufacture and package the Product.  
2.2 Quality Agreement. The parties shall use commercially reasonable efforts to execute a separate quality agreement (as may be amended by written agreement of both Parties the “Quality Agreement”) within ninety (90) days after the execution of this Agreement, which upon full execution shall be attached hereto as Exhibit 4. The Quality Agreement, when executed by the Parties will constitute an integrated part of this Agreement and will define the quality assurance and regulatory responsibilities of the Parties as they relate to this Agreement. Sanofi-aventis shall, in manufacturing the Product and performing the other services contemplated hereby, comply in all respects with its duties and obligations a set forth the Quality Agreement. Horizon shall also comply in all respects with its duties and obligations as set forth in the Quality Agreement.  
2.3. Affiliate Services. For ease of administration, sanofi-aventis is the party to this Agreement, and the point of contact for Horizon. All Purchase Orders for the Product shall be delivered to sanofi-aventis and sanofi-aventis shall issue all invoices to Horizon. Notwithstanding the fact that sanofi-aventis is the party to and undertakes to perform obligations under this Agreement, sanofi-aventis may cause its Affiliates sanofi-aventis Canada Inc. (Laval, Quebec, Canada Production Site) and Sanofi Winthrop Industrie (Compiegne, France Production Site) and such other Affiliates it reasonably determines are necessary and are approved as Production Sites in accordance with this Agreement, to perform some or all of the obligations under this Agreement; provided, however, that sanofi-aventis is obligated and shall remain obligated to be compliant and maintain Affiliate compliance with the terms of this Agreement and the Quality Agreement.  
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 ARTICLE 3  
COORDINATORS  
Within ten (10) days after the Effective Date, Horizon and sanofi-aventis shall each appoint one or more authorized representatives (“Coordinators”) for the exchange of all communications, other than formal notices hereunder, related to the manufacturing, labeling and packaging of the Product. Each Party shall provide notice to the other Party as to the name and title of the individuals so appointed. Each Party may replace its Coordinators at any time for any reason by providing written notice to the other Party in accordance with Section 25.1 hereof.  
ARTICLE 4  
PACKAGING AND ARTWORK  
4.1 Packaging. Sanofi-aventis shall procure all packaging materials for the Product in accordance with the Production Site receipt procedures.  
4.2 Artwork. At least […\*\*\*…] days prior to (a) the first delivery date for the Product or (b) any modification to the artwork for the Product pursuant to Article 5, as applicable, and from time to time thereafter with respect to the Product, as needed, but with no less than at least […\*\*\*…] days prior written notice from the anticipated date of implementation of any modification, Horizon shall provide at no cost to sanofi-aventis, artwork meeting the Packaging Specifications for all Packaging Components to be used in the manufacture of the Product. Horizon shall be responsible to insure that all such artwork complies with all applicable laws.  
ARTICLE 5  
SPECIFICATION CHANGES  
Upon any change in the Product Specifications, stability protocols, QC laboratory methods raw material specification or Packaging Specifications (whether initiated by Horizon or made in response to a request by sanofi-aventis that is agreed to by Horizon), including the addition of new packaging configurations, new SKUs, new formulations, or a change in either raw materials or Packaging Component supply, Horizon shall promptly advise sanofi-aventis in writing of such changes, and sanofi-aventis shall promptly advise Horizon as to any scheduling and/or price adjustments which may result from such changes. Prior to implementation of such changes, the Parties shall negotiate in good faith in an attempt to reach agreement on (a) the new Product Price for any Product which embodies such changes, (b) any amounts to be reimbursed by Horizon to sanofi-aventis as described in the next sentence of this paragraph, and (c) any other amendments to this Agreement which may be necessitated by such changes (i.e., an adjustment to the lead time for purchase orders). Horizon shall reimburse sanofi-aventis for the mutually agreed upon reasonable expenses incurred by sanofi-aventis as a result of such changes, including, but not limited to, reimbursing sanofi-aventis for its mutually agreed validation and development costs, capital expenditure costs, costs for any Packaging Components or other materials rendered unusable as a result of such changes, and cost of required stability to support a change. If during the Term Horizon amends the Product Specifications or Packaging  
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 Specifications (whether voluntarily or as required by law) so as to render obsolete quantities of the Active Ingredient, Excipients and/or Packaging Components for the Product on hand at sanofi-aventis, Horizon shall (i) accept the return of all such obsolete Active Ingredient and (ii) purchase from sanofi-aventis, at sanofi-aventis’ Acquisition Cost, all such obsolete Excipients and Packaging Components obtained by sanofi-aventis pursuant to its normal procurement policies to manufacture quantities of the Product pursuant to Horizon forecasts under Section 6.1. Sanofi-aventis’ normal procurement policies for purposes of the preceding sentence of this Article 5 shall be considered to be quantities of Excipients and Packaging Components corresponding to the immediately following […\*\*\*…] months of Horizon’s most recent forecasted Product demand. If a change in Specifications is initiated by sanofi-aventis and approved by Horizon, any cost associated with said change shall be borne by sanofi-aventis. In the event that a change in Specifications is initiated by Horizon or driven by a regulatory or business change, the costs associated with qualification of the change shall be paid by Horizon. The amount of the change shall be reasonable and customary and subject to written approval by Horizon, such approval not to be unreasonably withheld. Sanofi-aventis, with written agreement and approval from Horizon, will be responsible for the appropriate (cGMP) destruction of any materials covered under this Article 5, and sanofi-aventis shall be reimbursed by Horizon at the reasonable and customary approved rate.  
ARTICLE 6  
FORECASTS AND ORDERS  
6.1 Organization of the Production Site. Horizon acknowledges that sanofi-aventis requires sufficient lead times to schedule production capacity for the Product. As used in this Agreement, the term “Organizational Change” shall mean any of the following events: (i) a change in worker shift patterns related to the manufacture of the Product, including without limitation a change from a two-shift to a three-shift pattern; (ii) a change in the number of manufacturing lines involved in the manufacture of the Product; and/or (iii) adding an additional manufacturing site as a Production Site to manufacture the Product. The Parties agree that “back and forth” Organizational Changes should be avoided as much as possible, and that sanofi-aventis shall not be required to implement an Organizational Change more frequently than […\*\*\*…]. In the event of a labour action or dispute, […\*\*\*…] will use commercially reasonable efforts to […\*\*\*…], so long as […\*\*\*…]. All costs associated […\*\*\*…] will be borne by […\*\*\*…]. The Coordinators shall regularly discuss Horizon’s forecasts of demand for the Product and the resulting implications for Organizational Changes, if any. It is understood and acknowledged by Horizon that sanofi-aventis shall not be required to fill purchase orders for commercial supply quantities greater than the then-current actual capacity of the then-qualified sanofi-aventis Production Sites (at the time of receiving written notice from Horizon outlined immediately above) until such time as the an Organizational Change is implemented in accordance with this Agreement and applicable law.  
6.2 Communication of Forecasts and Purchase Orders by Horizon. On or before the […\*\*\*…] of each calendar quarter (Q) during the Term, Horizon shall submit in writing to  
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 sanofi-aventis a binding purchase order for the following calendar quarter (Q+1) specifying the quantity of Product that sanofi-aventis shall deliver to Horizon during each month of such following calendar quarter (Q+1), and a non-binding forecast reflecting Horizon’s best estimate of the monthly requirements for the Product for the next three (3) calendar quarters (Q+2) to (Q+4) after such following calendar quarter. Purchase orders for each month of such following calendar quarter (Q+1) may differ by […\*\*\*…] from the quantity forecasted for such month in the previous quarterly forecast, provided, however, that such variation does not require an unplanned Organizational Change. Sanofi-aventis may reject purchase orders for Product quantities outside the minimum and maximum quantity limits set out immediately above. Horizon shall order the Product in Batch sizes or whole multiples thereof. Each purchase order shall specify the quantity of Product being ordered.  
6.3 Confirmation by sanofi-aventis.  
(a) Order Confirmation. Sanofi-aventis shall accept all purchase orders submitted by Horizon in accordance with this Agreement which reflect the terms set out herein. No later than […\*\*\*…] days after receipt of Horizon’s purchase orders for the following calendar quarter (Q+1), sanofi-aventis shall confirm that it can fulfill the monthly quantities specified in such orders (based on then-current capacity). Sanofi-aventis shall be deemed to have provided such confirmation if it does not provide written notice to Horizon within such […\*\*\*…] day period stating that it cannot fulfill the monthly quantities specified in such orders and providing an explanation of the reasons therefor.  
(b) Forecast Analysis. No later than […\*\*\*…] days after receipt in each calendar quarter (Q) of Horizon’s forecast, sanofi-aventis shall inform Horizon of any Organizational Change threshold being reached as a result of Horizon’s forecasted monthly quantities for quarters (Q+2) to (Q+4). In such a case, the Parties shall discuss the Organizational Change, and evaluate any alternative option that would avoid the Organizational Change, such as bringing forward or postponing a portion of the monthly forecasts for quarters (Q+2) to (Q+4). The Parties shall use commercially reasonable efforts to reach a final decision on such matters within […\*\*\*…] days of sanofi-aventis having notified Horizon about the Organizational Change issue. Any Organizational Change shall be promptly confirmed in writing by the Parties and shall require the firm commitment from Horizon to order, in each of the […\*\*\*…] months following the implementation of the Organizational Change, a number of Batches equal to or above the corresponding Organizational Change threshold as specified in the Parties’ written confirmation of such Organizational Change. Any alteration to Horizon’s forecast for quarters (Q+2) to (Q+4), in accordance with the terms outlined in this section 6.4(b), shall be promptly confirmed in writing by the Parties, and any such amended forecast shall be deemed to be the forecast for quarters (Q+2) to (Q+4) communicated by Horizon in quarter (Q) for purposes of this Agreement.  
