EX-10.101 4 g94931exv10w101.htm MANUFACTURING AND SUPPLY AGREEMENT  
 Exhibit 10.101  
MANUFACTURING AND SUPPLY AGREEMENT  
 This Manufacturing and Supply Agreement (this “Agreement”) is effective as of March 28, 2005 (the “Effective Date”), by and between First Horizon Pharmaceutical Corporation, a Delaware corporation with its principal place of business located at 0000 Xxxxxx Xxxx, Xxxxxxxxxx, Xxxxxxx 00000 (“Purchaser”) and Andrx Pharmaceuticals, Inc., a Florida corporation with its principal office located at 0000 Xxxxxx Xxxxx, Xxxxx, Xxxxxxx 00000 (“Andrx”).  
RECITALS  
 WHEREAS, Andrx is engaged in the business of developing, manufacturing and selling pharmaceutical products;  
 WHEREAS, Purchaser is engaged in the business of marketing and distributing pharmaceutical products; and  
 WHEREAS, Purchaser, Andrx and certain Affiliates of Andrx have entered into an agreement to license and purchase dated as of March 2, 2005 (the “Agreement to License”) and the other agreements contemplated thereunder pursuant to which Purchaser has agreed to license from Andrx certain rights to the Products (as defined below).  
 NOW, THEREFORE, in consideration of the premises and other good and valuable consideration, the receipt and sufficiency of which is hereby acknowledged, the parties agree as follows:  
Article I. Definitions  
 1.1 Definitions. As used in this Agreement, the following capitalized terms shall have the following meanings:  
 “Act” shall mean the Federal Food Drug and Cosmetics Act of the United States of America, United States Code Title 21, Chapter I, as amended.  
 “Adverse Drug Experience Report” shall mean any oral, written or electronically transmitted report of any “Adverse Drug Experience” (as defined in the Act, including, but not limited to, 21 C.F.R. 314.80 or 312.32), associated with the use of the API (including the Products).  
 “Affiliate” shall mean any Person that directly or indirectly controls, is controlled by or is under common control with Andrx or Purchaser, as the case may be, but only for so long as said control shall continue. As used herein, the term “control” means possession of the power to direct or cause the direction of the management and policies of a Person whether by ownership,  
\* filed under application for confidential treatment  
 contract or otherwise. Andrx and Purchaser shall not be considered to be Affiliates of one another.  
 “Altoprev” shall have the meaning given on Exhibit A.  
 “Alzheimer’s Field of Use” shall mean the administration of lovastatin sodium for the treatment or prevention of Alzheimer’s disease or related APP processing disorders.  
 “Andrx Product Liability Claims” shall mean any Product Liability Claims (i) relating to Products sold by Andrx or its Affiliates prior to the Effective Date, or (ii) caused by Andrx’s failure to supply Product that is in compliance with the Manufacturing Requirements.  
 “API” shall mean active pharmaceutical ingredient; lovastatin for Altoprev, and metformin for Fortamet.  
 “Certificate of Analysis” shall have the meaning ascribed to it in Section 2.4.2.  
 “Confidential Information” shall mean, with respect to any party (the “Disclosing Party”), any information relating to the Disclosing Party, the Products or the Disclosing Party’s business (including, but not limited, to the formulation or specifications for any Products and any other know-how relating to the manufacture or use of any Products, or to the manufacture of and the formulation and specifications for the active ingredients thereof and technical information, research, personnel, financial, marketing, strategic or other information) that is disclosed in writing to the other party (“Receiving Party”) in the course of the parties’ negotiation of or performance under this Agreement (it being understood that if any information is disclosed verbally, in order for that information to be considered Confidential Information, the Disclosing Party must notify the Receiving Party in writing that the information is Confidential Information within thirty (30) days after disclosure), but shall not include information that: (a) the Receiving Party knew, owned or controlled prior to receipt from the Disclosing Party; (b) is or becomes public through no fault of the Receiving Party or any Affiliate thereof; (c) is developed by the Receiving Party independent of any disclosure from the Disclosing Party or (d) the Receiving Party obtains from a third party not under a confidentiality obligation to the Disclosing Party. The existence, terms and conditions of this Agreement do not constitute Confidential Information.  
 “Conforming Products” shall have the meaning ascribed to it in Section 2.4.2.  
 “Dosage” shall mean the specific strength of a Product.  
 “Facility” shall mean Andrx’s existing manufacturing facilities in Davie, Florida or such other location that Andrx determines to manufacture or have manufactured the Product in accordance with applicable Law and Section 2.1.2.  
 “FDA” shall mean the United States Food and Drug Administration or any successor governmental agency performing similar functions.  
 “Firm Order Period” shall have the meaning ascribed to it in Section 3.1.  
\* filed under application for confidential treatment  
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 “Force Majeure” shall have the meaning ascribed to it in Section 11.13.  
 “Forecast” shall have the meaning ascribed to it in Section 3.1.  
 “Fortamet” shall have the meaning given on Exhibit A.  
 “GMPs” and “GLPs” shall mean Good Manufacturing Practices and Good Laboratory Practices as defined in Parts 210 and 211 of Title 21 of the Code of Federal Regulations, as amended from time to time, or any successor thereto.  
 “Governmental or Regulatory Authority” shall mean: (a) any domestic or foreign national, federal, provincial, state, municipal or other governmental body, (b) any international or multi-lateral body, (c) any subdivision, ministry, department, secretariat, bureau, agency, commission, board, instrumentality or authority of any of the foregoing governments or bodies, (d) any quasi-governmental or private body exercising any regulatory, expropriation or taxing authority under or for any of the foregoing governments or bodies, or (e) any domestic, foreign, international, multi-lateral, or multi-national judicial, quasi-judicial, arbitration or administrative court, grand jury, tribunal, commission, board or panel.  
 “Laws” shall mean: (a) all constitutions, treaties, laws, statutes, codes, ordinances, orders, decrees, rules, regulations, and municipal by-laws, whether domestic, foreign or international, (b) all judgments, orders, writs, injunctions, decisions, rulings, decrees and awards of any Governmental or Regulatory Authority, and (c) all policies, practices and guidelines of any Governmental or Regulatory Authority.  
 “License Agreement” means that certain License Agreement between the parties, contemplated by the Agreement to License.  
 “Manufacturing Intellectual Property” means inventions or discoveries (whether or not patentable), Patent Rights, know-how, trade secrets, technical information and all other intellectual property rights owned by or licensed to Andrx and its Affiliates that relate to or are necessary to manufacture and distribute the Products, and all related documentation or other tangible expressions thereof, anywhere in the world, including without limitation, rights to the XXXX Technology.  
 “Manufacturing Requirements” shall have the meaning ascribed to it in Section 2.4.1.  
 “Material Breach” shall have the meaning ascribed to it in Section 6.2.3.  
 “NDA” shall mean the New Drug Applications filed with the FDA for each of the Products, as defined in the Act and the regulations promulgated thereunder.  
 “Opening Inventory Products” shall mean the supply of Products initially acquired by Purchaser pursuant to the Agreement to License.  
 “Other Country Applications” shall mean applications similar to NDAs filed under the laws of other countries, including without limitation Marketing Authorization Applications filed in the United Kingdom.  
\* filed under application for confidential treatment  
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 “Patent Right(s)” shall mean any and all patent applications, patents, and patentable subject matter, as well as any and all patent applications claiming priority to, or derived therefrom, both domestic and foreign, including all additions, divisions, continuations, continuations-in-part, divisions, improvements, reexaminations and substitutions, and any patents issuing therefrom including extensions, registrations and reissues thereof.  
 “Per Unit Price” shall have the meaning ascribed to it in Section 4.1.  
 “Person” shall mean any natural person, corporation, partnership, limited liability company, joint venture, trust, proprietorship or other entity or organization.  
 “Proceedings” shall mean claims, suits, actions, investigations or proceedings.  
 “Product(s)” shall mean Altoprev and Fortamet in various Dosages, including without limitation the Opening Inventory Products, and any modifications thereto and additional Dosages, in accordance with the terms of this Agreement.  
 “Product Liability Claim” shall mean any third party Proceedings involving any actual or alleged death or bodily injury arising out of or resulting from the use of the Products.  
 “Purchase Order” shall have the meaning ascribed to it in Section 3.2.  
 “Purchaser Product Liability Claims” shall mean all Product Liability Claims that do not constitute Andrx Product Liability Claims.  
 “Quality Assurance Agreement” shall mean the Quality Assurance Agreement of even date herewith between Andrx and Purchaser, as in effect from time to time.  
