Exhibit 10.1  
CERTAIN MATERIAL (INDICATED BY AN ASTERISK) HAS BEEN OMITTED FROM THIS DOCUMENT PURSUANT TO A REQUEST FOR CONFIDENTIAL TREATMENT. THE OMITTED MATERIAL HAS BEEN FILED SEPARATELY WITH THE SECURITIES AND EXCHANGE COMMISSION.  
AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT  
 THIS AMENDED AND RESTATED MANUFACTURING AND SUPPLY AGREEMENT (the “Agreement”) is made effective as of the 19th day of December, 2006 (the “Effective Date”) by and between Santarus, Inc., a Delaware corporation, having offices at 00000 Xxxx Xxxxx Xxx Xxxxx, Xxxxx 000, Xxx Xxxxx, Xxxxxxxxxx 00000, U.S.A. (“Santarus”) and Patheon Inc., a corporation incorporated under the laws of Canada, having offices at 0000 Xxxxxxxxxxx Xxxx, Xxxxx 000, Xxxxxxxxxxx, Xxxxxxx X0X 0X0, XXXXXX (“Patheon”) and replaces in its entirety the Manufacturing and Supply Agreement entered into between Santarus and Patheon on December 19, 2003, and any amendments thereto through the date hereof. Patheon and Santarus are sometimes referred to herein individually as a “Party” and collectively as the “Parties.”  
RECITALS  
 WHEREAS, Santarus is a specialty pharmaceutical company focused on acquiring, developing and commercializing products for the prevention and treatment of gastrointestinal diseases and disorders;  
 WHEREAS, Patheon is a leading global provider of outsourced drug development and manufacturing services to pharmaceutical and biotechnology companies;  
 WHEREAS, Santarus seeks to retain a contract manufacturer to manufacture and supply commercial quantities of its SAN-05 immediate release omeprazole pharmaceutical product;  
 WHEREAS, Patheon possesses substantial resources, experience, and expertise in the manufacture of pharmaceutical products; and  
 WHEREAS, the Parties mutually desire to enter into an agreement for the commercial manufacture and supply of Santarus’ SAN-05 product.  
 NOW THEREFORE, in consideration of the foregoing and the mutual covenants and agreements set forth below and in the Quality Agreement and the Capital Agreement, the Parties agree as follows:  
ARTICLE 1  
DEFINITIONS  
 1.1 “Affiliate” means any individual, corporation, association, or other business entity, which directly or indirectly controls, is controlled by, or is under common control with the Party in question. As used in this definition of “Affiliate,” the term “control” shall mean, as to an entity, (a) direct or indirect ownership of [\*\*\*] or more of the voting interests or other ownership interests in the entity in question; (b) direct or indirect ownership of [\*\*\*] or more of the interest in the income of the entity in question; or (c) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise).  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 1.2 “Annual API Cap” means a dollar amount not to exceed $[\*\*\*] in any calendar year.  
 1.3 “API” means the active pharmaceutical ingredient known as omeprazole (Chemical Abstract No. 73590-58-6).  
 1.4 “API Reimbursement Value” means [\*\*\*].  
 1.5 “Applicable Laws” mean all laws, statutes, ordinances, codes, rules, regulations, guidelines, and procedures enacted or made by a Government Authority, including, without limitation, the FDA and any applicable Foreign Regulatory Authority, that are in force during the Term, and in each case only to the extent applicable to the subject matter of, or the performance by the Parties of their respective obligations under, this Agreement, including without limitation, in respect of Patheon and Santarus, the commercial manufacture of the Finished Product by Patheon and, in respect of Santarus only, the commercial marketing of the Finished Product in the United States by Santarus. For purposes of this Agreement, “Applicable Laws” shall include, without limitation, the FFDCA, the regulations promulgated thereunder (including, without limitation, those regulations currently contained in Title 21 of the Code of Federal Regulations), and other rules and regulations promulgated under the FFDCA relating to the manufacture of pharmaceutical products; and equivalent laws, regulations and standards promulgated by a Government Authority that may assert jurisdiction over the Finished Product or any applicable Patheon manufacturing facilities, including without limitation, the laws of the Province of Ontario and the laws of Canada applicable therein; GMP, including the FDA’s Guidance for Industry, Manufacturing, Processing or Holding Active Pharmaceutical Ingredients, March 1998, and any updates thereto; and the FDA’s regulations for drug establishment registration.  
 1.6 “Bulk API” means the bulk form of API manufactured by a Third Party manufacturer and provided to Patheon for use in manufacturing the Finished Product in accordance with the terms and conditions of this Agreement.  
 1.7 “Business Day” means any day other than a Saturday, Sunday or statutory holiday in Ontario, Canada or San Diego, California.  
 1.8 “Capital Agreement” has the meaning set forth in Section 14.1.  
 1.9 “Certificates of Compliance” means (a) the certificate of analysis confirming the identity, strength, quality and purity of each batch of Finished Product to which it pertains (together with any certificate of analysis pertaining to the Bulk API contained in such batch), (b) the certificate of compliance confirming that each batch of Finished Product was manufactured, tested, stored and supplied by Patheon in compliance with this Agreement, including without limitation the Specifications, GMP and Applicable Laws, and (c) such other certificates and confirmations as described in the Quality Agreement, each such certificate signed by an authorized signatory of Patheon.  
 1.10 “Commencement of Commercial Manufacturing” means August 19, 2004.  
 1.11 “Deficiency Notice” has the meaning set forth in Section 3.5.1.  
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 1.12 “Effective Date” has the meaning specified on the first page of this Agreement.  
 1.13 “Existing Lines Capacity” has the meaning set forth in Section 2.2.4.  
 1.14 “Facility” means Patheon’s facilities located at 000 Xxxxxxxxx Xxxxx, Xxxxxx, Xxxxxxx, Xxxxxx, and any other facilities (including facilities utilized by subcontractors as permitted hereunder) that are used in connection with the activities performed by Patheon hereunder.  
 1.15 “FDA” means the United States Food and Drug Administration, and any successor thereto.  
 1.16 “FFDCA” means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321 et seq., as amended.  
 1.17 “Financial Penalty” has the meaning set forth in Section 2.7.  
 1.18 “Finished Product” means Santarus’ SAN-05 immediate-release omeprazole pharmaceutical product, as more particularly described in the Specifications.  
 1.19 “Firm Purchase Order” has the meaning set forth in Section 2.2.3.  
 1.20 “Forecast” has the meaning set forth in Section 2.2.2.  
 1.21 “Foreign Regulatory Authority” means, for each country other than the United States of America, the authority or authorities having jurisdiction over the Finished Product that correspond to the FDA.  
 1.22 “GMP” means current good manufacturing practices applicable in Canada and the United States of America as described in:  
(a) Division 2 of Part C of the Food and Drug Regulations (Canada); and  
(b) Parts 210 and 211 of Title 21 of the United States Code of Federal Regulations and the requirements imposed thereunder by the FDA,  
together with the latest Health Canada and FDA guidance and like documents pertaining to manufacturing and quality control practice, all as updated, amended and revised from time to time.  
 1.23 “Government Authority” means any supra-national, national, regional, state, provincial or local government, court, governmental agency, authority, board, bureau, instrumentality or regulatory body having jurisdiction over the Finished Product.  
 1.24 “INDA” means an investigational new drug application.  
 1.25 “Initial Term” has the meaning set forth in Section 11.1.  
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 1.26 “Invention” means information relating to any invention, innovation, improvement, development, discovery, computer program, device, trade secret, method, know-how, process, technique or the like, whether or not written or otherwise fixed in any form or medium, regardless of the media on which it is contained and whether or not patentable or copyrightable.  
 1.27 “Laws” means all laws, statutes, ordinances, regulations, rules, by-laws, judgments, decrees or orders of any Government Authority.  
 1.28 “Lines” has the meaning set forth in Section 2.2.4.  
 1.29 “Long Forecast” has the meaning set forth in Section 2.2.2.  
 1.30 “Minimum Run Quantity” means the minimum number of batches of Finished Product to be produced during the same cycle of manufacturing as set forth in Exhibit A hereto.  
 1.31 “NDA” means a New Drug Application filed with the FDA for marketing approval for a pharmaceutical product.  
 1.32 “Other Invention” has the meaning set forth in Section 9.1.  
 1.33 “Patheon Manufacturing Responsibilities” has the meaning specified in Section 3.1 of this Agreement.  
 1.34 “Patheon Supply Commitment” has the meaning set forth in Section 2.2.4.  
 1.35 “Price” means the price for the manufacture and supply of Finished Product under this Agreement specified in the pricing structure set forth in Exhibit B, as may be amended from time to time in accordance with Section 6.2 of this Agreement.  
 1.36 “Product Invention” has the meaning set forth in Section 9.1.  