6.4 Additional Quantities. In the event that Horizon desires to issue purchase orders for quantities in excess of the quantities it is entitled to order pursuant to Section 6.2 hereof, sanofi-aventis shall consider Horizon’s request in good faith, subject to then-available manufacturing capacity and agreement on commercially reasonable increases in the Product  
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 Price for such excess quantities to cover higher costs (including without limitation overtime pay for sanofi-aventis personnel) to accommodate such request, as applicable. Sanofi-aventis shall have no obligation to supply Horizon with such excess quantities of the Product.  
6.5 Long-Term Planning Forecasts. Within […\*\*\*…] after the first day of each Contract Year (Y), Horizon will supply sanofi-aventis with a written […\*\*\*…] year non-binding rolling forecast reflecting Horizons’ projected annual Product demand for the […\*\*\*…] Contract Years (Y+1) to (Y+[…\*\*\*…]) following the Contract Year in which such planning forecast is provided to sanofi-aventis. Such planning forecasts shall represent Horizon’s most current estimates for planning purposes only, and shall not be considered to be purchase commitments.  
ARTICLE 7  
SUPPLY OF ACTIVE INGREDIENT  
7.1 Active Ingredient. Sanofi-aventis shall, at its cost, procure the Active Ingredient(s) and applicable reference standards in quantities sufficient to meet Horizon’s requirements for Product as further set forth herein, provided such purchases of Horizon API shall be made under Horizon’s contracted conditions with Horizon API suppliers. Horizon shall be responsible for necessary supplier audits and cost of any audit of Horizon API suppliers, the frequency of such audits to be based upon site and regulatory requirements. Horizon shall make every effort to allow sanofi-aventis qualified personnel to participate in such Horizon API audits. In the event a sanofi-aventis qualified person is prohibited from participating in such an audit, sanofi-aventis will provide audit requirements and templates that can be substituted such that sanofi-aventis can meet its vendor qualification obligation. Horizon agrees to use commercially reasonable efforts to conduct an audit of the Horizon API suppliers, at sanofi-aventis’ request if Horizon has the right to do so under the applicable contracted conditions with such Horizon API suppliers; provided, that sanofi-aventis shall be responsible for all costs and expenses of Horizon in connection therewith. Horizon shall provide to sanofi-aventis a copy of any reports of any Horizon API supplier deficiencies discovered as a result of an audit or otherwise, and shall provide a written action plan for the prompt resolution of any such deficiencies and / or a report of the full resolution of the same. Notwithstanding anything contained herein to the contrary, sanofi-aventis shall have no liability in the event Product is delivered late by sanofi-aventis or in insufficient quantities or fails to comply with Specifications solely because and to the extent such Horizon API was delivered late or in insufficient quantities to sanofi-aventis or did not comply with the specifications for such Horizon API, respectively, in each case for reasons outside the reasonable control of sanofi-aventis. Sanofi-aventis shall be responsible for necessary supplier audits and cost of any audit of sanofi-aventis API suppliers, the frequency of such audits to be based upon site and regulatory requirements. Sanofi-aventis shall make every effort to allow Horizon qualified personnel to participate in such sanofi-aventis API audits. In the event a Horizon qualified person is prohibited from participating in such an audit, Horizon will provide audit requirements and templates that can be substituted such that Horizon can meet its vendor qualification obligation. Sanofi-aventis agrees to use commercially reasonable efforts to conduct an audit of the sanofi-aventis API suppliers, at Horizon’s request if sanofi-aventis has the right to do so under the applicable contracted conditions with such sanofi-aventis API suppliers; provided, that Horizon shall be responsible for all costs and expenses of sanofi-aventis in connection therewith. Sanofi-aventis shall provide to Horizon a copy of any reports of any  
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 sanofi-aventis API supplier deficiencies discovered as a result of an audit or otherwise, and shall provide a written action plan for the prompt resolution of any such deficiencies and / or a report of the full resolution of the same.  
7.2 Excipients. Sanofi-aventis at its cost shall procure, and test in accordance with the Production Site receipt procedures, all Excipients for the manufacture of the Product in quantities sufficient to meet Horizon’s requirements of Product as further set forth herein. If the supplier of Excipient(s), and or an Excipient, is not used by sanofi-aventis or its Affiliates for the manufacture of any product other than Product, Horizon shall be responsible for the cost of any such supplier audit. Audit frequency will be determined by sanofi-aventis based on local procedures and regulatory requirements.  
7.3 Packaging Components. Sanofi-aventis at its cost shall procure, and test in accordance with the Production Site receipt procedures, all Packaging Components for the manufacture of the Product. If the supplier of Packaging Components, and or a Packaging Component, is not used by sanofi-aventis or its Affiliates for the manufacture of any product other than Product, Horizon shall be responsible for the cost of any such supplier audit. Audit frequency will be determined by sanofi-aventis based on local procedures and regulatory requirements.  
ARTICLE 8  
DELIVERIES; INSPECTIONS  
8.1 Purchase Quantities. Quantities actually shipped pursuant to a given monthly purchase order may vary from the monthly quantities reflected in such purchase order by up to […\*\*\*…] percent ([…\*\*\*…]%) and still be deemed to be in compliance with such purchase order; provided, however, after commercial launch, and except as otherwise provided in this Agreement, Horizon shall only be invoiced and required to pay for the quantities of Product which sanofi-aventis actually ships to Horizon.  
8.2 Product Release. No Product shall be released to Horizon without a Certificate of Analysis and Certificate of GMP Compliance. Sanofi-aventis shall conduct such testing for the Product as is required by the Specifications and cGMPs. For clarity, sanofi-aventis shall be responsible, at its own cost, for routine annual stability testing. Any stability studies in excess of the once per year stability testing per site procedures will be considered non-routine. Sanofi-aventis shall be reimbursed by Horizon for all reasonable expenses incurred by sanofi-aventis for non-routine stability testing, which expenses will be quoted at the time prior to initiation of testing and agreed by sanofi-aventis and Horizon based on the extent and complexity of the study in question.  
8.3 Delivery Terms. The terms of delivery for the Product shall be EXW the Production Site at which packaging and labeling of the Product takes place (Incoterms 2010). Loading of the Product shall be performed at no cost by sanofi-aventis, but under the responsibility and liability of Horizon. All shipments of the Product to Horizon shall be made via such carrier(s) as Horizon may direct. Title and risk of loss shall pass to Horizon upon delivery to the carrier. Freight charges shall be billed ship collect. Horizon shall give to the  
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 sanofi-aventis Affiliate that operates the Production Site at which packaging and labeling of the Product takes place, if outside the USA, proof that the Product has been exported out of the country of such Affiliate in a reasonable time without further transformation.  
8.4 Shelf-Life. All Product delivered to Horizon by sanofi-aventis shall have not less than […\*\*\*…] percent ([…\*\*\*…]%) of its approved “shelf-life” (in terms of the then-current approved stability for the Product) remaining at the time of delivery, except Batches manufactured prior to NDA approval in the United States or for Batches of the Product for which release has been delayed because the relevant Batch was the subject of an Investigation.  
8.5 Inconsistencies. In the event of any inconsistencies between the terms of this Agreement and any purchase order issued by Horizon hereunder or any acceptance thereof by sanofi-aventis, the terms of this Agreement shall govern.  
8.6 Inspections by Horizon. Upon reasonable prior written notice, and no more frequently than once per year except for cause, Horizon or its designated agents shall have the right to inspect those portions of the manufacturing, storage and warehouse facilities of the Production Site where Product or Active Ingredient is being manufactured or stored, during regular business hours, to verify compliance with the terms and provisions of this Agreement or for insurance inspection purposes.  
8.7 Governmental Inspections. If sanofi-aventis is notified that the Product or the Production Site will be subject to an inspection by any governmental authority, sanofi-aventis shall promptly inform Horizon (within 48 hours) of such notice of inspection and shall cooperate with and allow such inspection to the extent required by applicable laws. Horizon shall not have the right to be present face to face with the inspecting agency at any meetings or events related to such inspection of its Product, but will be allowed on premises in a sanofi-aventis-designated room and will be consulted for any issues that could potentially impact the Product. Subject to confidentiality obligations of sanofi-aventis to Third Parties, sanofi-aventis shall provide copies of correspondence from such governmental authorities (such as inspection observation reports) to Horizon resulting from such inspection to the extent relevant to the Product.  
ARTICLE 9  
PRICE; PRICE ADJUSTMENTS; PAYMENT TERMS  
9.1 Price. The per-unit price payable by Horizon for all quantities of the Product ordered hereunder shall be as specified in the pricing schedule in Exhibit 1 hereto, as it may be revised from time to time pursuant to Article 5 and Sections 9.2, 9.3 and 9.4 hereof (the “Product Price”). An estimated Product Price shall be used for all purchases in a given Contract Year and shall be based on the quantities specified in the most recent forecasts for such Contract Year provided by Horizon to sanofi-aventis under Sections 6.2 prior to the beginning of such Contract Year and the then-current Product Price. Sanofi-aventis shall invoice and Horizon shall pay the estimated Product Price in accordance with the terms of this Agreement. Within forty five (45) days following the end of each Contract Year, sanofi-aventis shall submit to Horizon a quantity reconciliation of the total amount that should have been paid by Horizon for all quantities of the Product purchased during such Contract Year in accordance with the applicable Product Price for  
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 such actual quantities against the total amounts actually billed by sanofi-aventis and paid for by Horizon for such quantities based on the estimated Product Price for such Contract Year. If such reconciliation shows that Horizon has overpaid for such purchases, then sanofi-aventis shall, at Horizon’s election, either refund such overpayment within […\*\*\*…] days of its submission of such reconciliation or credit such overpayment against future purchases of the Product. If such reconciliation shows that Horizon has underpaid for such purchases, then Horizon shall remit the balance so determined to be due to sanofi-aventis within […\*\*\*…] days of its submission of such reconciliation.  