 “XXXX Technology” shall mean the know-how, applications, and patents relating to single composition osmotic table technology, including but not limited to the trade secrets and know-how required to manufacture the Products.  
“Second Quarter” shall have the meaning ascribed to it in Section 3.1.  
 “Serious Adverse Drug Experience Report” shall mean any Adverse Drug Experience Report that involves an Adverse Drug Experience or any other event which would constitute a “serious” Adverse Drug Experience under the Act, including, without limitation, 21 C.F.R Parts 20, 310, 312, 314 and 600 — Expedited Safety Reporting Requirement for Human Drug and Biological Products; Federal Register Xxx. 00, Xx. 000, pp. 52237-52253; Tuesday, October 7, 1997.  
 “Specifications” shall mean the internal control and regulatory specifications for the Products set forth on Exhibit A.  
 “Standard Costs” shall be Andrx’s standard manufacturing cost as of January 1, 2005 for the applicable Conforming Product, as modified and reflected in accordance with Exhibit B.  
 “Supply Failure Notice” shall have the meaning set forth in Section 3.3.  
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 “Takeda Arrangement” has the meaning set forth in the Agreement to License.  
 “Term” has the meaning set forth in Section 6.1.  
 “Territory” shall mean the United States of America, United Kingdom and any other jurisdiction which approves an Other Country Application filed by Andrx for Products.  
 “Trademark” shall mean any domestic or foreign registered or unregistered xxxx for Altoprev, including but not limited to U.S. Registration No. 2911749 as well as any domestic or foreign registered or unregistered xxxx for Fortamet, including but not limited to any registered or unregistered xxxx for Fortamet, including but not limited to U.S. Serial No. 78115656, together with any related marks, brands, logos, trade dress or designs, whether registered or unregistered.  
Article II.  
Manufacture and Supply of the Products  
 2.1 Manufacturing and Supply.  
 2.1.1 Obligations of Purchaser. During the Term, Purchaser shall purchase its entire requirement of the Products exclusively from Andrx, except as provided in Sections 5.2 and 11.13.  
 2.1.2 Obligations of Andrx. During the Term, Andrx shall manufacture and sell to Purchaser all of Purchaser’s requirements (subject to the provisions of Article III) of the Products on an exclusive basis within the Territory, subject to the exceptions set forth in Article 9 of the Agreement to License. Andrx shall manufacture the Products in the Facility. Andrx shall obtain necessary regulatory approvals prior to manufacturing the Products in any other facility.  
 2.2 Capacity. Andrx represents and warrants that it has and will continue to have at all times during the Term the capacity to produce minimum annual volumes of Altoprev tablets of various Dosages and Fortamet tablets of various Dosages. If at any time Purchaser’s volume requirements for either of the Products exceeds the foregoing amounts, Purchaser will promptly advise Andrx of same and Andrx will use its commercially reasonable efforts to increase its capacity as soon as practicable, to meet Purchaser’s forecasted volume requirements; provided that Andrx will not be required to increase its manufacturing capacity in order to accommodate volumes in excess of the foregoing amounts unless Purchaser agrees to pay the incremental out-of-pocket costs required to increase such capacity, either through increases in the Standard Costs or in another mutually satisfactory manner. If Purchaser makes such request and Andrx refuses to increase capacity as so requested, Purchaser will have the right to use or make the Manufacturing Intellectual Property available to a third party manufacturer pursuant to Section 5.2 to satisfy any capacity shortfall, provided Andrx is paid for its time and costs involved in assisting in this initiative and further provided that Andrx shall have the right to select the third party manufacturer to satisfy the capacity shortfall and shall do so diligently and in good faith. Upon request of Purchaser and subject to good faith agreement on pricing, Andrx shall use commercially reasonable efforts to increase its manufacturing capacity so that it can manufacture and distribute the Products for sale outside the United States, to the extent required to sell  
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 Products outside the United States. Nothing in this Agreement will prohibit Purchaser from selling Products outside the United States.  
 2.3 Packaging. If requested by Purchaser, and subject to Andrx’s right to subcontract certain obligations pursuant to Section 11.5, Andrx shall package the Products with labels, product inserts and other labeling as specified in Exhibit C. From time to time, Purchaser may, in its sole discretion, make changes to labels, product inserts and other labeling for the Products, which changes shall be prepared by Purchaser and provided to Andrx for review, approval and submission to any Governmental Authority required to review or approve such change prior to or effective with the effectuation of such change. Andrx shall not be permitted to withhold approval for such change if such change is required by Law, unless such change does not comply with applicable Law. In connection with Opening Inventory Products and Products ordered by Purchaser during the six months immediately following the Effective Date, Andrx will be entitled to utilize supplies of packaging, labels and inserts on hand and on order as of the date hereof, including items reflecting brands and trademarks owned by Andrx. Purchaser will have the right to sell such Products in accordance with this Agreement. Except as described in the fourth sentence of this Section 2.3, Andrx’s brand shall not appear on the label nor anywhere else on the Products unless required by a governmental authority or applicable Laws or as it appears on the existing and in-transition inventory provided by Andrx to Purchaser at the Effective Date in accordance with the terms and conditions set forth in the Agreement to License. Subject to the foregoing, Purchaser shall provide all designs and artwork necessary to produce packaging, labeling and inserts for the Products which shall be implemented into Product production immediately unless otherwise specified by Purchaser. If the designs and artwork provided by Purchaser result in an increase in the packaging cost incurred by Andrx, then Andrx shall give prompt notice of such increase to Purchaser and the Per Unit Price shall increase by the amount of such additional cost. If Purchaser requests that Andrx subcontract its obligations under this Section 2.3 to a different third party, Andrx shall attempt in good faith to enter into an arrangement with such third party as soon as reasonably practicable.  
 2.4 Quality Control and Assurance.  
 2.4.1 Manufacturing Requirements. Andrx shall manufacture, package, label, store, test and ship the Products in accordance with: (a) all applicable Laws, (b) the Specifications, including requirements for Product dating, (c) the requirements of the approved NDAs and any Other Country Application and (d) the Quality Assurance Agreement. Andrx’s responsibilities and obligations described in the foregoing sentence are hereinafter referred to as the “Manufacturing Requirements”. Andrx shall perform such quality control and quality assurance testing as is required (but in no event less than as generally practiced in the pharmaceutical manufacturing industry) to ensure that the Products comply with all of the Manufacturing Requirements. If the Products as manufactured by Andrx fail to meet the Manufacturing Requirements, Andrx shall, at its sole cost and expense, manufacture additional Products to replace such defective Products. Replacement of such non-conforming Products shall be Purchaser’s sole remedy for such failure, except to the extent provided elsewhere in this Agreement. In such circumstances, Purchaser will have no obligation to purchase or pay for any rejected Products, but shall pay for the replacement product.  
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 2.4.2 Certificate of Analysis. Each time Andrx ships the Products to or on behalf of Purchaser, it shall provide Purchaser with a “Certificate of Analysis” that sets out the actual test results for each lot of the Products, certifies that the Products shipped to Purchaser have been evaluated by Andrx and that the Products comply with the Manufacturing Requirements and describes the Products, Product numbers, lot numbers, expiration dates and test results for the Products, in each case as required by the NDA for such Product. Products that meet the foregoing are referred to as “Conforming Products.” Andrx shall not under any circumstances ship Non-Conforming Products (as defined in Section 2.4.3) to Purchaser. Andrx shall also provide Purchaser with Material Safety Data Sheets as required for the Products, and updates of same as necessary.  