 1.37 “Product Patents” means (i) United States patents 6,645,988, 6,699,885, 6,780,882, 6,489,346 and 5,840,737, (ii) any other United States patents or patent applications for an immediate-release buffered proton pump inhibitor, and (iii) any provisional, converted provisional, continued prosecution application, continuation, divisional and continuation-in-part thereof and any substitution, extension, registration, confirmation, reissue, re-examination, renewal and any like filing thereof, in each case owned by or licensed to Santarus during the Term.  
 1.38 “Quality Agreement” means that certain Quality Agreement dated February 9, 2004, by and between the Parties.  
 1.39 “Raw Materials” has the meaning set forth in Section 7.1.  
 1.40 “Regulatory Approval” means, with respect to a national or multinational jurisdiction, (a) any approvals, licenses, registrations, or authorizations necessary for the manufacture (where relevant), marketing and sale of the Finished Product in such nation or  
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 jurisdiction, and (b) where relevant, pricing approvals necessary to obtain reimbursement from a Government Authority.  
 1.41 “Renewal Term” has the meaning set forth in Section 11.1.  
 1.42 “Responsible Executive” means the President or the Chief Executive Officer of a Party, or his or her designated representative.  
 1.43 “Santarus Exclusivity Commitment” has the meaning set forth in Section 2.1.  
 1.44 “Specifications” means the specifications for the Finished Product set forth in the Quality Agreement (as amended from time to time) together with applicable manufacturing protocols, packaging specifications, testing methodologies and all applicable requirements set forth in regulatory filings made with the FDA (including INDA’s and NDA’s) for the Finished Product.  
 1.45 “Term” means the Initial Term and the Renewal Term.  
 1.46 “Territory” means the United States of America.  
 1.47 “Third Party” means any individual or entity other than Patheon or Santarus or their respective Affiliates.  
 1.48 “unit”, in reference to Finished Product, means a single packet/dose of such Finished Product.  
ARTICLE 2  
SUPPLY, STORAGE, AND DELIVERY OF FINISHED PRODUCT  
 2.1 Supply of Finished Product. During the Term, subject to the Patheon Supply Commitment (as defined in Section 2.2.4), Patheon shall manufacture and supply, in accordance with the provisions of this Agreement, the Specifications, GMP and Applicable Laws, [\*\*\*].  
 2.2 Commercial Supply.  
 2.2.1 Supply Obligations. Patheon shall manufacture and supply to Santarus, and Santarus agrees to purchase from Patheon, such quantities of Finished Product specified by Santarus in accordance with this Agreement at the Price. [\*\*\*].  
 2.2.2 Forecasts.  
 (i) Santarus shall use commercially reasonable efforts to determine its estimated requirements for Finished Product from Patheon and shall deliver to Patheon a written, non-binding, rolling [\*\*\*] month forecast, by month, of such estimated requirements (the “Forecast”). Santarus shall, in accordance with the terms of this Agreement, update and revise the Forecast on a monthly basis. Santarus shall provide each updated Forecast not less than [\*\*\*] calendar days prior to the beginning of the next month. Patheon shall use the Forecast for planning purposes and make available the production capacity and associated testing and release  
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 capacity required to manufacture and supply the forecasted quantities of Finished Product within the time frames specified in each Forecast; and  
 (ii) On or before June 30 in each calendar year, Santarus shall provide Patheon with a written non-binding three-year forecast (the “Long Forecast”) (broken down by quarters for the second and third years of the forecast) of the volume of Finished Product Santarus then anticipates will be required to be produced and delivered by Patheon to Santarus during the three-year period.  
 2.2.3 Firm Purchase Orders. Santarus shall submit to Patheon a firm, written purchase order (the “Firm Purchase Order”) for the purchase of Finished Product at least [\*\*\*] calendar days prior to the specified delivery date. Santarus shall submit Firm Purchase Orders on a monthly basis and acknowledges that quantities of Finished Product ordered in any single Firm Purchase Order will not be less than the Minimum Run Quantity. Each Firm Purchase Order shall specify the quantity or, if more than one shipment is requested, quantities of Finished Product ordered, the requested delivery date or dates, the delivery address(es) and any applicable shipping information. Patheon shall manufacture and supply the Finished Product in the quantities and by the delivery dates set forth in the applicable Firm Purchase Order, consistent with Patheon’s Supply Commitment.  
 2.2.4 Supply Commitment. Patheon shall, subject to Santarus’ Firm Purchase Order requirements, supply to Santarus (to the extent ordered by Santarus on any Firm Purchase Order) amounts of Finished Product [\*\*\*].  
 2.2.5 Firm Purchase Order Amendments. Santarus may amend a Firm Purchase Order by submitting an amended Firm Purchase Order, as follows: (i) at least [\*\*\*] days before the originally scheduled delivery date specified in the Firm Purchase Order, Santarus may amend the Firm Purchase Order to delay the delivery date to a date within [\*\*\*] days of the originally scheduled delivery date; or (ii) at least [\*\*\*] days before the originally scheduled delivery date specified in the Firm Purchase Order, Santarus may increase the quantity of Finished Product ordered and/or accelerate the delivery date to a date within [\*\*\*] days of the originally scheduled delivery date, subject to the Patheon Supply Commitment and all commercially reasonable efforts of Patheon to meet these amended Firm Purchase Orders.  
 2.3 Shipping and Delivery of Finished Product. Patheon shall as agent for Santarus, (i) arrange for shipping and insurance so that the Finished Product will be delivered to the delivery address on the delivery date set forth in the applicable Firm Purchase Order, at Santarus’ expense, and (ii) at Santarus’ risk and expense, obtain any export license or other official authorization and, in accordance with Santarus’ instructions, carry out all customs formalities necessary to export the Finished Products. Santarus may select the freight carrier used by Patheon to ship Finished Products and may monitor Patheon’s shipping and freight practices as they pertain to this Agreement. Finished Products shall be transported in accordance with the Specifications, GMP and Applicable Laws. Patheon shall notify Santarus in writing at the time of shipment as to the quantity of Finished Product shipped, the identity of the carrier and the anticipated delivery date. If any order is delayed and is not likely to be delivered on time, Patheon shall immediately notify Santarus and Santarus may direct Patheon to ship such order by expedited means of transportation as designated by Santarus. To the extent that any such delay is  
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 due to any action or failure to act of Patheon or otherwise due to matters within Patheon’s control, Patheon shall bear the expense of any difference in cost for the expedited means of transportation.  
 2.4 Title and Risk of Loss. Patheon shall deliver the Finished Product to the carrier selected by Santarus at Patheon’s shipping point unless otherwise mutually agreed in writing. Such title as Patheon has in Finished Products and risk of loss or of damage to Finished Products shall remain with Patheon until Finished Products are loaded onto the carrier’s vehicle by Patheon for shipment at Patheon’s shipping point at which time title and risk of loss or damage shall transfer to Santarus. Except as expressly provided otherwise in this Agreement, Santarus shall be responsible for all charges associated with shipping of Finished Product.  
 2.5 Documentation and Customs. Upon completion of manufacturing, packaging and testing of Finished Product pursuant to each Firm Purchase Order, Patheon shall deliver to Santarus by electronic means quality documentation for such Finished Product manufactured pursuant to such Firm Purchase Order as specified in the Quality Agreement, including without limitation, the Certificates of Compliance in respect of such Firm Purchase Order and, if requested by Santarus, completed batch production records (collectively, the “Pre-shipping Documentation”). Patheon acknowledges and agrees that Santarus shall be responsible, at all times, for the final release of the Finished Product and accordingly, Patheon shall not ship any Finished Product until Santarus has notified Patheon in writing that it has completed its final release. Concurrent with the shipment of each Firm Purchase Order of Finished Product, Patheon shall deliver to Santarus the customs documentation corresponding to such shipment and such other documentation and information as may be necessary or desirable for complying with import, export, and customs laws, regulations and like requirements, as applicable. All Finished Product, including its packaging, shall meet all applicable export and customs laws, regulations and like requirements for Canada and, in respect of the United States, shall be in accordance with the instructions of Santarus in respect of all applicable import and customs laws, regulations and like requirements for the United States. Patheon and Santarus will cooperate and provide such assistance to each other as may be reasonably necessary to permit the import of the Bulk API into Canada.  
 2.6 Invoices. Patheon may proceed to invoice Santarus for any order on the earlier of [\*\*\*].  
 2.7 Late Delivery/Shortages and Overages.  
 2.7.1 If a shipment of Finished Product ordered by Santarus under this Agreement has not been delivered at the shipping point within [\*\*\*] Business Days after the scheduled delivery date (any delivery that is more than [\*\*\*] Business Days after the scheduled delivery date stated on the corresponding Firm Purchase Order is hereinafter referred to as a “Late Shipment”), or if the shipment received by Santarus contains less than [\*\*\*] of the quantity specified in the corresponding Firm Purchase Order (a “Short Shipment”), Santarus shall notify Patheon promptly upon such discovery and, in any event, not later than [\*\*\*] days after receipt of, or failure to receive, such ordered Finished Product. Subject to the Patheon Supply Commitment, Patheon shall use its best efforts to deliver the quantity of Finished Product it had failed to ship in the case of a Late Shipment or the quantity by which the shipment is short of the quantity ordered in the case of a Short Shipment, as soon as possible after notification of  
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 such shortage, by expedited means of transportation at Patheon’s expense in respect of any difference in cost for such expedited means of transportation relative to regular delivery costs. If any shipment contains [\*\*\*] more than the quantity ordered, Santarus may elect either to: (a) return to Patheon, at Patheon’s expense, the excess of the quantity ordered, or (b) accept any excess quantity ordered and reserve the right to deduct such excess from future orders. Santarus shall have no obligation to receive any quantity of Finished Product in excess of that ordered.  