9.2 Technical Assumptions for Product Price. The Parties acknowledge and agree that the Product Price is based on the technical assumptions specified in Exhibit 5 hereto, which apply to standard practices for products manufactured at the Production Site as of the Effective Date. If any of these technical assumptions must be revised, the Parties shall discuss in good faith the adjustment in Product Price, if any, resulting from such revision. Sanofi-aventis shall upon Horizon’s request assist Horizon in the selection of industrial options that, while conforming to such revised technical assumptions, represent the best fit with the Production Site standard practices.  
9.3 Price Adjustments. (a) PPI. On or before February 15, 2012 and on or before each February 15 thereafter, subject to Article 5 and Sections 9.2 and 9.4 hereof, the portion of the Product Price applicable during the previous Contract Year exclusive of the cost of API and freight for the transport of API to the relevant Production Site (the “API Portion”) for such Contract Year for all SKUs of the Product ordered by Horizon during the current Contract Year shall be adjusted by a percentage equal to the percentage change in the Producer Price Index (Pharmaceutical Preparations, Mfg. ‘PCU325412325412’) published by the U.S. Department of Labor, Bureau of Labor Statistics (or such other index as the Parties may hereafter mutually determine) during the twelve (12) month period ending with the most recent month for which finalized published monthly statistics are available, and once such data is available for a given period, price increases will be retroactive to January 1 of the applicable Contract Year for any Product shipped after that date. For the avoidance of doubt, all adjustments pursuant to this Section 9.3(a), together with any other adjustments made pursuant to Article 5, Sections 9.2, 9.3(b) or 9.4, shall be cumulative.  
(b) API True Up and Adjustment. The API Portion of the Product Price will be adjusted […\*\*\*…] to reflect actual changes thereto and sanofi-aventis will […\*\*\*…] pursuant to the provisions of this subsection (b). Simultaneously with the quantity reconciliation submitted to Horizon pursuant to Section 9.1, sanofi-aventis shall submit to Horizon an API Portion reconciliation showing the difference between the API Portion paid by Horizon and the actual amount paid by sanofi-aventis to purchase the API converted into Product purchased by Horizon during the previous Contract Year. If such reconciliation shows that Horizon has overpaid for such purchases, then sanofi-aventis shall, at Horizon’s election, either refund such overpayment within […\*\*\*…] days of its submission of such reconciliation or credit such overpayment against future purchases of the Product. If such reconciliation shows that Horizon has underpaid for such purchases, then Horizon shall remit the balance so determined to be due to sanofi-aventis within […\*\*\*…] days of its submission of such reconciliation. The actual amount paid by sanofi-aventis to purchase the API converted into  
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 Product shall constitute the new adjusted API Portion for the then current Contract Year for purposes of calculating the estimated Purchase Price pursuant to Section 9.1.  
9.4 Improvement Program. Horizon and sanofi-aventis, through specifically designated personnel of each Party, shall collaborate on a regular basis during the Term to identify, track and review specific cost-saving improvement opportunities relating to the manufacturing process of the Product hereunder and shall agree funding for required technical or other resources to develop such improvements. Clearly identified and mutually agreed savings resulting from jointly developed technological changes or processes (and the costs incurred in connection with their industrial implementation at the Production Site) shall be shared equally by the Parties and shall be so reflected in the Product Prices.  
9.5 Payment Terms. Sanofi-aventis shall invoice Horizon for all quantities of the Product purchased hereunder concurrently with sanofi-aventis’ shipment thereof to Horizon. All amounts properly invoiced by sanofi-aventis hereunder shall be due and payable […\*\*\*…] days from the date of such invoice. Payment may be made by Horizon’s corporate check or by wire transfer of funds to such account as sanofi-aventis may designate.  
9.6 Tax. In addition to the Product Price, Horizon shall pay to sanofi-aventis all use, consumption, sales, withholding or excise taxes of any relevant taxing authority arising from sale of the Product by sanofi-aventis to Horizon, other than taxes based upon sanofi-aventis’ net income, and any tax that may be assessed on the bulk Product for shipment between Production Sites. The amount of such taxes will be added to the Product Price in effect at the time of shipment and will be reflected in the invoices submitted to Horizon by sanofi-aventis. To the extent services include research and development relating to the Product, then sanofi-aventis shall be exclusively entitled to claim any research and development tax credits relating to such research and development services under applicable law.  
ARTICLE 10  
CONFIDENTIALITY  
10.1 The Party receiving Information (the “Receiving Party”) from the other Party (the “Disclosing Party”) undertakes to treat the Information as strictly confidential and to use the Information in accordance with the terms and conditions set forth herein and will use such Information strictly to comply with its obligations set forth in this Agreement.  
10.2 The Receiving Party undertakes to make the Information available only to its employees on a need-to-know basis and to take all steps necessary to protect the Information and to ensure that these employees shall not disclose or use at any time such Information in a manner which is not authorized under this Agreement. In no event shall the Receiving Party communicate the Information to third parties without the prior written approval of the Disclosing Party. Notwithstanding the foregoing, should the Receiving Party require the assistance of Third Parties in order to perform its obligations under this Agreement, these Third Parties will be subject to substantially similar conditions of confidentiality as the Receiving Party.  
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 In the case of a breach of these obligations by these third parties, the Receiving Party remains responsible for them towards the Disclosing Party.  
10.3 The obligations of this Section 10 shall not apply however to Information that:  
 a. was known to the Receiving Party prior to its receipt from the Disclosing Party as documented by the Receiving Party’s written records, or,  
 b. was known to the public, or generally available to the public prior to its receipt from the Disclosing Party, or,  
 c. became known to the public or generally available to the public subsequent to its receipt from the Disclosing Party, through no breach of this Agreement by the Receiving Party, or,  
 d. was received by the Receiving Party, at any time, from a third party under no obligation of confidentiality to the Disclosing Party concerning such part of the Information, or,  
 e. was independently developed by the Receiving Party prior to disclosure or thereafter by the Disclosing Party, as documented by the Receiving Party’s written records.  
10.4 For the purposes of this Agreement, no Information shall be deemed to be in the public domain or knowledge or in the possession or knowledge of the Receiving Party merely because such Information is embraced by more general information in the public domain or knowledge or in the possession or knowledge of the Receiving Party.  
10.5 The Receiving Party may disclose the Information without violating its obligations under this Article 10, to the extent such disclosure is required by law or by court, provided that, in the event the Receiving Party is required to disclose Information, the Receiving Party shall provide prompt written notice to the Disclosing Party of such requirement so that the Disclosing Party may seek a protective order or other appropriate remedy. In the event no such protective order or other remedy is obtained, the Receiving Party agrees to disclose only that portion of Information it is legally required to disclose and to exercise all reasonable efforts to obtain confidential treatment for such Information.  
10.6 Within thirty (30) days after the termination or expiration of this Agreement and upon the written request of the Disclosing Party, the Receiving Party shall return or destroy all such Information and copies thereof in its possession, except that each Party may keep one copy of such Information in its Legal Department confidential files solely for archival purposes and this copy will not be distributed in any manner other than as provided in this Agreement, without the express prior written permission of the Disclosing Party.  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 15  
 10.7 Each Party specifically recognizes that any breach by it of this Article 10 may cause irreparable injury to the other Party and that actual damages may be difficult to ascertain, and in any event, may be inadequate. Accordingly (and without limiting the availability of legal or equitable, including injunctive, remedies under any other provisions of this Agreement), each Party agrees that in the event of any such breach, notwithstanding the provisions of this Agreement, the other Party shall be entitled to seek injunctive relief and such other legal and equitable remedies as may be available.  
10.8 The Parties acknowledge that Horizon may be required to file this Agreement with the U.S. Securities and Exchange Commission, and the Parties will consult with each other, and such consultation shall include sanofi-aventis having no fewer than […\*\*\*…] business days to prepare requests regarding, the provisions of this Agreement to be redacted in such filings by Horizon with the U.S. Securities and Exchange Commission or as otherwise required by applicable laws.  
10.9 Nothing in this Agreement shall be deemed to give either Party any rights to use the other Party’s trademarks or trade names without the other Party’s prior specific, written consent. Neither party will issue any press release or otherwise make any public statement, advertisement or disclosure with respect to this Agreement or the transactions contemplated hereby without the prior written consent of the other Party, which shall not be unreasonably withheld; provided, however, either Party shall be entitled to make a public announcement of this Agreement after giving prior written notice to the other Party hereto, subject to required compliance with law or by any securities exchange, regulatory or governmental body having jurisdiction.  
10.10 This Article 10 shall survive the expiration or termination of this Agreement for a period of five (5) years.  
ARTICLE 11  
EQUIPMENT / CAPITAL EXPENDITURE  
11.1 Horizon Equipment; sanofi-aventis Equipment  
Horizon shall bear at its own cost and shall be responsible for the purchase, installation, and qualification of the Horizon Equipment. The Horizon Equipment shall be delivered to the Production Site in Laval, Quebec and installed at such Production Site at Horizon’s sole cost and expense. Sanofi-aventis shall not relocate the Horizon Equipment from the Production Site in Laval, Quebec without Horizon’s prior written consent or as otherwise permitted in this Agreement.  
In the event that modification of the Horizon Equipment is requested by Horizon, Horizon will pay for the purchase, installation and qualification performed by sanofi-aventis or its designated Affiliate with respect to such modification. Upon payment by Horizon, any modifications to such Horizon Equipment shall become Horizon’s property and shall be deemed included in the Horizon Equipment.  