 2.4.3 Rejection of the Products. Purchaser shall inspect each lot of the Products manufactured by Andrx within thirty (30) days after the later of: (a) the date of Purchaser’s receipt of such lot of the Products, or (b) the date of Purchaser’s receipt of the Certificate of Analysis applicable to a Product, in order to determine whether a Product meets the Manufacturing Requirements. Purchaser shall provide Andrx with written notice (a “Deficiency Notice”), promptly, and, in no event later than ten (10) days, after determining that: (a) any of the Products do not conform to the tests results as shown on the Certificate of Analysis or the Manufacturing Requirements (“Non-Conforming Products”), or (b) the amount of delivered Products in a lot is less than the amount ordered by Purchaser. Purchaser’s failure to notify Andrx within the stipulated period will be deemed, for purposes of this Agreement, as Purchaser’s acceptance of such lot of the Products, however, such acceptance will not limit Purchaser’s right to reject such Product for latent defects discovered by Purchaser or Purchaser’s customer(s) after such stipulated period has expired. If a Deficiency Notice relates to a shortage in the delivered Products, then the parties shall deal with such shortage in accordance with normal commercial practices. If a Deficiency Notice relates to Non-Conforming Products, then Purchaser shall return to Andrx, at Andrx’s expense, all shipments of Non-Conforming Products. Andrx shall bear all cost and responsibility for disposing of any Non-Conforming Products returned by Purchaser to Andrx. Andrx will have no liability for any deviations or shortages for which it has not received notice within such thirty (30) day period, except with respect to (i) Product Recalls and Product Returns as provided in Sections 7.6 and 7.7, respectively and (ii) indemnification obligations under Article X. Upon receipt of a Deficiency Notice relating to Non-Conforming Products, Andrx will have ten (10) days to notify Purchaser in writing that it either: (x) agrees that the subject Products are Non-Conforming Products or (y) disputes Purchaser’s determination that the Products are Non-Conforming Products. If any dispute arises as to whether the subject Products are Non-Conforming Products, then the parties shall mutually select an independent laboratory to evaluate whether the Products are Non-Conforming Products. If the evaluation certifies that the subject Products are Non-Conforming Products or Andrx agrees that the subject Products are Non-Conforming Products, then Andrx shall, within thirty (30) days of such determination, replace such returned Non-Conforming Products at its expense or, if it is unable to make prompt replacement, either credit Purchaser’s account or refund any payment made on the rejected Products, depending on Purchaser’s account balance as Purchaser’s sole remedy with respect to such Non-Conforming Products, except to the extent provided elsewhere in this Agreement.  
 2.4.4 Stability Testing. Andrx shall conduct stability testing on the Products as required by GMPs and in accordance with the protocols approved in the NDA and any applicable  
\* filed under application for confidential treatment  
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 Other Country Application. Andrx shall comply with the Quality Assurance Agreement in making any changes to these testing procedures or specifications for stability testing. If any lot of Products fails stability testing, Andrx, after consulting with Purchaser, shall determine the Proceedings and methods to be undertaken to investigate the causes of such failure. Andrx shall bear the cost of such investigation. Andrx shall provide any and all data and results relating to the stability testing upon request by Purchaser, or as such results are generated.  
 2.4.5 Product Line Extensions. If requested by Purchaser, Andrx will reasonably consider developing and/or manufacturing an extension to Altoprev and/or Fortamet, including combination products other than the products expressly permitted by the Takeda Agreement or the Alzheimer’s Field of Use.  
 2.4.6 Performance Credit. If (i) the aggregate quantity of Conforming Products shipped by Andrx to Purchaser in any calendar quarter, in the case of Fortamet and any calendar quarter following [xxxx]\*, in the case of Altoprev, is less than [xxxx]\* of the amount ordered by Purchaser for such calendar quarter, (ii) the amount ordered is in accordance with the Forecast for such quarter and not in excess of the maximum available capacity designated for the Product, and (iii) such deficiency continues (in whole or in part) for at least ten (10) days, then, in addition to any other right or remedy of Purchaser under this Agreement, Andrx will issue a credit, applicable against the current invoiced amount, in an amount equal to [xxxx]\* of the aggregate price of the Products in such purchase order. [xxxx]\*. The provisions of this Section 2.4.6 shall not be applicable for any deficiency resulting from a Force Majeure event or an amount specified in a Purchase Order to the extent it exceeds the maximum amount specified in Section 3.2.4.  
 2.5 Sale of Inventory. All Opening Inventory Products sold by Andrx to Purchaser pursuant to the Agreement to License shall be subject to the terms hereof.  
Article III. Forecasts, Purchase Orders and Delivery  
3.1 Forecasts. Attached hereto as Exhibit D is an initial Forecast (as hereinafter defined) of Purchaser’s expected requirements for Products for the periods set forth therein (including a break-down of commercial quantities, dosages, samples and safety stock) . Not less than ninety (90) days prior to the beginning of each subsequent calendar quarter, Purchaser shall provide Andrx with a written, good faith, forecast (each, a “Forecast”) of the expected volume of each Product that Purchaser expects to require during the immediately following four (4) calendar quarters (including a break-down of commercial quantities, samples, and safety stock). Each Forecast shall set forth Purchaser’s expected requirements on a month-by-month basis. Purchaser’s sole obligations with respect to any Forecast will be (i) to purchase the volume of Products set forth in such Forecast for the first calendar quarter commencing at least ninety (90) days after such Forecast is delivered to Andrx (the “Firm Order Period”), as provided in Section 3.2.3 below, and (ii) to have its purchase requirements for the calendar quarter immediately following the Firm Order Period (the “Second Quarter”) be within the requirements set forth in Section 3.2.4.  
\* filed under application for confidential treatment  
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 3.2 Purchase Orders.  
 3.2.1 Delivery of Purchase Order. Upon execution of this Agreement and at least thirty (30) days prior to the start of each calendar quarter, Purchaser shall provide a written “Purchase Order” to Andrx for such following quarter that sets forth the following information:  
 (a) the identity of each Product ordered (including a break-down of commercial quantities, safety stock (if any), dosages and samples);  
 (b) the quantity of each Product ordered;  
 (c) the Per Unit Price for each Product ordered and the total amount to be remitted by Purchaser;  
 (d) any special packaging, handling or labeling instructions;  
 (e) the delivery destination for each Product;  
 (f) the delivery date for each Product;  
 (g) any other special instructions regarding the Products not inconsistent with this Agreement; and  
 (h) a reference to this Agreement.  
 3.2.2 Acceptance of Purchase Order. Andrx shall accept any Purchase Order submitted by Purchaser that complies with the requirements of Section 3.2.1 and may, in its discretion, accept any Purchase Order that does not comply with Section 3.2.1, and in either case shall deliver notice of its acceptance to Purchaser within five (5) days of its receipt of the Purchase Order; provided, that Andrx’s failure to deliver such notice will not constitute non-acceptance of any Purchase Order that complies with Section 3.2.1. Notwithstanding anything in this Agreement to the contrary, Andrx shall have no obligation to deliver Product with respect to any Purchase Order for a particular Dosage of Altoprev until it shall have met the Initial Trigger (as defined in the Agreement to License) with respect to such Dosage and shall have been paid by Purchaser the portion of the Holdback Amount (as defined in the Agreement to License) then payable with respect to such Dosage.  
 3.2.3 Performance of Purchase Order. If Purchaser submits a Purchase Order that complies with Sections 3.2.1 and 3.2.2, or is otherwise accepted by Andrx, Andrx shall deliver the Products so ordered to Purchaser in accordance with the terms of the Purchase Order and this Agreement.  
 3.2.4 Second Quarter. Unless otherwise agreed by Andrx, the volumes set forth in any Purchase Order for the Second Quarter shall be at least eighty five percent (85%) of the volumes ordered pursuant to the Purchase Order for the preceding Firm Order Period, and shall not exceed one hundred fifteen percent (115%) of the volumes ordered pursuant to the Purchase Order for the preceding Firm Order Period.  
\* filed under application for confidential treatment  
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 3.2.5 Transmission of Purchase Order; Governing Terms. Purchaser may submit a Purchase Order to Andrx by facsimile transmission or e-mail, and Andrx shall confirm receipt of each Purchase Order by facsimile transmission or e-mail. The terms set forth on any of Purchaser’s Purchaser Order forms shall be of no effect except as to quantities and delivery dates consistent with this Agreement.  
 3.2.6 Introduction of Generic Products. Notwithstanding anything set forth in this Section 3.2 and subject to the final sentence of this Section 3.2.6, if any third-party introduces a generic form of a Product, in the same Dosage, Purchaser will not be obligated to issue a Purchase Order for or purchase the forecasted volume for such Product or comply with its obligations set forth in Section 3.2.4 in respect of such Product. In such event, Purchaser and Andrx shall negotiate in good faith a revision to the forecast to reflect the effect of such introduction. Purchaser shall honor all Purchase Orders that have been accepted by Andrx and shall reimburse Andrx for all unused raw materials and packaging purchased in accordance with outstanding forecasts for the succeeding two calendar quarters; provided, however, that Andrx shall use commercially reasonable efforts to utilize any such unused raw materials and packaging materials in an effort to mitigate Purchaser’s obligation set forth in this sentence.  