 2.7.2 In the event that there is a Late Shipment of Finished Product solely as a result of Patheon [\*\*\*], the following additional provisions shall apply: (a) Santarus shall have the right, in its sole discretion and effective upon written notice, to require Patheon to [\*\*\*]. The Financial Penalty shall be calculated as follows: [\*\*\*].  
Notwithstanding provision (b) above, the imposition of a Financial Penalty pursuant to provision (b) shall not apply upon [\*\*\*]:  
 (i) [\*\*\*];  
 (ii) [\*\*\*];  
 (iii) [\*\*\*];  
 (iv) [\*\*\*];  
 (v) [\*\*\*]; or  
 (vi) [\*\*\*].  
 2.8 Key Performance Indicators.  
 2.8.1 For each [\*\*\*] period during the Term, Patheon shall meet or exceed the key performance indicators established in good faith by Patheon and Santarus for such [\*\*\*] period (collectively, as established with respect to the applicable [\*\*\*] period, the “KPIs”). The current KPIs are set forth in Exhibit C, and the parties mutually agree to review such KPIs at each [\*\*\*] review meeting contemplated by Section 2.12 with the intention of amending, if necessary, the KPIs in respect of the forthcoming [\*\*\*] period. If no such amendments are necessary or if amendments are not agreed, the KPIs in respect of such forthcoming [\*\*\*] period shall be at least as beneficial to Santarus as the KPIs for the then current [\*\*\*] period.  
 2.8.2 In the event that Patheon fails to meet one or more of the KPIs at any time during the term of this Agreement, then Patheon and Santarus shall work diligently to address such failure including, without limitation, the following:  
 (i) Patheon’s site director and the Director of Contracting of Santarus shall meet within [\*\*\*] days of the determination of the sustained failure in order to establish a procedure to address the problem (the “Remediation Plan”). If such meeting does not occur within such [\*\*\*] days or if there is no agreement as to the Remediation Plan (a “Stage 1 Failure”), then clause (ii) shall apply;  
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 (ii) Patheon’s Senior Vice President, Canadian Operations and Santarus’ Senior Vice President, Product Development and Manufacturing will meet within [\*\*\*] days of the Stage 1 Failure in order to establish a Remediation Plan. If such meeting does not occur within such [\*\*\*] days or if there is no agreement as to the Remediation Plan (a “Stage 2 Failure”), then clause (iii) shall apply; and  
 (iii) Patheon’s President and Santarus’ President shall meet within [\*\*\*] days of the Stage 2 Failure in order to establish a Remediation Plan.  
If the Remediation Plan is either not mutually agreed upon or is not, in the reasonable judgment of Santarus, implemented satisfactorily, then Patheon shall be deemed to be in material breach of its obligations hereunder. The Parties may mutually agree to extend any of the time periods referenced in this Section 2.8.  
 2.8.3 Notwithstanding anything to the contrary in this Section 2.8, Patheon shall not be responsible for the failure to achieve the KPIs to the extent caused by any of the following events:  
 (i) Santarus’ failure to have delivered to Patheon adequate supplies of Bulk API;  
 (ii) Santarus’ failure to deliver Forecasts in accordance with Section 2.2.2;  
 (iii) Santarus’ failure to timely deliver amended Specifications in the event that the Specifications are amended pursuant to Section 3.6.1 or 3.6.2;  
 (iv) Santarus’ failure to deliver the Firm Purchase Orders in accordance with Sections 2.2.3 and 2.2.5; or  
 (v) Santarus’ failure to timely complete the final release of the Finished Product in the absence of any production or quality issues.  
 2.9 Storage of Finished Product. Until Finished Product is shipped, Patheon shall store all Finished Product identifiably distinct from any other raw material and finished or filled product stocks and shall comply with all storage requirements set forth in the Specifications. Patheon shall assume responsibility for any loss or damage to such Finished Product while stored by Patheon.  
 2.10 Multi-Country Packaging Requirements. If and when Santarus decides that it wishes to have Patheon manufacture the Finished Product for countries in addition to the Territory, then Santarus shall inform Patheon of the packaging requirements for each new country and Patheon shall prepare a quotation for consideration by Santarus of the additional Raw Material costs, if any, and the Price for the Finished Product destined for such new country. The agreed additional packaging requirements and related packaging costs and Price shall be set out in a written amendment to this Agreement or otherwise recorded in a writing signed by the Parties.  
 2.11 API Reconciliation and Yield.  
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 2.11.1 Inventory Reports. Patheon shall promptly (and in any event no later than [\*\*\*] Business Days after Santarus’ request) provide an inventory status report to Santarus from time to time as reasonably requested by Santarus. In addition, Patheon shall monitor on a monthly basis the inventory of Bulk API held by Patheon and Patheon shall provide Santarus with a monthly inventory report (within [\*\*\*] Business Days following the last day of the applicable month) of the Bulk API held by Patheon, which shall contain the following information for such month:  
Quantity Received: The total quantity of Bulk API that complies with the Specifications and is received at the Facility during the applicable period.  
Quantity Dispensed: The total quantity of Bulk API dispensed is calculated by adding the Quantity Received to the inventory of Bulk API that complies with the Specifications and is held at the beginning of the applicable period, less the inventory of Bulk API that complies with the Specifications at the end of the applicable period.  
Quantity Converted: The total quantity of Bulk API contained within Finished Product batches released and shipped during the applicable period.  
 2.11.2 Quarterly Physical Inventory. In addition, Patheon shall reconcile the physical inventory of Bulk API and Finished Product held by Patheon on a quarterly basis to the quarter-end inventory status reports and shall provide a report to Santarus concerning such reconciliation within [\*\*\*] Business Days following the end of the applicable calendar quarter.  
 2.11.3 Annual Average Yield. In addition, within [\*\*\*] Business Days of the end of each calendar year, Patheon shall calculate the Annual Average Yield (AAY) for the Finished Product released and shipped during the calendar year and compare it to the target yield specified in Exhibit D for each of the following Finished Product sku’s, 20 mg 30’s, 40 mg 3’s, 40mg 5’s and 40mg 30’s (the “Target Yield”). The AAY shall be calculated by dividing the Quantity Converted by the Quantity Dispensed during the calendar year. Patheon shall strive to maintain AAY levels for each Finished Product above the applicable Target Yield. If the AAY falls more than [\*\*\*] percentage points ([\*\*\*]%) below the respective Target Yield in any calendar year, then Patheon shall reimburse Santarus for the cost of the shortfall within [\*\*\*] days of the end of each calendar year. The following calculation shall be used to determine reimbursement value, provided that Patheon’s liability for Bulk API calculated in accordance with this Section 2.11.3 in a year shall not exceed, in the aggregate, the Annual API Cap:  
[\*\*\*]  
It shall not constitute a material breach of this Agreement by Patheon if the AAY is less than the Target Yield.  
2.11.4 Other API Losses.  
(i) Patheon shall notify Santarus in writing in the event that an amount of [\*\*\*] kilograms or more of Bulk API is damaged, lost or otherwise rendered unusable at any one time (a “Significant API Loss”) as soon as practicable following such incident. In addition, and notwithstanding any provision in this Section 2.11 to  
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 the contrary, Patheon shall reimburse Santarus for such Bulk API at the API Reimbursement Value within [\*\*\*] days after discovery of the Significant API Loss. For clarity, amounts paid for Significant API Loss must be counted towards Annual API Cap, however for the purposes of calculating the Annual Average Yield under Section 2.11.3, all API reimbursed to Santarus pursuant to this Section shall be removed from the Quantity Received and Quantity Dispensed totals.  
(ii) Patheon shall notify Santarus in writing in the event that a batch of intermediate or Finished Product is potentially nonconforming as soon as practical, and in any event, within [\*\*\*] days following discovery thereof. Upon discovery of such potentially nonconforming product, Patheon shall initiate an investigation to reach a final determination. If the investigation results in a determination that such product is nonconforming, Patheon shall reimburse Santarus for the Bulk API in such product at the API Reimbursement Value within [\*\*\*] days of the determination. If there is a disagreement between the Parties as to whether product is nonconforming, the Parties shall follow the procedures outlined in Section 3.5.2 for submitting the product to an independent laboratory for final determination. Notwithstanding the foregoing, a final determination of whether product is nonconforming shall be made within [\*\*\*] days of discovering potentially nonconforming product and if a final determination is not made within such time period for reasons within Patheon’s control, Patheon shall immediately reimburse Santarus for any Bulk API in such potentially nonconforming product at the API Reimbursement Value.  