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 Both Parties acknowledge that the sanofi-aventis Equipment as of the Effective Date and the Horizon Equipment will not be sufficient to fulfill the currently anticipated commercial demand for Products and that additional presses required for commercial supply will be required. If Horizon determines that additional presses are necessary for commercial supply, it shall notify sanofi-aventis thereof, in writing, and sanofi-aventis shall purchase, install and qualify such additional press(es) (“Additional Presses”) in accordance with the timelines agreed by the Parties, at sanofi-aventis’ sole cost and expense, subject to any reimbursement as outlined in Section 11.5. It is understood and acknowledged by Horizon that sanofi-aventis shall not be required to fill purchase orders for commercial supply quantities greater than the then-current actual capacity of the then-qualified sanofi-aventis Production Sites (at the time of receiving written notice from Horizon outlined immediately above) until such time as the Additional Presses are approved and qualified in accordance with this Agreement and applicable law.  
The Parties agree that sanofi-aventis will purchase at its own cost and expense and be solely responsible for the purchase, installation, and qualification of all equipment necessary to manufacture and supply the Product in compliance with this Agreement (in addition to the Additional Presses), other than the Horizon Equipment (collectively, the “sanofi-aventis Equipment”).  
11.2 Ownership of Equipment  
Horizon owns all Horizon Equipment and sanofi-aventis will own all sanofi-aventis Equipment, including Additional Presses, if any. The Parties will take appropriate measures to ensure that any equipment owned by Horizon located at sanofi-aventis or its designated Affiliate Production Site will be clearly identified as Horizon property for future audit purposes, and Horizon shall have the right to obtain possession of any Horizon Equipment, at its sole cost and expense, at the expiry or termination of this Agreement in accordance with the terms and conditions set forth herein. Removal of any Horizon Equipment at the expiry or termination of this Agreement is conditional on Horizon bearing responsibility for the reasonable cost and expense of restoring any sanofi-aventis Equipment affected by the installation, modification or use of the Horizon Equipment to the status of such equipment at the time immediately prior to the installation or modification of any Horizon Equipment (ordinary wear and tear excepted and not including any modification made by sanofi-aventis or an Affiliate without the approval of Horizon). At the expiry or termination of this Agreement, sanofi-aventis and its designated Affiliate will remove any Horizon Equipment and restore any sanofi-aventis Equipment, but any such removal or restoration may, at the option of Horizon, be witnessed by Horizon. Sanofi-aventis will prepare a cost estimate at the time of the Horizon Equipment installation outlining the incurred costs for any renovations that were performed on the Production Site in order to accommodate Horizon Equipment, and this estimate will be the basis of any reimbursement should it become necessary.  
11.3 Maintenance of Equipment  
Sanofi-aventis and its designated Affiliates are responsible for the cost of routine maintenance of the Horizon Equipment while installed at the Production Site. Horizon is responsible for the cost of replacement parts, Third Party service, and any installation costs with respect to the Horizon Equipment only, except where any replacement costs results from the gross negligence or willful  
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 misconduct of sanofi-aventis or its designated Affiliate with respect to the Horizon Equipment, in which case sanofi-aventis or its designated Affiliate shall bear said repair or replacement cost. While Horizon Equipment is located at any Production Site, sanofi-aventis or such Affiliate will comply with any reasonable requests of Horizon with respect to such Horizon Equipment in order to satisfy any warranty with respect to such Horizon Equipment, including, without limitation, inspection of such Horizon Equipment.  
Sanofi-aventis and its designated Affiliate are responsible for the cost of routine maintenance of the sanofi-aventis Equipment while installed at any Production Site, as well as the cost of replacement parts, Third Party service, and any installation costs with respect to the sanofi-aventis Equipment.  
11.4 Liability in relation to Equipment and Horizon Materials  
Title to the Horizon Equipment and risk of loss, damage to or destruction of such Horizon Equipment remain with Horizon. Sanofi-aventis or designated Affiliate will have no liability for loss, damage or destruction of the Horizon Equipment, unless such loss, damage or destruction resulted from the gross negligence or willful misconduct of sanofi-aventis or designated Affiliate. Horizon will maintain commercially reasonable levels of insurance on any Horizon Equipment to cover any potential liability associated therewith.  
Title to the sanofi-aventis Equipment and risk of loss, damage to or destruction of such sanofi-aventis Equipment remain with sanofi-aventis. Horizon will have no liability for loss, damage or destruction of the sanofi-aventis Equipment. Sanofi-aventis will maintain commercially reasonable levels of insurance on any sanofi-aventis Equipment to cover any potential liability associated therewith.  
11.5 Limited Reimbursement Right for sanofi-aventis Equipment  
Within […\*\*\*…] days following any (a) expiration of this Agreement (either expiration of the Initial Term, if the term is not renewed by Horizon, or, if renewed, expiration of the last Renewal Term), or (b) early termination of this Agreement by Horizon prior to the expiration of the Initial Term pursuant to Section 15.2 or 15.7 hereof, Horizon shall reimburse sanofi-aventis in an amount equal to the depreciated net book value on the effective date of such expiration or termination, as reasonably determined by Horizon, and agreed to by sanofi-aventis, in accordance with applicable accounting rules, of any sanofi-aventis Equipment Additional Presses purchased by sanofi-aventis during the term of this Agreement pursuant to Section 11.1, and which are in sanofi-aventis’ control and possession on the date of such expiration or termination.  
ARTICLE 12  
INTELLECTUAL PROPERTY  
12.1 Ownership of Rights  
Each Party shall exclusively own and retain all right, title and interest in and to all Intellectual Property Rights, information, documents and tangible and intangible materials (with  
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 respect to each Party, its “Base Technology”) (i) owned by it as of the Effective Date, or (ii) conceived, reduced to practice, or created by such Party or its Affiliates or agents (including without limitation Intellectual Property Rights, information, documents and tangible and intangible materials based upon any background or preexisting technology of such Party) from and after the Effective Date and in the case of Horizon, shall include, without limitation, all information and Know-How developed by Horizon and communicated to sanofi-aventis in the technical transfer relating to the Product or manufacture of the Product, including, without limitation, the active and excipient components of the Product, under the Technical Transfer Agreement. For clarification, all Base Technology of a Party under the Technology Transfer Agreement shall be included in such Party’s Base Technology under this Agreement. Each Party shall be solely responsible for the conduct and costs of filing, prosecution and maintenance of patents and patent applications on its own Intellectual Property Rights, information, documents and tangible and intangible materials. Except as expressly set forth herein, nothing in this Agreement grants either Party any right, title or interest in the Intellectual Property Rights of the other Party hereto. Sanofi-aventis represents that, to its knowledge, sanofi-aventis does not currently have any right, title, or interest in any Intellectual Property Rights primarily relating to the Product. Each Party shall have the right to bring, defend, maintain and settle any suit, action or proceeding involving infringement of its Intellectual Property Rights, including without limitation its patent rights. Each Party shall pay all expenses incurred in connection with such suit, action or proceeding. Any amount recovered in any such suit, action or proceeding, whether by judgment or settlement shall be retained by the Party bringing the action.  
Horizon represents and warrants that, to the best of Horizon’s knowledge, practice by sanofi aventis or designated Affiliate of the Horizon IP that Horizon provides to sanofi-aventis or designated Affiliate pursuant to this Agreement to perform the services to be performed by sanofi aventis in compliance with this Agreement do not and, will not infringe the Intellectual Property Rights of any Third Party.  
Sanofi-aventis represents and warrants that, to the best of sanofi-aventis’ knowledge, practice by sanofi aventis of the SAUS IP that sanofi-aventis provides pursuant to this Agreement to perform the services to be performed by sanofi aventis in compliance with this Agreement do not and, will not infringe the Intellectual Property Rights of any Third Party.  
12.2 License from Horizon  
Horizon hereby grants to sanofi-aventis a royalty-free, non-exclusive, license during the Term to use and/or practice the Horizon IP solely to perform sanofi-aventis’ or designated Affiliates’ obligations in accordance with the terms of this Agreement.  
ARTICLE 13  
REPRESENTATIONS, WARRANTIES AND COVENANTS  
13.1 Sanofi-aventis. Sanofi-aventis represents, warrants and covenants to Horizon as  
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 follows:  
A. Product. The Product, at the time of sale and delivery to Horizon by sanofi-aventis, shall conform to the Specifications, as then in effect.  
B. Manufacturing Standards. Sanofi-aventis shall manufacture the Product in accordance with (i) the Specifications, (ii) then-current cGMPs, and (iii) ICH Guidelines.  
C. Compliance with Applicable Laws. Sanofi-aventis shall fully comply with all applicable national, federal, state and local laws in performing the services contemplated hereunder.  
D. Qualified Personnel. Sanofi-aventis shall engage and employ only professionally qualified personnel to perform the services contemplated hereunder.  
13.2 Horizon. Horizon represents, warrants and covenants to Sanofi-aventis as follows:  
A. No specific safe handling instructions are applicable to the Product, except as disclosed to sanofi-aventis in writing in the Product specific MSDS previously provided to sanofi-aventis by Horizon;  
B. All Product delivered to Horizon by Sanofi-aventis shall be held, sold, marketed and/or used by Horizon in accordance with all applicable national, federal, state and local laws;  
C. Horizon is in compliance with and shall comply with all laws, rules, regulations and guidelines applicable to Horizon’s performance under this Agreement and its sale or use of Products provided by Sanofi-aventis under this Agreement;  
D. The content of all artwork provided by Horizon to sanofi-aventis shall comply with all applicable national, federal, state and local laws.  
13.3 Mutual. Each Party hereby represents and warrants to the other Party as of the Effective Date that:  
A. such Party (1) is duly organized, validly existing and in good standing under the laws of the state in which it is organized, (2) has the power and authority and the legal right to own and operate its property and assets, and to carry on its business as it is now being conducted, and (3) is in compliance with all requirements of applicable national, federal, state and local law, except to the extent that any noncompliance would not materially adversely affect such Party’s ability to perform its obligations under this Agreement;  
B. such Party (1) has the power and authority and the legal right to enter into this Agreement and to perform its obligations hereunder and (2) has taken all necessary action on its part to authorize the execution and delivery of the Agreement and the performance of its obligations hereunder;  
C. this Agreement has been duly executed and delivered on behalf of such Party, and  
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 constitutes a legal, valid, binding obligation, enforceable against such Party in accordance with its terms;  
D. all necessary consents, approvals and authorizations of all agencies and other persons required to be obtained by such Party in connection with the execution and delivery of this Agreement have been obtained; and  
E. the execution and delivery of this Agreement and the performance of such Party’s obligations hereunder do not materially conflict with or violate any requirement of applicable national, federal, state and local laws or any material contractual obligation of such Party.  