 3.3 Delivery. Andrx shall deliver to Purchaser the amount of Products ordered by Purchaser in accordance with the delivery terms set forth in the Purchase Order. Notwithstanding anything to the contrary contained herein, Andrx shall not be required to deliver Products to Purchaser less than one hundred twenty (120) days after its receipt of the applicable Forecast; provided, that Andrx shall use commercially reasonable efforts to reduce its cycle time for the manufacture of the Products but shall have no liability solely as a result of its failure to achieve any level of cycle time reduction. Unless otherwise provided in a Purchase Order, title to the Products and the risk of loss shall pass from Andrx to Purchaser F.O.B. at Andrx’s Facility, and Purchaser shall be responsible for shipping costs related thereto. The parties may mutually agree to modify the date of delivery. Andrx shall promptly notify Purchaser in writing if for any reason Andrx has reason to believe that it will be unable to supply on a timely basis the quantities of Product ordered by Purchaser (a “Supply Failure Notice”), but notification shall not relieve Andrx from any obligation hereunder or limit any right or remedy of Purchaser in respect of Andrx’s failure.  
 3.4 Purchase of Products. All purchases of the Products shall be made solely pursuant to this Agreement and the terms required by Section 3.2 in each Purchase Order submitted by Purchaser to Andrx hereunder. This Agreement, the Agreement to License and the Purchase Orders constitute the entire and exclusive statement by the parties of the terms of their agreement regarding the manufacture and sale of the Products, notwithstanding any additional or different terms (including, without limitation, preprinted terms and conditions) contained in any Purchase Order, acknowledgment, invoice or other form furnished by either party. All such additional and different terms are hereby specifically rejected by the parties. All prior and contemporaneous proposals, negotiations, representations and agreements are merged into this Agreement.  
 3.5 Monthly Reports. Andrx shall provide Purchaser, on a monthly basis, manufacturing and supply reports containing reasonable and customary information on the status of outstanding Purchase Orders, including: (i) a schedule of all work in progress, (ii) shipping  
\* filed under application for confidential treatment  
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 information, expiration dating, lot numbers and release data, and the sufficiency of raw materials on hand to cover open purchase orders, (iii) third party packaging information for all packagers of Purchaser’s product, including status of all outstanding Purchase Orders and inventory on hand at each such packager, and (iv) such other information as Purchaser may, from time to time, reasonably request from Andrx.  
Article IV. Price and Payment  
 4.1 Prices. The “Per Unit Price” for each Product (other than samples) shall be equal to the [xxxx]\* The Per Unit Price for samples shall be equal to [xxxx]\*  
 4.2 Payment. Purchaser shall pay to Andrx the amount properly invoiced by Andrx for delivered, Conforming Products within thirty (30) days after Purchaser’s receipt of such invoice. If Purchaser disputes in good faith the amount of any invoice, Purchaser shall pay Andrx the undisputed portion of such invoice pending resolution of such dispute. Andrx shall not invoice Purchaser for Opening Inventory Products of Fortamet, payment for which is included as part of the Fortamet Amount under the Agreement to License.  
 4.2.1 Payment Credits. Purchaser shall receive a payment credit of [xxxx]\* per month towards the Products purchased under its Purchase Orders for the [xxxx]\* of this Agreement and a payment credit of [xxxx]\* per month towards the Product purchased under its Purchase Orders for the subsequent 12 month period.  
 4.3 Manner of Payments. All sums due under this Agreement shall be payable in United States dollars by wire transfer of immediately available funds to such bank account(s) as Andrx shall designate.  
 4.4 Interest on Late Payments. If Purchaser fails to make timely payment of all amounts not subject to a bona fide dispute pursuant to this Article IV, then following five (5) days’ written notice from Andrx, interest shall accrue on the past due amount at a rate equal to the prime rate effective for the date such payment is due, as published in the Wall Street Journal, plus (i) two percent (2%) for the first thirty (30) days such payment is delinquent or (ii) four percent (4%) thereafter.  
 4.5 Adjustments to Per Unit Price.  
 4.5.1 Product Changes.  
 (a) Each party shall promptly inform the other party of any proposed changes to the Products required by applicable Law. Andrx shall institute any such changes to the Products required by Law and shall bear all of its costs and expenses associated with implementing such changes. The parties shall mutually agree on an adjustment to the Per Unit Price reflecting any additional expense to be incurred by Andrx (including costs of equipment) resulting from ongoing compliance with such Law; provided, that, there shall be no increase in the Per Unit Price from the Closing contemplated by the Agreement to License if such requirement to change is promulgated: (i) in the case of Fortamet, within six months from such Closing, and (ii) in the case of Altoprev, within one year from such  
\* filed under application for confidential treatment  
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 Closing. If the parties are unable to agree to any permitted increase, then the parties shall, at their joint expense, engage a qualified third party to determine the appropriate adjustment to the Per Unit Price.  
 (b) Any discretionary changes to the Products requested by Purchaser shall be subject to the approval of Andrx, which approval shall not be unreasonably withheld. Andrx will provide Purchaser with a good faith estimate of the additional expense, if any, Andrx would incur as a result of such change. If Purchaser decides to proceed with the changes after receiving Andrx’s estimate of the additional expense, then the parties shall then mutually agree on an adjustment to the Per Unit Price reflecting the additional expense to be incurred by Andrx (including costs of equipment). Andrx shall provide reasonable documentation of all additional expenses incurred in connection with implementing the discretionary change, subject to Section 11.19.  
 (c) Andrx may make discretionary changes to the Products other than with respect to labeling and packaging; provided, that, such changes do not adversely affect the supply of the Products and such Products remain Conforming Products.  
 (d) Any change to the Products made in accordance with this Section shall constitute additional Intellectual Property which is deemed licensed, without further action required by either party, to Purchaser pursuant to the terms of the License Agreement.  
 4.5.2 Annual Adjustments. At the beginning of each calendar year, the Per Unit Purchase Price shall be adjusted for inflation as follows: the portion of the Standard Cost not associated with the API shall be adjusted for inflation by: (a) taking the product of: (y) the Standard Cost not associated with the API in the calendar year preceding the calendar year in which the inflation adjustment is being made and (z) the percentage increase in the pharmaceutical price sub-index of the producer price index published by the Bureau of Labor Statistics for the calendar year preceding the calendar year in which the inflation adjustment is being made, and (b) adding the resulting product to the Standard Cost not associated with the API for the calendar year preceding the calendar year for which the inflation adjustment is being made.  
 4.5.3 Other Adjustments. If at any time API for any Product increases or decreases from the amount included in the Standard Cost set forth in Exhibit B (the “Benchmark API”), Andrx shall change the Per Unit Cost for the Product once the API purchased at the Benchmark API price for use by Purchaser has been depleted, using the same costing methodology employed by this Agreement. [xxxx]\*  
 4.6 Other Expenses. Except for the amounts for which Purchaser is expressly obligated to pay hereunder, Andrx shall bear all costs and expenses to manufacture the Products and to fulfill its obligations under this Agreement.  
\* filed under application for confidential treatment  
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 Article V. Intellectual Property Licenses  
 5.1 License of Trademark. Purchaser hereby grants to Andrx (at Purchaser’s sole discretion) a revocable, non-exclusive, royalty free and non-transferable license, with the right to sublicense solely to Affiliates of Andrx, to use the Trademarks in the Territory for the limited purpose of Andrx performing the obligations of Andrx under this Agreement. Upon expiration or termination of this Agreement for any reason, the above license to use the Trademarks shall immediately terminate without any action by Purchaser. All goodwill associated with the use of the Trademarks under this Agreement shall inure to the benefit of Purchaser.  
 5.2 License of Manufacturing Intellectual Property. Andrx hereby grants to Purchaser an irrevocable (except as provided below), non-exclusive, and royalty-free license to use and employ the Manufacturing Intellectual Property, solely for the purpose of manufacturing or having manufactured the Products. Purchaser shall not exercise its rights to the foregoing license except under the following limited circumstances: (a) Andrx is declared insolvent or bankrupt by a court of competent jurisdiction; a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by Andrx; or this Agreement is assigned by Andrx for the benefit of creditors; (b) in the case of [xxxx]\*, for a [xxxx]\* during the term of this Agreement, Andrx fails to provide Purchaser with at least [xxxx]\* of its requirements for Products set forth in [xxxx]\* or more of the proper Purchase Orders delivered during such [xxxx]\*, for any reason other than the unavailability of API; (c) in the case of [xxxx]\*, for a consecutive, rolling [xxxx]\* period commencing on or after [xxxx]\* during the term of this Agreement, Andrx fails to provide Purchaser with at least [xxxx]\* of its requirements of Products set forth in [xxxx]\* or more of the proper Purchase Orders delivered during such [xxxx]\*, for any reason other than the unavailability of API; (d) Purchaser terminates this Agreement pursuant to Section 6.2.3 in respect of Andrx’s breach of its obligations under this Agreement; (e) Andrx terminates this Agreement pursuant to Section 6.2.2; (f) Andrx fails to use commercially reasonable efforts to increase its capacity as provided in Section 2.2; or (g) as provided in Section 11.13 upon the expiration of the time period therein provided for the resolution of a Force Majeure event. If any such event occurs, Purchaser will have the right to sublicense or transfer, or both, this license to a third party for the manufacture of Product. The license granted to Purchaser under this Section 5.2 will terminate automatically without any further action of Purchaser upon the termination of this Agreement by Purchaser pursuant to Section 6.2.1, or by Andrx pursuant to Section 6.2.4 or 6.2.5.  