 2.12 Cooperation and [\*\*\*] Review. Each Party shall forthwith upon execution of this Agreement designate those of its employees to be part of the team responsible for managing the relationship between the parties (the “Relationship Team”). The Relationship Team from each Party shall meet in person or by telephone or video conference not less than [\*\*\*] to review the current status of the business relationship (including performance against the KPIs as well as any additional manufacturing performance indicators established by the Parties) and address any issues that have arisen.  
ARTICLE 3  
STANDARDS OF MANUFACTURE  
 3.1 Finished Product. Patheon hereby covenants that all Finished Product manufactured and supplied to Santarus under this Agreement: (a) shall have been manufactured, packaged, tested and stored in compliance with the Specifications, GMP, Applicable Laws and the terms and conditions of this Agreement and the Quality Agreement; (b) shall not be adulterated, or misbranded within the meaning of the FFDCA or other Applicable Laws as of the time that the Finished Product is transferred to the carrier at Patheon’s shipping point; and (c) will have been shipped to Santarus not later than [\*\*\*] days after the date of its manufacture (unless any delay in shipment beyond such [\*\*\*] day period is due solely to a delay by Santarus in conducting its review for the final release of the Finished Product). The foregoing obligations are referred to in this Agreement as the “Patheon Manufacturing Responsibilities.”  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
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 3.2 Manufacturing Facility. Patheon will manufacture Finished Product at the Facility. Patheon shall not manufacture any Finished Product in any other facility without first obtaining Santarus’ prior written consent, such consent not to be unreasonably withheld.  
 3.3 Testing and Release by Patheon. Patheon shall conduct chemical identity testing for all Bulk API received at the Facility within [\*\*\*] days of such receipt. Further, Patheon shall conduct full release testing of all Bulk API received at the Facility not later than [\*\*\*] months after the date of receipt in accordance with the procedures and using the analytical testing methodologies set forth in the Specifications and the Quality Agreement. Patheon shall promptly (and in any event within [\*\*\*] days following completion of the applicable testing) notify Santarus in writing of any failure of the Bulk API to conform to the Specifications for same, and any other problem it may identify with the Bulk API detected during the inspection and testing process. Prior to shipping (or temporarily storing, if requested by Santarus) any order, Patheon shall test each batch of Finished Product manufactured under this Agreement, and Raw Materials used for such batch, for conformity with the Specifications (“Patheon Release Testing”). Patheon shall conduct all such Patheon Release Testing in accordance with the procedures and using the analytical testing methodologies set forth in the Specifications and the Quality Agreement. Patheon shall retain sufficient quantities of all shipped Finished Product, Bulk API and Raw Materials to perform at least full duplicate quality control testing. Retained repository samples of all shipped Finished Product, Bulk API and Raw Materials shall be maintained in a suitable storage facility until one (1) year after expiry or such longer period as may be required by Applicable Laws. All such samples shall be available for inspection and testing by Santarus at reasonable intervals upon reasonable notice. Santarus shall be responsible, at all times, for the final release of the Finished Product, and Patheon shall not ship any Finished Product until Santarus has completed its final release. Patheon may arrange for subcontractors to perform specific testing services for Raw Materials arising under this Agreement without the consent of Santarus; provided that (a) Patheon shall notify Santarus in writing prior to utilizing any subcontractor (which original notice shall suffice for future similar uses of the same subcontractor); (b) all such subcontractors shall be duly qualified by Patheon under GMP and Applicable Laws to perform such testing; (c) Patheon shall at all times remain fully responsible to Santarus for the performance of all obligations hereunder related to such subcontracted testing services; and (d) no subcontractors shall be utilized in connection with release testing of the Finished Product.  
 3.4 Stability Studies. Patheon shall conduct stability studies on the Finished Products according to the Specifications therefor, as required by the FDA or Foreign Regulatory Authorities as advised by Santarus or as requested by Santarus, and in any case on at least one batch of Finished Product from the Facility at least once per calendar year following Commencement of Commercial Manufacturing or more frequently as may be specified in the Quality Agreement. Patheon shall provide to Santarus a report of all results and data obtained from such stability studies annually or more frequently as may be specified in the Quality Agreement.  
 3.5 Acceptance Procedures.  
 3.5.1 Finished Product Claims. Santarus has the right to reject any portion of any shipment of Finished Products that deviates from the Patheon Manufacturing  
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 Responsibilities, without invalidating any remainder of such shipment. Santarus or its agent shall visually inspect the Finished Products manufactured by Patheon upon receipt thereof and shall give Patheon written notice (a “Deficiency Notice”) of all claims for Finished Products that deviate from the Patheon Manufacturing Responsibilities within [\*\*\*] days after Santarus’ receipt thereof (or, in the case of any defects not reasonably susceptible to discovery upon receipt by visual inspection of the Finished Product, including those requiring laboratory analysis, within [\*\*\*] days after discovery thereof by Santarus, but in no event after the expiration date of the Finished Product). Should Santarus fail to provide Patheon with the Deficiency Notice within the applicable [\*\*\*]—day period, then the delivery shall be deemed to have been accepted by Santarus on the [\*\*\*] day after delivery or discovery, as applicable. Patheon shall have no liability under Section 3.5.3 for any deviations for which it has not received notice within the applicable [\*\*\*]-day period.  
 3.5.2 Determination of Deficiency. Upon receipt of a Deficiency Notice, Patheon shall have [\*\*\*] days to advise Santarus by notice in writing that it disagrees with the contents of such Deficiency Notice. If Santarus and Patheon fail to agree within [\*\*\*] days after the Santarus’ receipt of Patheon’s notice as to whether any Finished Products identified in the Deficiency Notice deviate from the Patheon Manufacturing Responsibilities, then the Parties shall mutually select an independent laboratory to evaluate if the Finished Products deviate from the Patheon Manufacturing Responsibilities. Such evaluation shall be binding on the Parties, and if such evaluation certifies that any Finished Products deviate from the Patheon Manufacturing Responsibilities, Santarus may reject those Finished Products in the manner contemplated in this Section 3.5. If such evaluation does not so certify in respect of any such Finished Products, then Santarus shall be deemed to have accepted delivery of such Finished Products on the [\*\*\*] day after delivery (or, in the case of any defects not reasonably susceptible to discovery upon receipt by visual inspection of the Finished Product, including those requiring laboratory analysis, on the [\*\*\*] day after discovery thereof by Santarus, but in no event after the expiration date of the Finished Product). The expenses of such testing shall be borne by Patheon if the non-conformity with the Patheon Manufacturing Responsibilities is confirmed, and otherwise by Santarus. The Parties mutually agree that they shall resolve all determinations of deficiencies as quickly as possible, and in any event, within [\*\*\*] days of a Deficiency Notice.  
 3.5.3 Patheon Responsibility. In the event Santarus rejects Finished Products in accordance with this Section 3.5 and the rejected Finished Product is determined not to conform to the Patheon Manufacturing Responsibilities, Patheon will credit Santarus’ account for Patheon’s invoice price to Santarus for such non-conforming Finished Products. If Santarus shall have previously paid for such defective Finished Products, Patheon shall promptly, at Santarus’ election, either: (i) refund the invoice price for such defective Finished Products; (ii) offset such amount against other amounts due to Patheon hereunder; or (iii) replace such Finished Products with conforming Finished Products as soon as reasonably possible without Santarus being liable for payment therefor under Section 6.3, contingent upon the receipt from Santarus of all API required for the manufacture of such replacement Finished Products. Further, Patheon shall reimburse Santarus for all reasonable shipping, handling and storage charges incurred in association with such non-conforming Finished Product and for the Bulk API utilized in such non-conforming Finished Product in accordance with Section 2.11.4. Nothing in this Section 3.5.3 shall be construed to limit the rights and remedies available to Santarus at law or in equity.  
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 3.6 Specification Amendments.  
 3.6.1 Cooperation. Subject to Section 3.6.4, the Parties shall cooperate with each other to amend or supplement the Specifications to the extent necessary to comply with changes in GMP, Applicable Laws or other requirements of Government Authorities. If an amendment to the Specifications requires FDA approval and/or the approval of a Foreign Regulatory Authority, Patheon shall not implement such change unless and until the necessary approval has been obtained by Santarus in writing. In no event shall Patheon implement any other modification or addition to the Specifications, including without limitation, changes in raw materials, equipment or methods of production or testing for the Finished Product, without the prior written consent of Santarus, which consent may be withheld for any or no reason.  
 3.6.2 Santarus’ Request for Change. Subject to Section 3.6.4, Santarus shall have the right to amend the Specifications from time to time.  
 3.6.3 Patheon’s Request for Change. Subject to Section 3.6.4, if Patheon wishes to make any change to the Specifications, Patheon shall notify Santarus, and such notice shall describe the proposed change and the impact of such change on the manufacturing process, including details of any changes in manufacturing costs. Santarus may accept or reject, in its sole and absolute discretion, any such change proposed by Patheon.  