F. Debarment. As of the Effective Date, neither Party nor any of its Affiliates nor its or their employees has been debarred under FDCA 21 USC 335a, and to the best of its knowledge, is not subject to pending debarment under FDCA 21 USC 335a. Neither Party will, during the Term, employ or use the services of any person who is debarred in connection with the activities for which it is responsible under this Agreement, and, in the event that a Party becomes aware of the debarment or threatened debarment of any person providing services to such Party that directly or indirectly relate to activities for which it is responsible under this Agreement, such Party shall immediately notify the other Party in writing.  
ARTICLE 14  
Intentionally omitted.  
ARTICLE 15  
TERM; TERMINATION  
15.1 Term. Unless sooner terminated or renewed pursuant to the terms hereof, the term of this Agreement shall commence on the Effective Date and shall expire on the eighth (8th) anniversary of the First Commercial Sale (the “Initial Term”). Upon the expiration of the Initial Term, this Agreement shall automatically and continually renew for successive two (2) year terms (each, a “Renewal Term”, and the Initial Term and all Renewal Terms being collectively referred to as the “Term”) unless either Party notifies the other in writing at least twenty-four (24) months prior to the end of the Initial Term or any Renewal Term, as the case may be, of its intent that this Agreement shall expire without further renewal.  
15.2 Termination For Convenience. This Agreement may be terminated by either Party without cause upon two (2) years prior written notice to the other Party. Notice of termination without cause cannot be given by either Party before the third (3rd) anniversary of the date of the First Commercial Sale.  
15.3 Termination Upon Delay of Commercialization. Should the project of commercializing the Product be delayed beyond December 31, 2012, sanofi-aventis may terminate this Agreement upon six (6) months written notice to Horizon. Such termination shall be sanofi-aventis’ sole remedy for such event.  
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 15.4 Termination by Mutual Agreement. The Parties may terminate this Agreement at any time by mutual written agreement.  
15.5 Termination Upon Breach. Either Party may terminate this Agreement upon not less than thirty (30) days written notice to the other Party upon the material breach or default by the other Party of any of its representations, warranties, covenants or agreements, which breach or default is not cured within thirty (30) days after the date of such notice (provided, however, that such cure period shall be extended by such additional period as the breaching Party may request upon the breaching Party’s written certification that (i) such breach is not reasonably capable of being cured within such thirty (30) day period and (ii) it has commenced and is diligently pursuing efforts to cure such breach). Upon the expiration of such cure period, this Agreement shall terminate without the need for further action by either Party; provided, however, that if the breach upon which such notice of termination is based shall have been fully cured to the reasonable satisfaction of the non-breaching Party within such cure period, then such notice of termination shall be deemed rescinded, and this Agreement shall be deemed reinstated and in full force and effect. Such right of termination shall be in addition to such other rights and remedies specified in this Agreement.  
15.6 Intentionally omitted.  
15.7 Loss of Regulatory Approval in All Countries. Either Party may terminate this Agreement upon thirty (30) days written notice to the other Party in the event of Horizon’s loss of regulatory approval to market the Product in all of the countries within the Territory. Such termination shall be the terminating Party’s sole remedy for such event.  
15.8 Rights and Duties Upon Termination.  
(a) Upon the expiration or termination of this Agreement (other than termination by Horizon pursuant to Section 15.5 hereof), unless otherwise mutually agreed by the Parties, sanofi-aventis shall manufacture and ship, and Horizon shall purchase in accordance with the provisions hereof, all quantities of Product ordered by Horizon hereunder prior to the date of expiration or termination.  
(b) Upon the expiration or termination of this Agreement (other than termination by Horizon pursuant to Section 15.5 hereof), Horizon shall, if so requested by sanofi-aventis, purchase (i) all APIs, Excipients and Packaging Components acquired by sanofi-aventis hereunder to manufacture the Product, at sanofi-aventis’ Acquisition Cost plus the cost of […\*\*\*…] thereof, (ii) all work-in-progress of the Product at […\*\*\*…] thereof, and (iii) all finished Product inventory then in sanofi-aventis’ possession at the […\*\*\*…] (as adjusted in accordance with Article 9 above). In addition, in such case Horizon shall pay sanofi-aventis for any uncancellable commitments made by sanofi-aventis for Excipients and Packaging Components hereunder. Notwithstanding anything to the contrary in the preceding two sentences, the foregoing purchase and payment obligations of Horizon shall be limited to a […\*\*\*…] month supply of Excipients and Packaging Components and Product quantities manufactured and commitments incurred by sanofi-aventis  
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 for quantities of the Product as to which Horizon’ forecasts under Section 6.1 hereof constitute a firm commitment.  
ARTICLE 16  
CLAIMS; RECALLS  
16.1 Claims. Horizon may reject any quantity of the Product which fails to materially conform to any applicable purchase order, warranty, Specifications or laws upon providing samples of such Product along with written notice to sanofi-aventis describing such nonconformity or shortage and given within […\*\*\*…] days after Horizon’s receipt thereof (or, in the case of any Latent Defects, within […\*\*\*…] days after discovery thereof by Horizon). Sanofi-aventis shall have no liability to Horizon with respect to any such nonconformity or shortage to the extent that the Parties agree in writing (or, absent such agreement, which a mutually acceptable independent laboratory or consultant determines) that such nonconformity or shortage (i) was caused as a result of information supplied by Horizon, (ii) was otherwise caused by Horizon or its agents, (iii) was caused after delivery thereof to the carrier at the Production Site, (iv) was a change in the color or characteristics of conforming Product occurring after sanofi-aventis QA release of the Product that is related to the quality of the Horizon API or (v) was caused by the failure of otherwise attributable to or arising from the Horizon API. In all other cases, at Horizon’s election, sanofi-aventis shall promptly credit Horizon’s account for sanofi-aventis’ invoice price to Horizon of such nonconforming or short Product or deliver the amount of the shortages; or if Horizon shall have previously paid for such nonconforming Product, sanofi-aventis shall promptly, at Horizon’s election, either (a) refund the invoice price thereof, (b) offset the amount thereof against other amounts then due sanofi-aventis hereunder or (c) replace such nonconforming or short Product with conforming Product at no additional cost to Horizon. The foregoing remedy constitutes the exclusive remedy against sanofi-aventis and the entire liability of sanofi-aventis in connection with any rejected or short shipment. The fees and expenses of any independent laboratory or consultant engaged by the Parties for purposes of this section shall be paid by the Party which is determined to bear responsibility for the nonconformity or shortage in question.  
16.2 Recalls.  
(a) Notices. Each Party shall notify the other Party as soon as possible when they receive information, whether received directly or indirectly, which might affect the marketability, quality, safety or effectiveness of the Product and/or which might result in the Recall or seizure of the Product. For purposes of this Agreement, a “Recall” shall mean any action: (i) by either Party to recover title to or possession of quantities of the Product sold or shipped to Third Parties (including, without limitation, the voluntary withdrawal of the Product from the market) or (ii) by any regulatory authorities to detain or destroy any of the Product. “Recall” shall also include the election by either Party to refrain from selling or shipping quantities of the Product to Third Parties that would have been subject to a Recall if sold or shipped. Each Party shall maintain records as may be necessary to permit a Recall of the Product. The Quality Agreement will provide further details regarding Recall procedures.  
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 (b) Discretion. Horizon shall have the sole right to institute a Recall or field alert of the Product as a consequence of any defect that Horizon deems sufficiently serious. Horizon shall consult with sanofi-aventis regarding any Recall or Field Alert that may be due to manufacture; provided, however, that Horizon shall retain sole discretion whether to institute a Recall. Sanofi-aventis shall provide a rapid initial response and a full report with respect thereto within ten (10) working days of such notification.  
(c) Responsibilities. Sanofi-aventis shall have no liability to Horizon with respect to any Recall to the extent the Parties agree in writing (or, absent such agreement, which a mutually acceptable independent laboratory or consultant determines) that the Recall (i) was caused by information supplied by Horizon, (ii) was otherwise caused by Horizon or its agents, (iii) was caused by factors occurring after delivery of the Recalled Product to the carrier at the Production Site (other than Latent Defects), or (iv) did not result from a breach of sanofi-aventis’ warranties provided under this Agreement. In addition, Horizon shall reimburse sanofi-aventis for all reasonable out-of-pocket Third Party costs and expenses incurred and not recovered by sanofi-aventis directly resulting from such Recall (subject to the limitations set forth in Sections 17.5). For all Recalls which result from a breach of sanofi-aventis’ warranties provided under this Agreement, except to the extent sanofi-aventis does not have liability pursuant to this Section 16.2(c), sanofi-aventis shall: (i) promptly credit Horizon’s account for sanofi-aventis’ invoice price to Horizon of such Recalled Product; if Horizon shall have previously paid for such Product, sanofi-aventis shall promptly, at Horizon’s election, either (A) refund the invoice price, (B) offset the amount thereof against other amounts then due sanofi-aventis hereunder or (C) replace such Product at no additional cost to Horizon; and (ii) reimburse Horizon for all reasonable out-of-pocket Third Party costs and expenses incurred and not recovered by Horizon directly resulting from such Recall (subject to the limitations set forth in Sections 17.5 and 17.6 hereof).  