Article VI. Term and Termination  
 6.1 Term. The term of this Agreement shall commence on the Effective Date and shall extend for an initial term of ten (10) years thereafter, unless earlier terminated in accordance herewith (collectively, the “Term”).  
\* filed under application for confidential treatment  
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 6.2 Termination.  
 6.2.1 Termination by Purchaser without Cause. Purchaser may terminate this Agreement at any time after the fifth anniversary of the Effective Date, without cause, by providing Andrx with written notice at least 180 days prior to the date of termination.  
 6.2.2 Termination by Andrx without Cause. Andrx may terminate this Agreement at any time after the fifth anniversary of the Effective Date, without cause, by providing Purchaser with written notice at least two (2) years prior to the date of termination.  
 6.2.3 Termination by Purchaser for Material Breach. Purchaser may terminate this Agreement in respect of a material breach by Andrx of this Agreement or any representation, warranty or covenant contained herein (a “Material Breach”) if Andrx fails to cure such Material Breach within sixty (60) days after receipt of written notice from Purchaser specifying the Material Breach in sufficient detail to give Andrx adequate notice of and opportunity to cure such Material Breach.  
 6.2.4 Termination by Andrx for Material Breach. Andrx may terminate this Agreement in respect of a Material Breach by Purchaser if Purchaser fails to cure any such breach within thirty (30) days after receipt of written notice from Andrx specifying the Material Breach in sufficient detail to give Purchaser adequate notice of and opportunity to cure such Material Breach.  
 6.2.5 Termination for Insolvency or Bankruptcy. Either party may immediately terminate this Agreement upon written notice to the other party in the event that: (a) the other party is declared insolvent or bankrupt by a court of competent jurisdiction; (b) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other party; or (c) this Agreement is assigned by such other party for the benefit of creditors.  
 6.2.6 Termination for Governmental Action. Purchaser may terminate this Agreement as to any Products upon thirty (30) days’ written notice in the event that any Governmental Authority takes any action or raises any objection that prevents Purchaser from selling the Products in the Territory.  
 6.3 Effect of Termination.  
 6.3.1 Termination of Rights and Obligations. On the date of termination or expiration of this Agreement, all rights and obligations granted under or imposed by this Agreement will cease and terminate, except as set forth in Section 6.4. Except as provided in Section 6.3.2, and notwithstanding any other provision to the contrary contained herein, such expiration or termination shall not affect any claim, demand, liability or right of a party arising pursuant to this Agreement prior to the expiration or termination hereof.  
 6.3.2 Transitional Matters.  
 (a) The exercise by Purchaser or Andrx of the right to terminate this Agreement under Section 6.2 will not affect any Purchase Order that was delivered to Andrx and accepted by Andrx in accordance with this Agreement and that is outstanding  
\* filed under application for confidential treatment  
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 on the date that such right is exercised, except that, in the case of a termination by Purchaser pursuant to Section 6.2.3, Purchaser will have the right to terminate any outstanding Purchase Order in whole or in part.  
 (b) Andrx agrees that the continuity of supply of Products is critical to the success of Purchaser’s business. In the event that either party terminates this Agreement, Andrx will use commercially reasonable efforts (subject to cost allocations as provided below) to provide for the continued supply of Products to Purchaser on the terms (including pricing) under this Agreement, and an amicable transition of manufacture of the Products. If Purchaser terminates this Agreement, Andrx will use commercially reasonable efforts to assist Purchaser in the transfer of the manufacturing of the Products to a manufacturer of Purchaser’s choosing, provided such manufacturer agrees, in a writing reasonably acceptable to Andrx, to limit its application of the manufacturing know-how it obtains by or through Andrx for the application of the XXXX technology solely to the Products. In addition, in the event Purchaser terminates this Agreement pursuant to Section 6.2.3, Andrx shall, if requested by Purchaser, continue to fill orders for Products in accordance with this Agreement, until such time as the new site for manufacturing the Products is qualified by the FDA to manufacture the Products not to exceed [xxxx]\*.  
 (c) In the case of [xxxx]\*, unless such transition is caused by a termination of this Agreement due to Force Majeure, [xxxx]\* shall be responsible for the payment of all reasonable third party costs and out of pocket expenses incurred by [xxxx]\* in performing any activities relating to the manufacturing transfer of [xxxx]\*, if [xxxx]\* requests such transfer.  
 (d) In the case of [xxxx]\*, if such transition is a result of [xxxx]\* breach of this Agreement or is caused by a termination of this Agreement due to Force Majeure, then [xxxx]\* shall be responsible for the payment of all reasonable third party costs and out of pocket expenses incurred by [xxxx]\* relating to the manufacturing transition of [xxxx]\*.  
 (e) In the case of any transition of the manufacturing other than due to the circumstances contemplated in subsections (c) and (d) above, including, without limitation, due to [xxxx]\* excess capacity needs as contemplated by Section 2.2 or upon a permitted termination by [xxxx]\* without cause pursuant to Article VI, then [xxxx]\* shall be responsible for the payment of all reasonable third party costs and out of pocket expenses relating to the manufacturing transition.  
 (f) Upon termination of this Agreement other than for breach by Andrx (or such later completion of Andrx’s commitment to supply Product hereunder following a termination for other than breach), Purchaser shall reimburse Andrx for all unused raw materials and packaging purchased by Andrx in accordance with outstanding forecasts for the succeeding two calendar quarters; provided, that, if requested by Purchaser, Andrx shall use commercially reasonable efforts to utilize such unused materials into the market and, to the extent not utilized, shall deliver such unused raw materials and packaging to Purchaser or its designee. Upon termination of this Agreement by Purchaser for breach  
\* filed under application for confidential treatment  
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 by Andrx, Purchaser shall have no obligation to reimburse Andrx for unused raw materials and packaging.  
 6.3.3 Business Disruption. No party shall be liable to another party hereto for damages, losses, indemnity, compensation, costs or expenses of any kind or character whatsoever on account of the expiration or termination of this Agreement, whether such damages, losses, costs or expenses arise from loss of prospective sales, or expenses incurred or investments made in connection with the establishment, development or maintenance of a party’s business, creation of goodwill, markets and customers for the Products or any other reason whatsoever.  
 6.4 Survival. The following provisions shall survive the termination or expiration of this Agreement for a period of ten (10) years: Section 5.2, Article VI, Article VII, Article VIII, Article IX, Article X, and Section 11.14.  
Article VII. Regulatory Matters and Product Returns  
 7.1 Regulatory and Legal Matters. Except as otherwise provided in this Article VII, Andrx and its Affiliates will have the sole authority and responsibility to obtain and maintain any FDA or other Governmental or Regulatory Authority approvals with respect to the Products, including, without limitation, those relating to labels, labeling, package inserts and packaging used in connection with the Products. Each party shall, promptly upon receipt of any communication from the FDA or from any other Governmental or Regulatory Authority relating to the Products or the API generally, forward a copy or description of the same to the other party and respond to all inquiries by the other party relating thereto. Each party shall provide the other party in advance with a copy of any proposed written communication with the FDA or any other Governmental or Regulatory Authority, and to the extent any communication reasonably relates to the other party’s obligations hereunder, shall cooperate with any and all reasonable requests of the other party concerning any meeting or written or oral communication with the FDA or any other Governmental or Regulatory Authority. Purchaser will be responsible for providing Andrx with the information it needs to respond to all FDA inquiries, Notices of Violation, Warning Letters and other actions of the FDA addressed to Andrx and related to promotional activities, and Andrx shall bear the cost of such response. Andrx will be responsible for providing Purchaser with the information it needs to respond to all FDA inquiries, Notices of Violation, Warning Letters and other actions of the FDA addressed to Purchaser and related to promotional activities and Purchaser shall bear the cost of such response. Purchaser shall provide Andrx with copies of all final submissions that are intended to change or modify the packaging, label or labeling for, or the indications of, the Products, for submission to the FDA. Andrx will remain solely responsible for responding to and complying with, all FDA inquiries, Notices of Violation, Warning Letters and other regulatory matters related to manufacturing of the Products by Andrx, including the payment of all expenses associated with the foregoing.  