 3.6.4 Price Adjustments. Amendments to the Specifications or the Quality Agreement requested by Santarus will only be implemented following a technical and cost review in good faith by Patheon and are subject to Santarus and Patheon reaching agreement as to revisions, if any, to the Price specified in Exhibit B necessitated by any such amendment. If Santarus accepts a proposed Price change, the proposed change in the Specifications shall be implemented, and the Price change shall become effective only with respect to those orders of Finished Products that are manufactured in accordance with the revised Specifications. In addition, Santarus agrees to reimburse Patheon for the cost of Raw Materials in accordance with, and under the circumstances described in, Section 7.3.  
 3.7 Records. Patheon shall maintain all records necessary to comply with all GMP and Applicable Laws relating to the manufacture, packaging, testing, storage and shipment of Finished Product. All such records shall be maintained for such period as may be required by Applicable Laws; provided, however, that all records relating to the manufacture, stability and quality control of each batch of Finished Product shall be retained until the Parties agree in writing to dispose of such records.  
 3.8 Audit. Upon reasonable prior notice and at reasonable intervals, Patheon shall allow Santarus and its representatives to inspect Patheon’s books and records relating to the manufacture of the Finished Product and permit Santarus to access Patheon’s facilities used to manufacture the Finished Product for the purposes of (a) making quality assurance audits of the facilities and of the procedures and processes used by Patheon in manufacturing, packaging, testing, storing and shipping Finished Product, and (b) confirming Patheon’s compliance with this Agreement, provided that a Patheon representative is present during any such inspection. Santarus, or its representative(s), shall conduct such audit during normal business hours at a time  
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 on which the Parties have mutually agreed, and in such a manner that does not unreasonably interfere with Patheon’s normal business activities.  
ARTICLE 4  
REGULATORY MATTERS AND QUALITY CONTROL  
 4.1 Compliance by Patheon. Patheon shall remain in compliance with all Applicable Laws, including GMP, at all times during the Term and, without limiting the generality of the foregoing, maintain a quality control program consistent with GMP as required by the FDA, and to the extent the parties have reached agreement pursuant to Section 2.10 with respect to countries in addition to the Territory, the applicable Foreign Regulatory Authorities.  
 4.2 Santarus’ Regulatory Responsibility. Santarus shall be responsible for obtaining and maintaining all regulatory filings and approvals (excluding the overall licensure and permitting of the Facility) for the manufacture and marketing of the Finished Product, including without limitation all INDA’s and NDA’s for the Finished Product. Santarus shall control and own all such filings and approvals. Patheon will supply to Santarus from time to time, all such data relating to the Finished Product, including release test results, complaint test results, all investigations (in manufacturing, testing and storage), and the like, that Santarus reasonably requires in order to complete any such filing or approval, including any annual product review report that Santarus is required to file with the FDA and as provided in the Quality Agreement. At Santarus’ request and subject to an additional fee to be agreed by the Parties, Patheon may prepare annual product review reports on behalf of Santarus and in accordance with Santarus’ instructions.  
 4.3 Manufacturing Process. If any process event occurs during the manufacturing of any Finished Product, which event is likely materially to affect the safety, efficacy or regulatory status of the Finished Product, then Patheon shall promptly notify Santarus. Further, Patheon shall fully and appropriately investigate and report to Santarus on all complaints and notices of quality issues concerning the Finished Products from the FDA, any Foreign Regulatory Authority or Government Authority of which Santarus shall have given Patheon notice. Santarus and Patheon shall consult with each other as to the disposition of all affected batches of such Finished Product. Patheon shall report to Santarus in writing any other atypical process event that is unlikely to materially affect the safety, efficacy or regulatory status of the Finished Product within a reasonable time after occurrence. No Bulk API or Finished Product may be reprocessed without the prior written consent of Santarus.  
 4.4 Communications. Each party may communicate with the FDA or any Foreign Regulatory Authority or Government Authority regarding the Finished Products if such communication is necessary to comply with the terms of this Agreement or the requirements of any Applicable Law, governmental order or regulation; provided, however, in the event such requirement applies to Patheon, Patheon shall notify Santarus in writing of the requirement and pending communication and, unless there is a legal prohibition against doing so, Patheon shall permit Santarus to accompany Patheon and take part in any communications with the FDA or any Foreign Regulatory Authority or Government Authority, and to receive copies of all such communications to and from the FDA or any Foreign Regulatory Authority or Government Authority.  
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 4.5 Government Inspection.  
 4.5.1 Patheon shall make its internal practices, books and records relating to its manufacture of the Finished Product available and allow access to all facilities used for manufacturing the Finished Product to the FDA, any Foreign Regulatory Authority and any other Government Authority having jurisdiction over the manufacture of the Finished Product for the purposes of determining Patheon’s compliance with GMP and Applicable Laws.  
 4.5.2 Patheon agrees to advise Santarus by telephone and facsimile immediately of any proposed or announced visit or inspection, and as soon as possible but in any case within [\*\*\*] hours after any unannounced visit or inspection, by the FDA, any Foreign Regulatory Authority or any other Government Authority relating to the Finished Product. Patheon shall provide Santarus with a reasonable description in writing of each such visit or inspection promptly (but in no event later than [\*\*\*] calendar days) thereafter, and with copies of any letters, reports or other documents (including form 483’s) issued by any such authorities that relate to the Finished Product. Santarus may review Patheon’s responses to any such reports and communications, and Santarus’ comments and suggestions shall, in Patheon’s reasonable discretion, be incorporated into such response.  
 4.5.3 If the FDA or any other Foreign Regulatory Authority or any other Government Authority conducts an inspection of the Facility in circumstances that are not related to the manufacturing of the Finished Product (as contemplated by subsection 4.5.2 above) and issues a 483 observation, inspection report or other formal or informal document in respect of such inspection which questions Patheon’s compliance with critical or major GMP standards relating to operations at the Facility which is otherwise could have an adverse impact on the Finished Product then Patheon shall notify Santarus promptly (but in no event later than [\*\*\*] calendar days) after Patheon receives a written copy of such observation, report or document.  
 4.5.4 Patheon shall keep Santarus informed of (i) the remediation plan Patheon adopts to alleviate any concerns raised by the FDA or any other Foreign Regulatory Authority contemplated by Sections 4.5.2 or 4.5.3, (ii) progress in implementing the remediation plan and (iii) the formal responses of the FDA or applicable Foreign Regulatory Authority to such remediation plan and its implementation.  
 4.6 Environmental and Other Laws and Regulations. In carrying out its obligations under this Agreement, Patheon shall comply with all applicable environmental and health and safety laws (current or as amended or added), and shall be solely responsible for determining how to comply with same in carrying out these obligations. Notwithstanding the foregoing, nothing provided to Patheon by Santarus, by way of materials, specifications, processing information or otherwise, is meant to diminish Patheon’s responsibility for such compliance. Patheon shall obtain and maintain all necessary licenses, permits and governmental approvals (except for product-related Regulatory Approvals such as NDA’s) required to perform its manufacturing and supply services hereunder, including licensure and permitting of its manufacturing facilities by the FDA and Foreign Regulatory Authorities. Patheon shall promptly notify Santarus of any circumstances, including the receipt of any notice, warning, citation, finding, report or service of process or the occurrence of any release, spill, upset, or discharge of  
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 hazardous substances (as may be defined under Applicable Laws) relating to Patheon’s compliance with this Section 4.6 and which relates to the manufacture of Finished Product. Santarus reserves the right to conduct an environmental inspection of the Facility, at reasonable intervals during normal business hours and with reasonable advance notice, for the purpose of determining compliance with this Section 4.6. Such inspection shall not relieve Patheon of its obligation to comply with all applicable environmental and health and safety laws and does not constitute a waiver of any right otherwise available to Santarus.  
 4.7 End-User Inquiries and Complaints. Subject to Patheon’s obligation to report certain information on a more expedited basis in respect of Adverse Experiences as described in Section 5.1 below, Patheon shall notify and refer to Santarus, within three (3) Business Days after receipt, all communications from end-users of the Finished Product, including without limitation, inquiries regarding the Finished Product and its uses, and complaints, comments and suggestions regarding the Finished Product and its effects on users. Santarus shall have the sole right to respond to all such communications and Patheon shall provide to Santarus reasonable cooperation and assistance in effecting such responses.  