(d) Independent Laboratory Costs. The fees and expenses of any independent laboratory or consultant engaged by the Parties for purposes of this Section 16.2 shall be paid by the Party which is determined to bear responsibility for the Recall in question.  
16.3 Disposition of Nonconforming or Recalled Product. Horizon shall not dispose of any damaged, nonconforming or Recalled Product as to which it intends to assert a claim against sanofi-aventis without sanofi-aventis’ written authorization to do so. Alternatively, sanofi-aventis may instruct Horizon to return such Product to sanofi-aventis. Sanofi-aventis shall bear the cost of disposition (as well as all applicable shipping costs) with respect to any damaged, nonconforming or Recalled Product as to which it bears responsibility under Section 16.1 or 16.2 hereof.  
ARTICLE 17  
INDEMNIFICATION  
17.1 By sanofi-aventis  
Sanofi-aventis shall indemnify, defend and hold harmless Horizon and its officers, directors,  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 24  
 agents, affiliates and their respective employees and representatives, from and against any and all Third Party losses, damages, claims, injuries, costs or expenses, including reasonable attorneys’ fees and expenses, including any illness or personal injury, including death, or property damage (collectively, “Losses”) that arise out of or are attributable to (a) the failure of the Product to meet the Specifications at the time of delivery to Horizon; (b) any claim by a Third Party that the use by sanofi-aventis of the SAUS IP to perform the obligations of sanofi-aventis under this Agreement in compliance with the terms of this Agreement, including, without limitation, the manufacture or testing of the Products, infringes its intellectual property rights; (c) any breach of any representation, warranty or covenant made by sanofi-aventis hereunder; or (d) the gross negligence or willful misconduct of sanofi-aventis or any person whose actions or omissions sanofi-aventis is legally liable for (including, without limitation, its Affiliates), except, in each of (a), (b), (c), or (d) to the extent that such Losses are indemnified by Horizon pursuant to Section 17.2.  
17.2 By Horizon  
Horizon shall indemnify, defend and hold harmless sanofi-aventis and its officers, directors, agents, affiliates and their respective employees and representatives from and against any and all Third Party Losses that arise out of or are attributable to (a) any claim by a Third Party that the use by sanofi-aventis of the Horizon IP to perform the obligations of sanofi-aventis under this Agreement in compliance with the terms of this Agreement or as directed by Horizon, including, without limitation, the manufacture or testing of the Products, infringes its intellectual property rights; (b) any breach of any representation, warranty or covenant made by Horizon hereunder; (c) any claim by a Third Party with respect to the development, testing, use, marketing, distribution, importation, sale or offer for sale of the Product by or on behalf of Horizon (including, without limitation, product liability claims), subject to Article 16, where applicable, or (d) the gross negligence or willful misconduct of Horizon or any person whose actions or omissions Horizon is legally liable for, except, in each of (a), (b), (c), or (d), to the extent that such Losses are indemnified by sanofi-aventis pursuant to Section 17.1.  
If a Party becomes aware of any claim or allegation by any Third Party that the performance of any services contemplated by this Agreement infringe such Third Party’s intellectual property rights, it shall promptly inform the other Party, and the Parties shall discuss such matter and a proposed resolution. Either Party may, following such discussion, delay performance of its obligations hereunder pursuant to the force majeure provision in Section 22 pending satisfactory resolution of such matter or terminate this Agreement upon written notice to the other party, provided that neither party shall be permitted to terminate this Agreement as set forth in this sentence in the event it or the other party promptly resolves the matter pursuant to one of the following two sentences. If the use of the Horizon IP in the manufacture or testing of the Product pursuant to this Agreement becomes, or in Horizon’s opinion is likely to become, the subject of an action by a Third Party alleging infringement of such Third Party’s intellectual property rights, Horizon may, at Horizon’s sole election and expense, either (a) procure, in form and manner satisfactory to sanofi-aventis , the right to continue using the relevant Horizon IP to permit sanofi-aventis to perform its obligations under this Agreement without infringing such rights, or (b) replace or modify the Horizon IP or the process for manufacturing or testing the Product with non-infringing intellectual property. If the use of the SAUS IP in the manufacture  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 25  
 or testing of the Product pursuant to this Agreement becomes, or in sanofi-aventis’ opinion is likely to become, the subject of an action by a Third Party alleging infringement of such Third Party’s intellectual property rights, sanofi-aventis may, at sanofi-aventis’ sole election and expense, either (a) procure, in form and manner satisfactory to Horizon, the right to continue using the relevant the SAUS IP to permit sanofi-aventis to perform its obligations under this Agreement without infringing such rights, or (b) replace or modify the SAUS IP with non-infringing intellectual property.  
17.3 Procedure  
If any Third Party notifies a Party or any of its officers, agents or Affiliates, or their respective employees or representatives (an “Indemnified Party”) with respect to any matter (a “Third Party Claim”) that may give rise to a claim against the other Party (the “Indemnifying Party”) under this Article, then the Indemnified Party will promptly give written notice to the Indemnifying Party; provided, however, that no delay on the part of the Indemnified Party in notifying the Indemnifying Party will relieve the Indemnifying Party from any obligation under this Article, except to the extent such delay actually prejudices the Indemnifying Party. The Indemnifying Party will have the right to defend the Indemnified Party against the Third Party Claim, at its sole expense, with counsel of its choice reasonably satisfactory to the Indemnified Party so long as (i) the Indemnifying Party gives written notice to the Indemnified Party of its assumption of responsibility for any Losses arising out of such Third Party Claim and its assumption of control and defense of the Third Party Claim within […\*\*\*…] days after the Indemnified Party has given notice of the Third Party Claim to the Indemnifying Party, (ii) the Indemnifying Party provides the Indemnified Party with evidence reasonably acceptable to the Indemnified Party that such Indemnifying Party has and will have adequate financial resources to defend against the Third Party Claim and fulfill its indemnification obligations hereunder, (iii) the Third Party Claim does not seek an injunction or other equitable relief against the Indemnified Party (provided, however, that to the extent that sanofi-aventis has sought indemnification from Horizon regarding a Third Party Claim that the Horizon IP infringes the intellectual property rights of a Third Party, Horizon shall have the right to defend such Third Party Claim with counsel of its choice reasonably satisfactory to sanofi-aventis and, provided further that to the extent that Horizon has sought indemnification from sanofi-aventis regarding a Third Party Claim that the SAUS IP infringes the intellectual property rights of a Third Party, sanofi-aventis shall have the right to defend such Third Party Claim with counsel of its choice reasonably satisfactory to Horizon), (iv) the Third Party Claim does not relate to or otherwise arise in connection with any criminal or regulatory enforcement action, and (v) the Indemnifying Party conducts the defense of the Third Party Claim actively and diligently. The Indemnified Party may retain separate co-counsel at its own cost and expense and participate in the defense of the Third Party Claim. The Indemnifying Party will not consent to the entry of any judgment or enter into any compromise or settlement with respect to the Third Party Claim without the prior written consent of the Indemnified Party unless such judgment, compromise or settlement (a) provides for the payment by the Indemnifying Party of money as sole relief for the claimant, and (b) results in the full and general release of the Indemnified Party from all liabilities arising or relating to, or in connection with, the Third Party Claim. The Indemnifying Party is expressly prohibited from consenting to the entry of any judgment or entering into any compromise or settlement that (1) involves a finding or admission of any violation of legal requirements or the  
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 rights of any Third Party by the Indemnified Party or (2) grants an injunction or other equitable relief against the Indemnified Party, and any such purported consent, compromise or settlement entered into without the prior written consent of the Indemnified Party shall be null and void ab initio. The Indemnified Party may not consent to the entry of any judgment or enter into any compromise or settlement with respect to a Third Party Claim with respect to which indemnification is being sought hereunder without the prior written consent of the Indemnifying Party.  
If the Indemnifying Party does not assume the control and defense of a Third Party Claim in accordance with the immediately preceding paragraph, the Indemnified Party may defend such Third Party Claim and seek indemnification hereunder from the Indemnifying Party for any Losses associated therewith after […\*\*\*…] business days’ notice to the Indemnifying Party of its intent to do so. The Indemnifying Party or the Indemnified Party, as the case may be, shall at all times use reasonable efforts to keep the other reasonably apprised of the status of the defense of any Third Party Claim and to cooperate in good faith with each other with respect to the defense of any such matter, and provide the non-defending party with copies of all correspondence and documents relating to or in connection with a Third Party Claim.  
17.4 Disclaimer of Warranties  
EXCEPT FOR THE EXPRESS REPRESENTATIONS AND WARRANTIES IN THIS AGREEMENT NEITHER PARTY MAKES ANY REPRESENTATIONS OR WARRANTIES OF ANY KIND, EXPRESS OR IMPLIED, INCLUDING IMPLIED WARRANTIES OF MERCHANTABILITY, FITNESS FOR A PARTICULAR PURPOSE OR ANY OTHER MATTER RELATING TO THE PRODUCT, INFORMATION, MATERIALS OR EQUIPMENT PROVIDED UNDER THIS AGREEMENT.  
17.5 Damages  
NEITHER PARTY SHALL BE LIABLE TO THE OTHER UNDER THE TERMS OF THIS AGREEMENT OR OTHERWISE BY REASON OF ANY REPRESENTATION OR WARRANTY, CONDITION OR OTHER TERM OR ANY DUTY OF COMMON LAW, OR UNDER THE EXPRESS TERMS OF THIS AGREEMENT, FOR ANY CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE, WHETHER FOR LOSS OF CURRENT OR FUTURE PROFITS, LOSS OF ENTERPRISE VALUE OR OTHERWISE AND WHETHER OCCASIONED BY THE NEGLIGENCE OR INTENTIONAL ACTS OF THE RESPECTIVE PARTIES, THEIR EMPLOYEES OR AGENTS OR OTHERWISE, EXCEPT TO THE EXTENT SUCH CONSEQUENTIAL, SPECIAL OR INCIDENTAL OR PUNITIVE LOSS OR DAMAGE SHALL BE PAYABLE TO A THIRD PARTY; PROVIDED THAT, THE LIMITATIONS IN THIS SECTION 17.5 ON CLAIMS FOR CONSEQUENTIAL, SPECIAL OR INCIDENTAL DAMAGES (BUT NOT PUNITIVE DAMAGES) SHALL NOT APPLY TO LOSSES SUSTAINED AS A RESULT OF BREACH OF THE CONFIDENTIALITY PROVISIONS OF ARTICLE 10.  