 7.2 Communication with Regulatory Authorities. Each party shall provide the other party with copies of all complaints which it receives concerning the Product within five (5) business days after its receipt of the same provided, that all complaints concerning suspected or actual Product tampering, damage, contamination or mix-up (e.g., wrong ingredients or incorrect  
\* filed under application for confidential treatment  
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 labeling) shall be delivered to the other party within two (2) business days of a party’s receipt of the same. Neither party shall take any other action in respect of any such complaint that could reasonably be expected to adversely affect the other party without the other party’s consent, unless otherwise required by Law.  
 7.3 Regulatory Information. Each party agrees to provide the other party with all reasonable assistance and take all actions reasonably requested by the other party that are necessary or desirable to enable the other party to comply with any Law applicable to the Products or the API in general. Such assistance and actions shall include, among other things, keeping the other party informed, commencing within two (2) business days of notification of any action by, or notification or other information which it receives (directly or indirectly) from, the FDA or any other Governmental or Regulatory Authority which: (a) raises any material concerns regarding the safety or efficacy of the Product; (b) indicates or suggests a potential material liability for either party to third parties arising in connection with the Product or (c) is reasonably likely to lead to field alert report, recall or market withdrawal of the Products; provided, that neither party shall be obliged to disclose information in breach of any contractual restriction.  
 7.4 Adverse Drug Experience Reports.  
 7.4.1 Reporting Adverse Drug Experiences. Each party shall promptly notify the other party of any potential serious Adverse Drug Experience Reports as defined in 21 C.F.R. Section 314.80(a), within three (3) calendar days after such report becomes known to such party. For all other Adverse Drug Experience Reports, the notification shall be five (5) calendar days. Each party shall consult with, and reasonably consider input of the other party in making the determination whether any complaint, Adverse Drug Experience Report or Serious Adverse Drug Experience Report must be reported to the FDA or any other Governmental or Regulatory Authority or any other Person. Andrx will have sole responsibility for evaluating and reporting of Adverse Drug Experiences to the FDA as required by Law. Prior to reporting any Adverse Drug Experience to the FDA, Andrx shall deliver to Purchaser copies of any report it proposes to deliver.  
 7.4.2 Provision of Reports. In accordance with periodic reporting requirements, Purchaser shall provide Andrx with copies of all adverse event reports relating to the Product and submitted to the FDA in accordance with 21 C.F.R. 314.80(c)(1). Within ten business days after submission, Andrx shall provide Purchaser with copies of all Periodic Adverse Drug Experience Reports relating to the Product and submitted in accordance with 21 C.F.R. 314.80(c)(2).  
 7.4.3 Further Cooperation. Purchaser and Andrx shall enter into such other agreements as are reasonably necessary to ensure that satisfactory systems and procedures are in place to effect the effective exchange of safety and other medical information between the two parties as necessary to fulfill all applicable legal and regulatory requirements.  
 7.5 Records and Accounting.  
 7.5.1 By Andrx. Andrx shall keep records of the manufacture, testing and shipping of the Products, and retain samples of such Products in order to comply with applicable  
\* filed under application for confidential treatment  
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 Law as well as to assist with resolving product complaints and other similar investigations. Copies of such records and samples shall be made available to Purchaser upon its request and shall be retained by Andrx and be available to Purchaser for a period of one (1) year after the expiration dates of the packaged batch, or longer if required by Law.  
 7.5.2 By Purchaser. Purchaser shall keep records of the shipping of the Products, and retain samples of such Products in order to comply with applicable Law as well as to assist with resolving product complaints and other similar investigations. Copies of such records and samples shall be made available to Andrx upon its request and shall be retained by Purchaser and be available to Andrx for a period of one (1) year after the expiration dates of the packaged batch, or longer if required by Law.  
 7.6 Product Recalls.  
 7.6.1 Records. The parties shall each maintain records as may be necessary to permit a recall or a field correction of any the Products delivered to Purchaser or customers of Purchaser, effected voluntarily or under a threat of, or a directive by, any Governmental or Regulatory Agency. Each party shall give notice within twenty four (24) hours by telephone (to be confirmed in writing promptly) or in person to the other party upon discovery that any Products should be recalled or corrected, or may be required to be recalled or corrected, and, each party upon receiving any such notice or upon any such discovery, shall cease and desist from further shipments of such Products in its possession or control until a decision has been made whether a recall or some other corrective action is necessary. Each party shall co-operate with the other in developing any necessary recall plan, and the manner and extent of such plan shall be subject to prior consultation, which consultation shall not unreasonably delay such plan.  
 7.6.2 Responsibilities Respecting Recall. Notwithstanding Section 7.6.1, except as otherwise set forth below in this Section 7.6.2, Andrx and its Affiliates shall make all decisions (but shall follow requirements of Law) with respect to any recall, market withdrawal or any other corrective action related to the Products. Andrx shall consult with Purchaser in connection with such decision. Purchaser will co-operate with Andrx as reasonably required by Andrx with regard to all applicable Laws. If a recall, discretionary or required by law, results predominately from any breach by Andrx of the Manufacturing Requirements then: (a) such recall and all reasonable out of pocket costs and expenses incurred by Purchaser to third parties to perform such corrective action shall be made at Andrx’s cost and expense, and (b) Andrx shall use its reasonable efforts to replace the recalled Products with new Products within one hundred twenty (120) days from the date that Andrx decides to recall the Products. In the event that: (x) Andrx is unable to replace the recalled Products within this one hundred twenty (120) day period, or (y) such new Products are also recalled or returned due predominately to a breach by Andrx of the Manufacturing Requirements, then Purchaser may request Andrx to reimburse Purchaser for the purchase price that Purchaser paid Andrx for the affected Products plus all of the reasonable out of pocket costs and expenses incurred by Purchaser to third parties to perform such corrective action. Purchaser will also have the right to effect a recall, market withdrawal or other corrective action related to the Products (a “Purchaser Recall”). If Purchaser elects to conduct a Purchaser Recall, then Andrx shall cooperate to effectuate such recall. Any Purchaser Recall shall be at Purchaser’s expense; provided, that, if the Purchaser Recall results predominately from a breach by Andrx of the Manufacturing Requirements and results in a bona fide health and/or safety concern, such recall shall be at Andrx’s expense.  
\* filed under application for confidential treatment  
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 7.7 Product Returns. To the extent that any return of Products results solely from any breach by Andrx of the Manufacturing Requirements, in addition to any other rights and remedies available to Purchaser at Law or under this Agreement, Andrx shall, at its sole cost, replace the returned Products with new Products within a period of up to one hundred twenty (120) days from the date that Purchaser notifies Andrx about the returned Products or sooner if reasonably practicable. In the event that: (a) Andrx is unable to replace the returned Products within a period of up to one hundred twenty (120) day period or (b) such new Products are also returned or recalled due predominately to a breach by Andrx, then in addition to any other right or remedy available to Purchaser, Purchaser may request Andrx to reimburse Purchaser the purchase price that Purchaser paid Andrx for the affected Products plus all of the reasonable out of pocket costs and expenses actually incurred by Purchaser to third parties to perform such corrective action. In all other circumstances, customer returns shall be made at Purchaser’s cost and expense.  
Article VIII. Representations, Warranties and Covenants  
 8.1 Andrx Representations, Warranties and Covenants. Andrx hereby represents, warrants and covenants to Purchaser as follows:  
 (a) Andrx has, and will maintain throughout the term of this Agreement, all permits, licenses, representations and governmental authorizations and approvals as required by Law in order for Andrx to execute, deliver and perform its obligations hereunder;  
 (b) Andrx shall carry out, or shall cause its Affiliates to carry out, the manufacturing and distribution of the Product and Andrx’s other obligations and activities under this Agreement in accordance with: (i) the terms of this Agreement and the Quality Assurance Agreement; (ii) the Manufacturing Requirements and (iii) all applicable Laws;  
 (c) upon delivery, the Products will be free and clear from all liens and encumbrances, other than any liens and encumbrances that are a result of actions taken by Purchaser;  
 (d) the Products will be manufactured at an FDA approved facility and in compliance with the applicable regulatory requirements for such a facility;  
 (e) any new intellectual property to the extent created as a result of any change to the Product manufacturing process or to the Products or any component thereof will not infringe any intellectual property rights of any third parties (this representation will expire after a period of 18 months from the date that Product is first manufactured with the new intellectual property);  
 (f) the Products delivered to Purchaser under this Agreement shall not, at the time of delivery, be adulterated or misbranded within the meaning of the Act, as amended, or within the meaning of any applicable Laws in which the definition of adulteration and  
\* filed under application for confidential treatment  
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 misbranding is substantially the same as that contained in the Act, as such Act and such Laws are effective at the time of delivery;  
 (g) Andrx and its employees, Affiliates and agents have never been (i) debarred or (ii) convicted of a crime for which a person can be debarred, under Section 306(a) of the Generic Drug Enforcement Act of 1992 (Section 306 (a) or (b)); and  
 (h) the amounts set forth in the Standard Costs identified in Exhibit B represent the current standard cost for manufacturing Conforming Products, and do not include any materially significant costs associated with any Products that are Non-Conforming; and.  