ARTICLE 5  
ADVERSE EVENTS; RECALL  
 5.1 Adverse Experience Reporting. Patheon shall notify Santarus promptly and not later than [\*\*\*] hours after it becomes aware of (a) any information concerning any potentially serious or unexpected side effect, injury, toxicity or sensitivity reaction or any unexpected incidence or other adverse experience (an “Adverse Experience”) and the severity thereof associated with the use of the Finished Product, whether or not determined to be attributable to the Finished Product; or (b) any information regarding any pending or threatened action which may affect the safety or efficacy claims of the Finished Product or the continued marketing of the Finished Product in any nation or jurisdiction. Further and without limiting the foregoing, Patheon shall notify Santarus by telephone and facsimile within [\*\*\*] hours after Patheon first becomes aware of any serious Adverse Experience that gives cause for concern or is unexpected or that is fatal, life-threatening (as it occurred), permanently disabling, requires (or prolongs) inpatient hospitalization, represents a significant hazard, or is a cancer or a congenital anomaly or represents an overdose, or any other circumstance that might necessitate a recall, expedited notification of FDA or any other relevant Government Authorities or a significant change in the label of the Finished Product, including, without limitation, information concerning any incident that causes Finished Product shipped to Santarus or its labeling to be mistaken for or, applied to, another product, information concerning any bacteriological contamination, or any significant chemical, physical, or other change or deterioration in the Finished Product shipped to Santarus, or any failure of one or more batches of Finished Product shipped to Santarus to meet Specifications or to conform with Applicable Laws, and any deviation from the specified environmental conditions for shipping or storage of the Finished Product. To the extent that Santarus becomes aware of any Adverse Experience that appears to be related to the manufacture of Finished Product, Santarus shall notify Patheon promptly and not later than [\*\*\*] hours after Santarus becomes aware of such Adverse Experience. In connection with any such Adverse Experience, each Party shall make such reports as are necessary to comply with Applicable Laws, at its sole expense. Further, in the event a Party (or its Affiliates) receives a communication or directive from a Government Authority commencing or threatening seizure of Finished Product,  
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 or other removal from the market of Finished Product, such Party shall transmit such information to the other Party within [\*\*\*] hours of receipt.  
 5.2 Notification and Recall. The handling of recalls and withdrawals of Finished Products shall be within the sole discretion of Santarus, unless otherwise required by Applicable Laws. If any Government Authority issues or requests a recall or takes similar action in connection with Finished Product, or if Santarus determines that an event, incident or circumstance has occurred which may reasonably result in the need for a recall or market withdrawal (collectively, “Recalls”), Santarus shall, within [\*\*\*] hours, advise Patheon thereof by telephone or facsimile, after which the Parties shall promptly discuss and work together to effect an appropriate course of action. Notification to FDA (or such other Foreign Regulatory Authority or Government Authority) and conducting such Recall shall be the responsibility of Santarus. Patheon shall (a) cooperate fully with Santarus in the event of any such Recall, withdrawal and/or related disposition of any affected Finished Products in Patheon’s possession and (b) provide such assistance in connection therewith as Santarus may reasonably request.  
 5.3 Recall Expense. [\*\*\*]. Nothing in this Section 5.3 shall be construed to limit the rights and remedies available to Santarus at law or in equity.  
ARTICLE 6  
COMPENSATION; PAYMENT  
 6.1 Price of Finished Product. The Price includes all Raw Materials, manufacturing, packaging, testing and temporary storing costs associated with manufacturing and supplying the Finished Product, and includes the costs of such quality control measures as required by the Specifications and the Quality Agreement. The cost of the Bulk API shall form no part of the Price. The costs of shipping, handling, insurance and freight will be borne by Santarus and form no part of the Price.  
 6.2 Changes in Price of Finished Product. The Price during any period after the first anniversary of the Commencement of Commercial Manufacturing shall be determined in accordance with the following:  
 (a) Annual Review. On or about December 1st of each year Patheon and Santarus will meet (in person or by telephone or video conference) to consider whether any adjustment to the Price in respect of the Finished Products upward or downward is appropriate to account for increases or decreases in the cost of manufacture and/or the cost of Raw Materials. In considering whether a change in the Price is justified, the Parties may consider all published economic data, including without limitation, price indices that are demonstrated to have a rational connection to the cost of Raw Materials or Patheon’s cost of manufacturing the Finished Product.  
 (b) Extraordinary Changes in Raw Material Costs. If at any time market conditions result in Patheon’s cost of Raw Materials being materially greater than normal forecasted increases, then Patheon shall be entitled to request an adjustment to the Price to compensate it for such increased Raw Material costs. If at any time market conditions result in Patheon’s cost of Raw Materials being materially  
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 lesser than anticipated, then Santarus shall be entitled to request an adjustment to the Price to compensate it for such reduced Raw Material costs. For the purposes of this Section 6.2(b), changes materially greater than normal forecasted increases or materially lesser than anticipated shall be considered to have occurred if: (i) the cost of a Raw Material increases or decreases, as applicable, by [\*\*\*] or more of the cost for that Raw Material upon which the Price then in effect was based; or (ii) the aggregate cost for all Raw Materials required to manufacture the Finished Product increases or decreases, as applicable, by [\*\*\*] or more of the total Raw Material costs for the Finished Product upon which the Price then in effect was based. To the extent that the Price has been previously adjusted pursuant to this Section 6.2(b) to reflect an increase or decrease in the cost of one or more Raw Materials, the adjustments provided for in (i) and (ii) above shall operate based on the costs attributed to such Raw Material (or Raw Materials) at the time the last such adjustments were made.  
 In connection with a Price review pursuant to clause (a) of this Section 6.2, Patheon shall deliver to Santarus reasonably detailed documentation concerning increases or decreases in the cost of Raw Materials or Patheon’s cost of manufacturing to facilitate the discussion. In connection with all fee adjustment requests pursuant to clause (b) of this Section 6.2, Patheon shall deliver to Santarus a revised Exhibit B and such budgetary pricing information or other documentation reasonably sufficient to demonstrate that a Price adjustment is justified, provided that Patheon shall have no obligation to provide any supporting documents to the extent such documents are subject to obligations of confidentiality between Patheon and its suppliers. Each of Santarus and Patheon shall forthwith use all reasonable efforts to agree on a revised Price in respect of each affected Finished Product. In the event the Parties are unable to reach agreement concerning adjustments to the Price, such dispute shall be resolved in accordance with Article 13. Until such time as dispute is resolved the price per Finished Product shall be the most current mutually agreed upon Price adjusted by an amount equal to the actual increase in that portion of the Price that relates to Patheon’s labour costs as reasonably demonstrated by Patheon; provided, however, that following resolution of any dispute regarding Price, the Price agreed upon as part of the dispute resolution shall be applied retroactively for any applicable periods.  
 6.3 Payment Terms. Santarus shall pay Patheon for the Finished Product shipped to Santarus within [\*\*\*] days of the date of the invoices issued pursuant to Section 2.6. Patheon shall send all invoices by email or facsimile to the email address or facsimile number of the accounts payable personnel designated by Santarus from time to time. All invoices shall be dated as of the date of the email or facsimile as noted in the foregoing sentence, and not any earlier date. Patheon’s invoice shall reference the Firm Purchase Order number and be sent to the “Xxxx to” address of Santarus specified on the Firm Purchase Order, and Patheon’s packing list must reference the Firm Purchase Order number and be sent to the applicable “Ship to” address on the Firm Purchase Order. Santarus may withhold a portion of any invoice that it disputes in good faith pending resolution of such dispute.  
 6.4 Form of Payment. Each Party shall make all payments due the other Party under this Agreement in U.S. Dollars by check made payable to the order of the other Party or by wire transfer of immediately available funds to such account notified by the receiving Party from time to time to the other Party in writing.  
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 6.5 Taxes. If any sales or value added taxes are payable under the laws of the United States of America, Canada, or any other country, state, territory or jurisdiction having taxing authority, such taxes shall be the responsibility of Santarus. Santarus shall withhold from any payment to Patheon under this Agreement any taxes required to be withheld by Santarus under the applicable laws of the United States of America, Canada or any other country, state, territory or jurisdiction. Upon request, Santarus shall provide Patheon with authority for the withholding obligation, documentation of such withholding and payment in a manner that is satisfactory for purposes of such taxing authority. Any withholdings paid when due hereunder shall be for the account of Patheon.  
 6.6 Disputed Invoices. In the event that Santarus disputes any amounts under any invoice for Finished Product supplied by Patheon, such dispute shall be resolved in accordance with Section 3.5 (with respect to non-conformance of Finished Product) or otherwise under Article 13. Pending resolution of such dispute, Santarus shall be obligated to pay any amounts under such invoice that are not in dispute. Upon resolution of any such dispute in favor of Patheon, Santarus shall pay all remaining amounts owing under such invoice within the later of [\*\*\*] Business Days after such resolution or [\*\*\*] days after the date of such invoice.  
ARTICLE 7  
RAW MATERIALS  
 7.1 Purchase of Raw Materials. Except for the Bulk API which will be supplied to Patheon by Santarus, Patheon shall purchase all packaging components (including labels, product inserts and other labeling for the Finished Product), raw materials and other ingredients for the manufacture of the Finished Product (collectively, “Raw Materials”).  
 7.2 Storage of Bulk API and Raw Materials. Patheon shall store the Bulk API and Raw Materials at Patheon’s storage facility at the Facility with due care and attention to the requirements set forth in the Specifications and in accordance with GMP and Applicable Laws so as to protect such materials from loss or damage. While the Bulk API and the Raw Materials are in storage, Patheon shall assume the risk of loss or damage to such materials from any cause whatsoever. Patheon shall ensure that, while such Bulk API and Raw Materials are in storage, such materials do not become subject to any lien or other security interest securing any obligation owed or alleged to be owed by Patheon to any person or entity.  