17.6 Limitation  
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 IN NO EVENT SHALL SANOFI-AVENTIS’ TOTAL AGGREGATE LIABILITY FOR ALL CLAIMS ARISING OUT OF OR RELATED TO THIS AGREEMENT EXCEED, ON A CUMULATIVE BASIS, […\*\*\*…], REGARDLESS OF THE CAUSE OF ACTION UPON WHICH SUCH CLAIM IS BASED. NOTHING IN THIS AGREEMENT WILL PERMIT ANY PARTY TO RECOVER TWICE FOR THE SAME LOSS.  
ARTICLE 18  
INSURANCE  
Each Party represents that it has and shall maintain during the Term hereof, as well as after the expiration or termination of this Agreement, sufficient insurance or an appropriate program of self insurance, and in particular products liability insurance, with appropriate policy limits to cover all risks associated with the performance of its obligations under this Agreement. Each Party agrees to provide upon request copies of the relevant certificate(s) of insurance.  
ARTICLE 19  
Intentionally omitted.  
ARTICLE 20  
BOOKS AND RECORDS  
Each Party shall maintain and retain for three (3) years following the end of the applicable Contract Year (or such longer period as may be required by law) true and accurate books and records relating to its charges under this Agreement, including in the case of sanofi-aventis its Acquisition Costs and all adjustments made pursuant to Article 5 or 9, and all other costs incurred in connection herewith. Each Party may request documentation necessary for the purpose of resolving disputes regarding payments, pricing, invoicing, or similar matters, provided that such requests shall be made no more than once each Contract Year. The other Party shall provide the requested information within […\*\*\*…] days from receipt of such request. If the requesting Party, in its sole discretion, has not received sufficient information for resolving disputed payment, pricing or invoice, or similar matters, the requesting Party, through its independent accounting firm, may audit the books and records of the other Party. The review and report of any such designated independent accounting firm shall be restricted to those records reasonably necessary to the enforcement by the requesting Party of its rights hereunder. Such review and report shall be made with due regard to any information which is competitively sensitive, and the independent accounting firm shall not disclose to the requesting Party any information that would reasonably deemed to be competitively sensitive. Prior to the beginning of any such audit, the independent accounting firm and the other Party shall establish procedures reasonably designed to protect sensitive information from disclosure. The foregoing record keeping and review provisions shall be in addition to and distinct from the record keeping and review provisions of the Quality Agreement. The Party requesting an audit will be responsible for paying for said audit, unless such audit discloses an overpayment of more than […\*\*\*…]% for a given quarter, in which case, the audited Party shall bear the full cost of such audit.  
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 MANUFACTURING AND SUPPLY AGREEMENT PAGE 28   
 ARTICLE 21  
COOPERATION WITH GOVERNMENTAL REQUIREMENTS  
The Parties shall cooperate with one another as may be reasonably necessary or appropriate to satisfy all governmental requirements and obtain all needed permits, approvals and licenses with respect to the manufacture, storage, packaging and sale of the Product. Such cooperation shall include, without limitation, communicating with regulatory authorities and making available as promptly as practicable all information, documents and other materials which result from the performance by sanofi-aventis of its services hereunder which Horizon is required to submit or which Horizon may otherwise reasonably request in connection with governmental filings relating to the Product. The costs and expenses of such cooperation, if applicable, shall be subject to the Parties’ mutual written agreement. Notwithstanding the foregoing, it shall be the responsibility of (i) Horizon to obtain and maintain all such permits, approvals and licenses which are specific to the Product, and (ii) sanofi-aventis to obtain and maintain all such permits, approvals and licenses which are generally required for the Production Site.  
ARTICLE 22  
FORCE MAJEURE  
22.1 Effects of Force Majeure. Neither Party shall be held liable or responsible for failure or delay in fulfilling or performing any of its obligations under this Agreement (other than the payment of money owed hereunder) to the extent that such failure or delay results from any cause beyond its reasonable control, including, without limitation, fire, flood, natural disaster, explosion, war, strike, labor unrest, riot, embargo, acts or omissions of carriers, or act of God (each, a “Force Majeure Event”). Such excuse shall continue as long as the Force Majeure Event continues, following which such Party shall promptly resume performance hereunder, provided that the affected Party makes good faith efforts to avoid the effects of such condition and to perform if possible.  
22.2 Effects of Regulatory Changes. Neither Party shall be held responsible or liable for failure or delay in fulfilling or performing any of its obligations under this Agreement to the extent that such failure or delay results from good faith efforts to comply with the enactment or revision of any law, rule, regulation or regulatory advisory opinion or order applicable to the manufacturing, marketing, sale, reimbursement and/or pricing of the Product (a “Regulatory Change”). Such excuse shall continue as long as performance is prevented by the Regulatory Change, provided that the affected Party makes good faith efforts to comply with such Regulatory Change, following which such Party shall promptly resume performance hereunder.  
22.3 Notice. The Party affected by a Force Majeure Event or a Regulatory Change shall notify the other Party thereof as promptly as practicable after its occurrence. Such notice shall describe the nature of such Force Majeure Event or Regulatory Change and the extent and expected duration of the affected Party’s inability to fully perform its obligations hereunder. The affected Party shall use due diligence, where practicable, to minimize the effects of or end any such event so as to facilitate the resumption of full performance hereunder and shall notify the  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 29  
 other Party when it is again fully able to perform such obligations.  
ARTICLE 23  
INDEPENDENT CONTRACTORS  
The relationship between Horizon and sanofi-aventis is that of independent contractors and nothing herein shall be deemed to constitute the relationship of partners, joint venturers, nor of principal and agent between Horizon and sanofi-aventis. Neither Party shall have any express or implied right or authority to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement or undertaking with any Third Party.  
ARTICLE 24  
FURTHER ACTIONS  
24.1 General. The Parties agree to execute such additional documents and to perform all such other and further acts as may be necessary or desirable to carry out the purposes and intents of this Agreement.  
24.2 Transfer of Manufacturing. In the event sanofi-aventis experiences a material change in its operations, including but not limited to a discontinuation of operations at a Production Site, a shift in manufacturing operations for its own products at the Production Site which limits its capacity to manufacture products for other parties, or otherwise changes strategic direction, and such change in sanofi-aventis’ sole judgment will render it unable to provide services at a Production Site, then sanofi-aventis shall immediately notify Horizon and take all commercially reasonable measures necessary to either change the Production Site to another facility of one of its Affiliates with similar capabilities or subcontract the services, in each case at sanofi-aventis’ expense (including, without limitation, any expense relating to technology transfer, excess shipping costs and tariffs related to finished bulk product including transfer, installation and validation of any Horizon Equipment or sanofi-aventis Equipment to another facility); provided, however, that (a) sanofi-aventis shall not change a Production Site or otherwise subcontract the services without the prior written approval of Horizon as set forth in this Agreement, not to be unreasonably withheld, and (b) until such time as the Parties otherwise agree, sanofi-aventis shall continue to be responsible for performing all obligations set forth in this Agreement at the current Production Site(s) and at the current Product Prices. If no such alternative is available, and the Parties cannot come to an alternative arrangement in good faith negotiations and consultations (for a period not to exceed […\*\*\*…] days from the notice), then either Party may terminate this agreement by sending a further notice of no less than […\*\*\*…] days. During this notice period, Horizon shall be able to increase its forecast, subject to then-applicable capacity limits of Production Site(s), in order to build up an adequate inventory of Product to meet its demand pending a shift in regulatory approval to its alternative manufacturing site or order such additional required Products from a third party contract manufacturer. Sanofi-aventis shall provide all reasonable assistance at it’s expense to assist Horizon with obtaining regulatory authorizations resulting from a change in a Production Site or in transitioning manufacture of the Product to a Third Party, at sanofi-aventis’ expense (including, without limitation, any expense relating to technology transfer, including transfer,  
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 MANUFACTURING AND SUPPLY AGREEMENT PAGE 30   
 installation and validation of any Horizon Equipment or sanofi-aventis Equipment).  
24.3 Qualification of an Affiliate facility. If capacities warrant the qualification of an alternate Affiliate facility, sanofi-aventis will notify Horizon regarding a needed change to the manufacturing strategy. Horizon has the right to approve the facility, such approval not to be unreasonably withheld.  
ARTICLE 25  
MISCELLANEOUS  
25.1 General Notices. Except as otherwise provided in Section 25.2 hereof, all notices, requests, instructions, consents and other communications to be given pursuant to this Agreement shall be in writing and shall be deemed received (i) on the same day if delivered in person, by same-day courier or by telegraph, telex or facsimile transmission, (ii) on the next day if delivered by overnight mail or courier, or (iii) on the date indicated on the return receipt, or if there is no such receipt, on the third calendar day (excluding Sundays) if delivered by certified or registered mail, postage prepaid, to the Party for whom intended to the following addresses:  
If to Horizon:  
Horizon Pharma USA, Inc.  