 (i) Andrx has never been and, to the best of its knowledge after due inquiry, none of its employees, affiliates or agents has ever been (i) threatened to be debarred or (ii) indicted for a crime or otherwise engaged in conduct for which a person can be debarred, under Section 306(a) or (b). Andrx shall promptly notify Purchaser upon learning of any such debarment, conviction, threat or indictment.  
 (j) For the period prior to August 31, 2005, any and all Altoprev Product delivered by Andrx to Purchaser shall have an expiration date not less than 15 months from the date such Product is delivered, unless otherwise accepted by Purchaser, in its sole discretion. For the period from and after August 31, 2005, any and all Altoprev Product delivered by Andrx to Purchaser shall have an expiration date not less than 18 months from the date such Product is delivered, unless otherwise accepted by Purchaser, in its sole discretion.  
 (k) Throughout the term of this Agreement, any and all Fortamet Product delivered by Andrx to Purchaser (other than the Opening Inventory) shall have an expiration date not less than 18 months from the date such Fortamet Product is delivered.  
 8.2 DISCLAIMER OF WARRANTIES. EXCEPT AS SET FORTH IN THIS SECTION 8.2 OR THE AGREEMENT TO LICENSE, ANDRX GIVES NO OTHER WARRANTY, EXPRESS OR IMPLIED. ALL WARRANTIES, INCLUDING, WITHOUT LIMITATION, WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, OTHER THAN THOSE SET FORTH IN THIS AGREEMENT, ARE EXPRESSLY DISCLAIMED.  
 8.3 Purchaser Representations, Warranties and Covenants. Purchaser hereby represents, warrants and covenants to Andrx as follows:  
 (a) Purchaser is properly registered, licensed and qualified, and has all requisite power and authority under its organizational documents and in accordance with the Laws of the Territory to market and sell the Products, and to conduct its business and perform its obligations hereunder and, during the Term of this Agreement and the Quality Assurance Agreement and any extensions thereof, it shall take all action as may be  
\* filed under application for confidential treatment  
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 required and necessary to obtain and keep current any governmental licenses, permits, registrations and approvals that are necessary or advisable for it to carry out its activities hereunder;  
 (b) Purchaser shall carry out its obligations and activities under this Agreement and the Quality Assurance Agreement in accordance with: (i) the terms of this Agreement and the Quality Assurance Agreement, and (ii) all applicable Laws.  
Article IX. Confidentiality and Press Releases  
 9.1 Confidentiality. For a period of five (5) years following termination of this Agreement, each party shall hold in confidence and use only in furtherance of its rights and obligations under this Agreement all Confidential Information that it acquires from the other party pursuant to this Agreement, unless (a) the Disclosing Party consents to the Receiving Party’s disclosure or use or (b) disclosure of the Disclosing Party’s Confidential Information by the Receiving Party is required by law or by order of any Governmental or Regulatory Authority, in which event the Receiving Party will notify the Disclosing Party of that order as soon as practicable, shall use reasonable efforts (at the Disclosing Party’s expense) to obtain a protective order covering the Confidential Information and shall disclose only such Confidential Information that its legal counsel determines is legally required. Each party shall make Confidential Information that it acquires from the other party pursuant to this Agreement available only to those of its Affiliates, directors, officers, employees, consultants, advisors or representatives who need to have access thereto for the purposes of this Agreement and who are bound by an obligation of confidentiality consistent with the provisions herein.  
 9.2 Press Releases. Except as required by Law (including securities laws and rules of any securities exchange or quotation system) or any Governmental or Regulatory Authority, neither party shall make any press release or other public announcement relating to the Agreement or the transactions described herein without the prior written consent of the other party.  
Article X. Indemnification  
 10.1 Indemnification by Andrx. Andrx agrees to defend, indemnify and hold harmless Purchaser, its Affiliates, officers, directors, employees and agents as provided in the Agreement to License. Notwithstanding the foregoing, Purchaser shall not be entitled to indemnification with respect to any matters covered by Sections 2.4.1, 2.4.3, 2.4.6, 7.6 and 7.7 and not involving third party claims.  
 10.2 Indemnification by Purchaser. Purchaser agrees to defend, indemnify and hold harmless Andrx, its Affiliates, officers, directors, employees and agents as provided in the Agreement to License.  
 10.3 Exclusive Remedy. The rights and remedies set forth in this Agreement and Article 10 of the Agreement to License shall constitute the sole and exclusive rights and remedies of either party with respect to this Agreement; provided, that nothing contained in this  
\* filed under application for confidential treatment  
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 Section shall be deemed to restrict a party from seeking specific performance, an injunction or other equitable relief to enforce the terms and conditions hereof, nor shall the foregoing limitation apply in the case of fraud or other willful breach by a party to this Agreement.  
 10.4 CONSEQUENTIAL DAMAGES. NO PARTY TO THIS AGREEMENT SHALL BE LIABLE TO OR OTHERWISE RESPONSIBLE TO ANY OTHER PARTY HERETO OR ANY BENEFICIARY HEREOF FOR ANY LOSS OF PROFITS, DIMINUTION IN VALUE, OR INCIDENTAL, INDIRECT, CONSEQUENTIAL, SPECIAL, EXEMPLARY OR PUNITIVE DAMAGES THAT ARISE OUT OF OR RELATE TO THIS AGREEMENT OR THE PERFORMANCE OR BREACH HEREOF OR OTHERWISE AND WHETHER IN CONTRACT, TORT, STRICT LIABILITY OR OTHERWISE, EXCEPT AND TO THE EXTENT THAT ANY SUCH DAMAGES SHALL HAVE RESULTED FROM THE WILLFUL MISCONDUCT OF SUCH PARTY.  
Article XI. Miscellaneous  
 11.1 Choice of Law. This Agreement shall be governed by and construed exclusively in accordance with the law of the State of New York, without regard to the conflicts of law rules of such state. The parties hereby agree to the non-exclusive jurisdiction of any state or federal court sitting in New York, New York for purposes of any dispute arising out of this Agreement.  
 11.2 Waiver. The waiver by any party of a breach of any provision of this Agreement shall not operate, or be construed, as a waiver of any subsequent breach.  
 11.3 Modification. No change, modification, or waiver of any term of this Agreement shall be valid unless it is in writing and signed by both parties.  
 11.4 Entire Agreement. This Agreement and the Purchase Orders delivered in accordance herewith constitute the entire agreement between the parties with respect to the subject matter hereof, and supersede all prior agreements and understandings, whether oral or written, between the parties.  
 11.5 Assignments. This Agreement shall be binding upon and inure to the benefit of the parties hereto and their respective successors and permitted assigns. Neither party may assign its rights or delegate its duties under this Agreement without the prior written consent of the other party, except as expressly provided herein. Notwithstanding the foregoing, a party may assign all or any portion of its rights or delegate its duties to any subsidiary or, in the event of a merger or sale of all or substantially all of its assets, any successor entity, without the necessity of obtain the other party’s consent. Andrx may subcontract all or a portion of its obligations hereunder to any third party without the prior written consent of Purchaser, provided, that Andrx shall be responsible for such third party subcontractor’s performance in accordance with this Agreement and such third party shall be bound by an obligation of confidentiality substantially similar to that by which Andrx is bound hereunder. Any prohibited assignment shall be null and void and of no force or effect.  
 11.6 Independent Contractor. This Agreement shall not be construed as constituting a partnership, joint venture or any other form of legal association that would impose liability upon one party for the act or failure to act of the other party, or as providing either party with the right, power or authority (express or implied) to create any duty or obligation of the other party.  
\* filed under application for confidential treatment  
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 11.7 Third Party Beneficiaries. The parties do not intend, nor will any Section of this Agreement be interpreted, to create for any person any third party beneficiary rights.  
 11.8 Headings. The headings have been inserted for convenience only and are not to be considered when interpreting the provisions of this Agreement.  
 11.9 Time of Essence. Time is of the essence in the performance of this Agreement.  
 11.10 Counterparts. This Agreement may be executed in multiple counterparts, each of which will be deemed an original, but all of which together shall constitute one and the same instrument.  