 7.3 Responsibility for Cost of Raw Materials.  
 7.3.1 Patheon understands and acknowledges that Santarus has engaged Patheon, in its capacity as a contract manufacturer, to be responsible for purchasing and maintaining adequate and reasonable inventories of Raw Materials to satisfy Firm Purchase Orders. Santarus understands and acknowledges that Patheon will rely solely on Firm Purchase Orders submitted pursuant to Section 2.2.3 in ordering the Raw Materials required to meet such Firm Purchase Orders and agrees that Patheon may make such other purchases of Raw Materials to meet production requirements during such longer periods as may be agreed to in writing from time to time by Santarus at the request of Patheon or Santarus. For clarity, prior to making any purchases of Raw Materials based on Firm Purchase Orders provided by Santarus pursuant to Section 2.2.3, Patheon shall reconcile the forecasted Firm Purchase Order requirements against  
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 existing inventories of Raw Materials. Santarus’ liability for the costs of Raw Materials ordered pursuant to the terms of this Section shall [\*\*\*]. For clarity, while Patheon shall purchase Raw Materials in quantities only to satisfy the requirements of a Firm Purchase Order, there will be, in some cases, minimum order quantities stipulated by a vendor that will result in an excess quantity of certain Raw Materials after the completion of a manufacturing campaign. In such cases, Patheon shall attempt to utilize such excess quantities, subject to the provisions of Section 7.3.2 below, for subsequent Firm Purchase Orders. However, if the excess materials are not consumed within [\*\*\*] months of the date of purchase, Santarus shall reimburse Patheon for it’s cost of such excess materials within [\*\*\*] days of the date of an invoice for said quantity, in accordance with the provisions of Section 7.3.6 and Exhibit E.  
 7.3.2 Subject to Patheon’s obligations set forth in Section 7.3.3, Santarus shall reimburse Patheon for Raw Materials, including Patheon’s out of pocket expenses actually incurred in connection therewith, to the extent that: (a) the Raw Materials are no longer usuable in the manufacturing process due to (i) a change in the Specifications pursuant to Section 3.6, or (ii) a change in label copy or artwork; (b) the Raw Materials have not been utilized to fulfill Firm Purchase Orders issued by Santarus within [\*\*\*] months following the date of purchase of the Raw Materials (collectively, the “Obsolete/Excess Raw Materials”). Notwithstanding the foregoing, Obsolete/Excess Raw Materials shall not include any Raw Materials purchased by Patheon in excess of the Firm Purchase Order to which they relate, unless otherwise mutually agreed by the parties in a signed writing. In no event shall Santarus be liable (y) for Raw Materials purchased prior to January 1, 2006, or (z) to third-party suppliers of Raw Materials purchased by Patheon hereunder.  
 7.3.3 Before requesting reimbursement from Santarus pursuant to Section 7.3.2, Patheon shall first use its commercially reasonable efforts to cover the cost of Obsolete/Excess Raw Materials by: (a) returning such Raw Materials to the vendor, (b) utilizing such Raw Materials in manufacturing products for its other customers to the extent possible, and (c) implementing other reasonable measures to mitigate the loss due to such excess Raw Materials. To the extent that Patheon is unable to off-set such loss fully, Santarus shall reimburse Patheon in accordance with Section 7.3.1 and 7.3.2.  
 7.3.4 In the event such Raw Materials are incorporated into Finished Products subsequently purchased by Santarus or into third party products manufactured by Patheon and subsequently purchased by a third party, Santarus will receive credit for any costs of such Raw Materials previously paid to Patheon by Santarus pursuant to Section 7.3.2 as follows: (a) at the time of invoice if Raw Materials are incorporated into Finished Product or (b) within thirty (30) days if Raw Materials are incorporated into third party products.  
 7.3.5 In the event Raw Materials expire or become obsolete or are otherwise no longer useable in the manufacturing process for the Finished Product because (a) Patheon failed to manufacture and supply the quantities ordered by Santarus pursuant to a Firm Purchase Order, (b) quantities of such Raw Materials are in excess of the limits of Santarus’ liability set forth in Section 7.3.2, or (c) Patheon failed to store Raw Materials as required by the applicable Specifications or under Section 7.2, then Patheon shall bear all responsibility for the cost of such Raw Materials.  
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 7.3.6 Attached as Exhibit E is a Raw Material Purchasing Summary setting out Patheon’s purchasing plan for Raw Materials, based on Firm Purchase Orders, on an agreed manufacturing campaign (of lots per campaign), and including any vendor stipulated minimum order quantity for each material. Exhibit E indicates the maximum financial exposure Santarus shall have at any one time for Raw Materials under this Agreement at the conclusion of each manufacturing campaign. Exhibit E shall be updated prior to the commencement of each Year of this Agreement, starting in 2008.  
 7.4 Disposal of Raw Materials. Patheon may dispose of Raw Materials upon Santarus prior written approval and Santarus shall reimburse Patheon for the cost of disposal of such Raw Materials which (a) Patheon purchased subsequent to January 1, 2006, and (b) meet the requirements of Section 7.3 above.  
ARTICLE 8  
CONFIDENTIALITY  
 8.1 Confidentiality; Exceptions. The Parties agree that, for the Term and for ten (10) years thereafter (other than for trade secrets, for which the confidentiality obligations set forth herein shall last as long as trade secret law shall allow), all non-public, proprietary or “confidential” disclosures, know-how, data, and technical, financial and other information of any nature whatsoever (collectively, “Confidential Information”), disclosed or submitted, either orally or in writing (including, without limitation, by electronic means) or through observation, by one Party (the “Disclosing Party”) to the other Party (the “Receiving Party”) hereunder, including, without limitation, the terms of this Agreement, shall be received and maintained by the Receiving Party in strict confidence, shall not be used for any purpose other than the purposes expressly contemplated by this Agreement, and shall not be disclosed to any Third Party (including, without limitation, in connection with any publications, presentations or other disclosures). Notwithstanding the foregoing, (a) Santarus may disclose on a need-to-know basis the existence of this Agreement and the terms hereof to any bona fide potential acquirers, corporate partners, investors or financial advisors; (b) Patheon may disclose on a need-to-know basis the existence of this Agreement and the terms hereof to its financial advisors; and (c) Patheon may disclose the fact that Santarus is a client of Patheon but shall not disclose any other information relating to any product for which Patheon provides services to Santarus. The Receiving Party will promptly notify the Disclosing Party upon discovery of any unauthorized use or disclosure of the Disclosing Party’s Confidential Information. Confidential Information belongs to and shall remain the property of the Disclosing Party.  
 8.2 Exceptions. The provisions of this Article 8 shall not apply to any information of the Disclosing Party which can be shown by competent evidence by the Receiving Party:  
 8.2.1 To have been known to or in the possession of the Receiving Party prior to the date of its actual receipt from the Disclosing Party;  
 8.2.2 To be or to have become readily available to the public other than through any act or omission of any Party in breach of any confidentiality obligations owed to the Disclosing Party;  
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 8.2.3 To have been disclosed to the Receiving Party, other than under an obligation of confidentiality, by a Third Party which had no obligation to the Disclosing Party not to disclose such information to others; or  
 8.2.4 To have been subsequently independently developed by the Receiving Party without use of or reference or access to the Disclosing Party’s Confidential Information.  
 8.3 Authorized Disclosure. The Receiving Party may disclose the Disclosing Party’s Confidential Information hereunder solely to the extent (a) approved by the Disclosing Party; or (b) the Receiving Party is legally required to disclose such Confidential Information, provided, however, that prior to any such required disclosure, the Receiving Party will, except where impracticable, give reasonable advance notice to the Disclosing Party of such disclosure (so that the Disclosing Party may seek a protective order and or other appropriate remedy or waive compliance with the confidentiality provisions of this Article) and will use its reasonable efforts to secure confidential treatment of such Confidential Information required to be disclosed.  
 8.4 Return of Confidential Information. The Receiving Party shall keep the Disclosing Party’s Confidential Information in appropriately secure locations. Upon the expiration or termination of this Agreement or at any time upon the Disclosing Party’s request, the Receiving Party shall destroy or return to the Disclosing Party, at the Disclosing Party’s written request, all Confidential Information belonging to the Disclosing Party possessed by the Receiving Party, or its officers, directors, employees, agents and consultants; provided however that a Receiving Party may retain one (1) copy of the Disclosing Party’s Confidential Information in an appropriately secure location, which by Applicable Laws it must retain, for so long as such Applicable Laws require such retention but thereafter shall dispose of such retained Confidential Information in accordance with Applicable Laws or this Section 8.4.  