0000 Xxxxxx Xxxx, Xxxxx 000  
Xxxxxxxxxx, Xx 00000  
Attention: Xxx Xxxxxxx, VP Medical Affairs  
Facsimile: 000-000-0000  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 31  
 If to sanofi-aventis:  
sanofi-aventis U.S. LLC  
00 Xxxxxxxxx Xxxxx  
Xxxxxxxxxxx, Xxx Xxxxxx 00000  
Attention: Director of CEPIA  
Facsimile: 000-000-0000  
with a copy to:  
sanofi-aventis U.S. LLC  
North American Legal Department; General Counsel  
00 Xxxxxxxxx Xxxxx  
Xxxxxxxxxxx, Xxx Xxxxxx 00000-0000, XXX  
Each Party may by written notice given to the other in accordance with this Agreement change the address to which notices to such Party are to be delivered.  
25.2 Subject to the terms of the Quality Agreement, each Party shall notify the other by telephone as soon as practicable (with written confirmation within three business days) upon its receipt of any technical complaint or notice of adverse reaction; provided, however, that notification of serious, new or unexpected experiences reported with increased frequency shall be made immediately (but in any event not more than […\*\*\*…] hours after the notifying Party learns of such experiences). All such notices shall be directed to the Parties at the addresses set forth in Section 25.1 to the attention of the personnel listed in the Quality Agreement.  
25.3 Entire Agreement. This Agreement, the Quality Agreement and the Technical Transfer Agreement, together with the exhibits hereto and thereto, contain the entire understanding of the Parties with respect to the subject matter hereof and supersedes all prior agreements and understandings, whether written or oral, between them with respect to the subject matter hereof. Each Party has executed this Agreement without reliance upon any promise, representation or warranty other than those expressly set forth herein.  
25.4 Amendment. No amendment of this Agreement shall be effective unless embodied in a written instrument executed by both of the Parties.  
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 MANUFACTURING AND SUPPLY AGREEMENT PAGE 32   
 25.5 Waiver of Breach. The failure of either Party at any time to enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor in any way to affect the validity of this Agreement or any provisions hereof or the right of any Party to thereafter enforce each and every provision of this Agreement. No waiver of any breach of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the Party against whom or which enforcement of such waiver is sought; and no waiver of any such breach shall be construed or deemed to be a waiver of any other or subsequent breach.  
25.6 Subcontracting. Neither Party shall subcontract any of its obligations under this Agreement; provided, however, that (i) either party may subcontract to a Third Party any of its obligations under this Agreement with the prior written approval of the other Party, such approval not to be unreasonably withheld, and (ii) sanofi-aventis may subcontract as permitted in Section 24.2. For clarification, nothing in this Agreement limits sanofi-aventis from acquiring Excipients and / or Packaging Components from Third Parties in accordance with the terms of this Agreement.  
25.7 Assignment. Except as otherwise expressly provided in this Section 25.7, neither Party may assign this Agreement in whole or in part to a Third Party without the prior written approval of the other Party (such approval not to be unreasonably withheld or delayed). Any such attempted assignment without such prior written consent shall be void and ineffective. However, each Party may assign this Agreement, without the other Party’s consent, to (i) a successor in interest to all or substantially all of the business of such Party to which this Agreement relates, whether by merger, sale of stock, sale of assets or otherwise, or (ii) any Affiliate, provided that such successor or Affiliate assumes all of the obligations of such Party under this Agreement.  
25.8 Governing Law. This Agreement shall be governed by and construed in accordance with the laws of New York, without regard to its conflicts of laws principles.  
25.9 Severability. All of the provisions of this Agreement are intended to be distinct and severable. If any provision of this Agreement is or is declared to be invalid or unenforceable in any jurisdiction, it shall be ineffective in such jurisdiction only to the extent of such invalidity or unenforceability. Such invalidity or unenforceability shall not affect either the balance of such provision, to the extent it is not invalid or unenforceable, or the remaining provisions hereof, nor render invalid or unenforceable such provision in any other jurisdiction.  
25.10 Intentionally omitted.  
25.11 Survival. The provisions of Article 1 (Definitions), Article 10 (Confidentiality), Article 12 (Intellectual Property), Section 15.8 (Rights and Duties Upon Termination), Article 16  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 33  
 (Claims; Recalls), Article 17 (Indemnification), Article 18 (Insurance), Article 20 (Books and Records), Article 21 (Cooperation with Governmental Requirements), and Article 25 (Miscellaneous) shall survive the expiration or termination of this Agreement.  
25.12 Headings. The headings of articles and sections have been included for convenience only and shall not be considered in interpreting this Agreement.  
25.13 Counterparts. This Agreement may be executed in one or more counterparts, each of which shall be deemed to be an original, and all of which together shall constitute one and the same Agreement. This Agreement may be executed and delivered via electronic facsimile transmission with the same force and effect as if it were executed and delivered by the Parties simultaneously in the presence of one another.  
25.14 Execution. At the time of execution of this Agreement, the Parties shall cause their authorized officers to execute two original copies of this Agreement, one copy of which shall be maintained by each Party at that Party’s offices. Each Party represents that the person who executes this Agreement is authorized and empowered to obligate and bind his or her Party under this Agreement.  
[Remainder of this page left blank intentionally.]  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 34  
 IN WITNESS WHEREOF, the Parties have caused this Agreement to be executed by their respective duly authorized representatives as of the day and year first above written.  
 HORIZON PHARMA USA, INC.  
By: /s/ Xxxxxxx X. Xxxxxxx  
Name: Xxxxxxx X. Xxxxxxx  
Title: Chariman, President & CEO  
SANOFI-AVENTIS U.S. LLC  
By: /s/ Xxxxx Xxxxxx  
Name: Xxxxx Xxxxxx  
Title: Vice President, U.S. Industrial Affairs  
 MANUFACTURING AND SUPPLY AGREEMENT PAGE 35  
 Exhibit 1  
PRODUCT PRICES  
 Configuration / Unit Volume / Price per increment per Contract Year  
 < […\*\*\*…] ³ […\*\*\*…]  
 […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…]  
90ct Bottle  
 […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…]  
Single Blister in \*15 x 1ct  
 […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…] […\*\*\*…]  
 \* Price based on blister material as non child proof Aclar,  
 1. Such pricing is subject to adjustment pursuant to Articles 5 and 9 of the Agreement.  
 2. Such pricing is based on and applies to annual production for the given Contract Year.  
 3. Such pricing includes packaging in a round 90ct bottle or single one count (1ct) blister packaged in a (15 x 1ct) per specifications in Exhibit 2. Pricing for other SKUs, such samples and blister packaging shall be agreed in writing by the Parties.  
 4. Such pricing is exclusive of all taxes.  
\* \* \* \* \*  
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 MANUFACTURING AND SUPPLY AGREEMENT   
 EXHIBIT 2  
PACKAGING SPECIFICATIONS  
[Insert packaging specifications].  
[…\*\*\*…]  
 \*\*\*Confidential Treatment Requested  
 MANUFACTURING AND SUPPLY AGREEMENT   
 EXHIBIT 3  
PRODUCT SPECIFICATIONS  
[Insert Product Specifications].  
[…\*\*\*…]  
 \*\*\*Confidential Treatment Requested  
 MANUFACTURING AND SUPPLY AGREEMENT   
 EXHIBIT 4  
QUALITY AGREEMENT  
 MANUFACTURING AND SUPPLY AGREEMENT   
 EXHIBIT 5  
TECHNICAL ASSUMPTIONS FOR PRODUCT PRICESs  
 No. Technical Assumption Laval Compiegne  
1  
 Anticipated Manufacturing Batch sizes . Final commercial batch sizes will be determined during each Production Site technical transfer according to equipment constraints. […\*\*\*…] […\*\*\*…]  
2  
 Dispensing sanofi-aventis standard procedures will apply sanofi-aventis standard procedures will apply  
3  
 Famotidine core tablets  
Final commercial batch sizes will be determined during each Production Site technical transfer according to equipment constraints..  
 […\*\*\*…] […\*\*\*…]  
4  
 HZT-501 Compression […\*\*\*…] […\*\*\*…]  
5  
 Estimated Coating pan loads per Batch.  
Final number of coating pans will be determined during each Production Site technical transfer according to equipment constraints..  
 […\*\*\*…] […\*\*\*…]  
6  
 There are no anticipated cleaning issues specific to the Product sanofi-aventis standard procedures will apply sanofi-aventis standard procedures will apply  
7  
 Packaging Specifications As per attached Will perform no packing until a Blister packing configurations is determined. Specifications will be added to this agreement  
8  
 Manufacturing Process Flowchart As per attached As per attached  
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 MANUFACTURING AND SUPPLY AGREEMENT   
 In the event that new SKUs are added to the scope of this Agreement pursuant to Article 5, the Parties shall cooperate in the selection of industrial options for the manufacture of such SKUs.  
Note that final batch sizes will be determined by the equipment capacities at each respective manufacturing site.  
 MANUFACTURING AND SUPPLY AGREEMENT   
 Exhibit 5 (Continued)  
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 MANUFACTURING AND SUPPLY AGREEMENT   
 […\*\*\*…]  
 \*\*\*Confidential Treatment Requested  
 MANUFACTURING AND SUPPLY AGREEMENT   
 EXHIBIT 6  
Horizon Equipment  
Item  
[…\*\*\*…]  
[…\*\*\*…]  
[…\*\*\*…]  
[…\*\*\*…]  
 \*\*\*Confidential Treatment Requested  
 MANUFACTURING AND SUPPLY AGREEMENT   
 EXHIBIT 0  
Xxxxxxxxx  
 Xxxxxx  
 Xxxxxxxxx  
Xxxxxx Xxxxxx  
 Bolivia  
Mexico  
 Brazil  
 Chile  
Austria  
 Columbia  
Belgium  
 Peru  
Czech Republic  
 Venezuela  
Denmark  
 Finland  
 France  
 Germany  
 Greece  
 Ireland  
 Italy  
 Luxembourg  
 Netherlands  
 Norway  
 Portugal  
 Spain  
 Sweden  
 AUSTRALIA  
KOREA  
THAILAND  
TAIWAN  
CHINA HOSPITAL  
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