 11.11 Severability. Each provision of this Agreement will to the extent possible be interpreted in such manner as to be effective and valid under applicable law, but if any provision of this Agreement is held to be prohibited by or invalid under applicable law, such provision will be ineffective only to the extent of such prohibition or invalidity, without invalidating the remainder of such provision or the remaining provisions of this Agreement.  
 11.12 Incorporation of Exhibits. The Exhibits identified in this Agreement and attached hereto are incorporated herein by this reference and made a part hereof.  
 11.13 Force Majeure. If the actual performance of this Agreement (other than the obligation to pay money) is prevented with by any circumstance beyond the reasonable control of the party affected, including any act of God (such as fire, flood, earthquake or other natural cause), terrorist events, riots, insurrections, declared or undeclared war or national emergency, strikes by laborers of third parties, boycotts by laborers of third parties, lockouts by laborers of third parties or other labor difficulties by laborers of third parties, the party affected by such “Force Majeure” event is excused on a day-by-day basis to the extent of the prevention; provided, that such party notifies the other party as soon as practicable of the nature and expected duration of the claimed Force Majeure, uses all commercially reasonable efforts to avoid or remove the causes of nonperformance and resumes performance promptly after the causes have been removed. If a party is unable to perform its obligations under this Agreement (other than the obligation to pay money) due to a Force Majeure event for a period in excess of three (3) months, then the other party may terminate this Agreement with no further obligation to the non-performing party, subject to Section 5.2. During the foregoing three month period (and without prejudice to Purchaser’s rights under the preceding sentence), Andrx may, at its election, either: (i) procure another manufacturer for the Products, such manufacturer to be to the reasonable satisfaction of Purchaser, or (ii) if Andrx demonstrates to Purchaser’s reasonable satisfaction that it would be more expeditious for Andrx to continue manufacturing the Products than to qualify another manufacturer, Andrx may continue to manufacture the Products on the terms of this Agreement.  
 11.14 Disputes. If there is a dispute arising out of this Agreement that cannot be reasonably resolved in the ordinary course of business, either party may initiate the dispute resolution process by providing written notice to the other party’s first level of dispute management of the nature of the dispute accompanied by relevant documents and facts supporting the party’s position. The other party shall have ten (10) business days to provide its  
\* filed under application for confidential treatment  
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 written answer accompanied by relevant documents and facts supporting the party’s position. Within ten (10) business days following delivery of the answer, if the parties have not agreed to a resolution of the dispute or mutually agreed to extend the time for resolution of the dispute, the second level management of each party shall meet and negotiate in good faith to resolve the dispute. If the parties are unable to resolve the dispute within ten (10) business days thereafter or mutually agree to extend the time for resolution of the dispute, either party may seek resolution of the dispute through litigation, or if both parties agree, through binding arbitration. Notwithstanding the foregoing, if a dispute arises that if not immediately resolved would result in immediate and irrevocable harm to a party (such as a breach of the confidentiality and/or the data protection provisions of this Agreement), such affected party may seek immediate judicial relief.  
 11.15 Notices. All notices or other communications hereunder shall be deemed sufficient if given in writing, mailed registered mail (return receipt requested), postage paid, or by facsimile (confirmed by such registered mail) or by courier addressed to the appropriate party at the address set forth below, or at such other place as such party may designate in writing to the other party.  
 If to Andrx: Andrx Pharmaceuticals, Inc.  
 0000 Xxxxxx Xxxx, 0xx Xxxxx  
 Xxxxxxxxxx, Xxxxxxx 00000  
 Attn: Xxxxx Xxxxx, Esq.  
 Executive Vice President and General Counsel  
 If to Purchaser: First Horizon Pharmaceutical Corporation  
 0000 Xxxxxx Xxxx  
 Xxxxxxxxxx, Xxxxxxx 00000  
 Attn: Xxxxxx Xxxxx, Esq.  
 General Counsel  
All such notices shall be effective five (5) days following the date of mailing.  
 11.16 Permits. Each party shall, at its own expense, obtain and maintain the necessary permits required to perform its obligations hereunder.  
 11.17 Annual Product Review Report. Andrx shall prepare on an annual basis supply product data, including, without limitation, release test results, complaint investigation results, and all investigations (in manufacturing, testing and storage) as required by GMPs.  
 11.18 Insurance. Each party shall maintain comprehensive general liability insurance, including blanket contractual liability insurance covering the obligations of that party under this Agreement through the term of this Agreement and for five (5) years thereafter, which insurance shall afford limits of not less than $10,000,000 for each occurrence for bodily injury liability, personal injury liability, products liability, property damage liability, contractual liability and completed operations liability with an aggregate annual cap of at least $40,000,000. Each party will provide the other with a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date and the limits  
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 of liability. The insurance certificate shall further provide for a minimum of thirty (30) days written notice to the recipient of a cancellation of, or material change in, the insurance, subject to the insurer’s agreement to so state on the certificate. Each party shall cause its insurance policy to name the other party hereto as an additional insured and a loss payee. Each party’s general liability insurance policy shall contain a waiver of subrogation rights which that party’s insurer(s) may have against the other party.  
 11.19 Audit Rights. During the term of this Agreement, Andrx, its Affiliates and any sublicensees shall afford Purchaser and its representatives full access, at all reasonable times and upon reasonable notice to the offices, properties, books, records, officers, employees and other assets of the Andrx, and shall provide such assistance as is reasonably requested by Purchaser in order to provide Purchaser a full opportunity to investigate, evaluate and confirm the accuracy of the invoices and reports provided by Andrx under this Agreement, including, without limitation, any such invoices or reports relating to Andrx’s: determination of the API cost, the pharmaceutical price index and packaging costs, in each case in connection with the determination of the Per Unit Price. Purchaser may exercise the foregoing audit rights once per calendar year, to be exercised in December or January of each calendar year, unless Purchaser demonstrates a compelling need to conduct such audit at a different time of year. If an audit concludes that Andrx has not fully satisfied its obligations under this Agreement or has misstated any of the foregoing costs or prices resulting in excess payments by Purchaser, then Andrx shall immediately take action to cure any failure to perform its obligations under this Agreement within the thirty (30) days period provided in Section 6.2.3, and refund any resulting overpayments within thirty (30) days of the conclusion of the audit. If an audit concludes that the costs or prices set forth above were understated, then Purchaser shall pay any additional fees required within thirty (30) days of concluding such audit. If either party disputes the conclusion of an audit, then the parties shall engage a qualified arbitrator to resolve the dispute. The fees charged by such arbitrator shall be paid in equal shares by Purchaser and Andrx; provided, that if the audit discloses that the payments by Purchaser for the audited period are more than one hundred ten percent (110%) of the payments required for such period, then Andrx shall pay all fees and expenses charged by such accounting firm.  
 11.20 Manufacturing Forecasting Meeting. The parties shall meet every six months during the term of this Agreement to discuss the manufacturing capacity of Andrx and shall discuss in good faith Andrx’s ability to meet the ongoing manufacturing capacity needs of Purchaser.  
 11.21 Covenant of Cooperation. The parties covenant to timely and diligently cooperate to effect the goals, objectives and purposes of this Agreement and to facilitate the performance of their respective duties and obligations under this Agreement in a commercially reasonable manner. Further, the parties agree to deal and negotiate with each other diligently and in good faith in the execution and implementation of their duties and obligations under this Agreement. There may be functions, responsibilities, activities and tasks not specifically described in this Agreement which are required for the performance and provision of the parties’ obligations and are an inherent part of, or a necessary element included within, the parties’ obligations. If such functions, responsibilities, activities and tasks are mutually determined by the parties to be required for the proper performance of the other obligations or are an inherent part, or a necessary part, thereof, such functions, responsibilities, activities and tasks shall be deemed to be  
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 implied by and included within the scope of this Agreement and the obligations established hereunder to the same extent and in the same manner as if specifically described in this Agreement; provided, that this Section 11.21 shall not be interpreted to impose any material obligations or liabilities on any party that are not expressly set forth in this Agreement.  
[Signatures on following page]  
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 IN WITNESS WHEREOF, this Agreement has been executed by a duly authorized officer of each party as of the Effective Date.  
 “Purchaser” FIRST HORIZON PHARMACEUTICAL CORPORATION   
 By: /s/ Xxxxxxx X. Xxxxxxxx   
 Name: Xxxxxxx X. Xxxxxxxx   
 Title: CEO and President   
 “Andrx” ANDRX PHARMACEUTICALS, INC.   
 By: /s/ Xxxxxx X. Xxxxxxxx   
 Name: Xxxxxx X. Xxxxxxxx   
 Title: Executive Vice President   
 \* filed under application for confidential treatment  
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