 8.5 Equitable Relief. The Receiving Party agrees that, due to the unique nature of the Confidential Information, the unauthorized disclosure or use of the Confidential Information of the Disclosing Party may cause irreparable harm and significant injury to the Disclosing Party, the extent of which may be difficult to ascertain and for which there may be no adequate remedy at law. Accordingly, the Receiving Party agrees that the Disclosing Party, in addition to any other available remedies, shall have the right to seek an immediate injunction and other equitable relief enjoining any breach or threatened breach of this Agreement. The Receiving Party shall notify the Disclosing Party in writing immediately upon the Receiving Party’s becoming aware of any such breach or threatened breach.  
ARTICLE 9  
INTELLECTUAL PROPERTY MATTERS  
9.1 Ownership of Intellectual Property.  
 Patheon agrees that Santarus shall own all right, title and interest in and to all Inventions, and any intellectual property rights (including patent rights and trade secret rights) therein, covering: (a) Santarus’ SAN-05 immediate release omeprazole pharmaceutical product, the Specifications therefor and the uses thereof; and (b) any composition of matter, method of manufacture or use covered by the Product Patents, regardless of whether such Invention was  
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 conceived, reduced to practice or created solely by employees or agents of Patheon or its Affiliates or jointly by the employees or agents of Santarus or its Affiliates with the employees or agents of Patheon or its Affiliates (collectively, the “Product Inventions”). As to all Inventions other than Product Inventions, including without limitation, those Inventions relating to manufacturing process innovations that are generally applicable to the manufacture of drug compounds and not solely to the manufacture of the Finished Product (collectively, the “Other Inventions”), the parties agree that the following shall apply:  
 (i) All Other Inventions, which are conceived, reduced to practice, or created solely by employees or agents of Patheon or its Affiliates in the course of performing the services under this Agreement (including any pre-existing technology of Patheon which Patheon so employs), shall be owned by Patheon. Patheon shall and hereby does grant to Santarus and its Affiliates a perpetual, royalty-free, exclusive, worldwide, irrevocable license, to use and practice all such Patheon-owned Other Inventions (which are used by Patheon hereunder to supply Finished Products to Santarus) to manufacture and have manufactured the Finished Products and to use, import, offer to sell, and sell the same, with full right to sublicense to any Third Party in connection with the manufacture, sale or distribution of the Finished Product.  
 (ii) All Other Inventions which are conceived, reduced to practice, or created by employees or agents of Santarus or its Affiliates (including any pre-existing technology of Santarus which Santarus shares with Patheon hereunder), shall be owned by Santarus. Santarus shall and hereby does grant to Patheon and its Affiliates a royalty-free, non-exclusive license during the Term, without the right to sublicense, to use and practice all such Santarus-owned Other Inventions solely to manufacture the Finished Products hereunder.  
 (iii) All Other Inventions which are conceived, reduced to practice, or created jointly by: (i) employees or agents of Santarus or its Affiliates; and by (ii) employees or agents of Patheon or its Affiliates, pursuant to this Agreement, shall be owned by Santarus, unless the parties have agreed in writing to a different arrangement in another consulting or services agreement which is more specific to the services provided by Patheon in connection with such Other Invention. Santarus shall and hereby does grant to Patheon and its Affiliates a perpetual, royalty-free, non-exclusive, worldwide, irrevocable license to use and practice all such Santarus-owned Other Inventions, with the right to sublicense to any Third Party.  
 9.2 Assignment. Each Party agrees to disclose promptly in writing to the other all Product Inventions and Other Inventions to be owned by the other pursuant to Section 9.1 and hereby irrevocably transfers, conveys and assigns, and agrees to transfer, convey and assign, to the other, its successors and assigns, without reservation or additional consideration, all of its right, title and interest (anywhere in the world) in, to, and under the Product Inventions and Other Inventions, whether currently existing or created or developed later, including, without limitation, all copyrights, trademarks, trade secrets, patent rights, industrial rights and all other intellectual property and proprietary rights related thereto, including all rights to protect, enforce (whether for past, present or future infringement), defend and exploit such Product Inventions and Other  
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 Inventions and collect and retain all proceeds therefrom, effective immediately upon the inception, conception, creation or development thereof.  
 9.3 Assistance. Each Party shall have the first right to file and prosecute patent applications in respect of those Inventions it is to own pursuant to Section 9.1 and such Party shall be solely responsible for the costs of filing, prosecution and maintenance of such patents and patent applications. Each Party agrees to cooperate with the other or its designee(s), both during and after the Term, in applying for, obtaining, perfecting, evidencing, sustaining and enforcing the other’s right, title and interest in and to the Product Inventions and Other Inventions, including, without limitation, executing such written instruments as may be prepared by the other and doing such other acts as may be necessary in the opinion of the other to obtain a patent, register a copyright, or otherwise enforce the other’s rights in such Product Inventions and Other Inventions (and each Party hereby irrevocably appoints the other and any of its officers and agents as its attorney in fact to act for and on the other’s behalf and instead of it, with the same legal force and effect as if executed by it). Each Party hereby represents, warrants, and covenants that all employees, consultants and agents performing services for it hereunder have assigned in writing all of their right, title and interest in, to and under any and all Product Inventions and Other Inventions to such Party. All Product Inventions and Other Inventions and embodiments thereof shall be deemed to be Confidential Information of the Party to own such Invention pursuant to Section 9.1, and the other Party shall be subject to the obligations of nonuse and nondisclosure under Article 8 with respect thereto.  
ARTICLE 10  
REPRESENTATIONS, WARRANTIES AND COVENANTS  
 10.1 Representations and Warranties of the Parties. Each Party represents, warrants and covenants to the other Party that:  
 10.1.1 such Party is duly organized and validly existing and in good standing under the laws of the jurisdiction of its formation;  
 10.1.2 such Party has the full corporate power and is duly authorized to enter into, execute and deliver this Agreement, and to carry out and otherwise perform its obligations thereunder;  
 10.1.3 this Agreement has been duly executed and delivered by, and is a legal and valid obligation binding upon such Party and the entry into, the execution and delivery of, and the carrying out and other performance of its obligations under this Agreement by such Party (a) does not conflict with, or contravene or constitute any default under, any agreement, instrument or understanding, oral or written, to which it is a party, including, without limitation, its certificate of incorporation or by-laws, and (b) does not violate Applicable Law or any judgment, injunction, order or decree of any Government Authority having jurisdiction over it; and  
 10.1.4 in connection with its performance under this Agreement, it shall comply with all Applicable Laws.  
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 10.2 Additional Representations, Warranties and Covenants of Patheon. In addition to representations and warranties set forth elsewhere in this Agreement, Patheon further represents, warrants to, and covenants with, Santarus that:  
 10.2.1 At all times during the Term, all parts of the Facility that are directly associated with the testing and storage of the Bulk API and Raw Materials and the manufacturing, packaging, testing and storage of the Finished Products shall remain in compliance with all Applicable Laws, and all other parts of the Facility shall remain, in all material respects, in compliance with all Applicable Laws.  
 10.2.2 Patheon shall obtain and maintain all necessary licenses, permits or approvals required by Applicable Laws in connection with the manufacture, packaging, testing and storage of the Finished Product, including, without limitation, permits related to manufacturing facilities;  
 10.2.3 Patheon’s manufacturing facilities are in compliance with GMP;  
 10.2.4 Patheon has disclosed to Santarus any and all form 483’s, warning letters or similar notices relating to its Facility and import alerts for any other products manufactured in such Facility issued during the last five (5) years;  
 10.2.5 Title to all the Finished Product sold hereunder, upon payment thereof by Santarus as provided herein, shall pass to Santarus free and clear of any security interest, lien or other encumbrance;  
 10.2.6 Throughout the Term, Patheon has, and shall maintain, sufficient facilities, resources, and a work force suitably qualified and trained to meet its obligations to supply the Finished Product to Santarus pursuant to this Agreement;  
 10.2.7 The contributions of Patheon to the manufacture of the Finished Product in accordance with this Agreement do not infringe any Third Party rights (including, without limitation, any intellectual property rights) anywhere in the world; provided, however, that Patheon does not warrant against infringement attributable to the API or Raw Materials or Finished Product which, when used together with Patheon’s manufacturing processes, results in a claim for infringement;  
 10.2.8 Patheon is not aware of any pending or threatened claims against Patheon asserting that any of the activities of Patheon relating to the manufacture, import, use, or sale of pharmaceutical products, or the conduct of the activities contemplated herein by Santarus, infringe, misappropriate, or violate the rights of any Third Party; and  
 10.2.9 All employees, consultants, subcontractors and agents performing services for Patheon hereunder have assigned in writing to Patheon all of their right, title and interest in, to and under any and all Product Inventions and Other Inventions.  
 10.3 Additional Representations, Warranties and Covenants of Santarus. In addition to the representations and warranties set forth elsewhere in this Agreement, Santarus further represents, warrants to and covenants with, Patheon that:  
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 10.3.1 The Specifications for each of the Finished Products are its or its Affiliate’s property and that Santarus may lawfully disclose the Specifications to Patheon;  
 10.3.2 Santarus is not aware of any actions or other legal proceedings against Santarus, the subject of which is the infringement of Third Party rights related to any of the Specifications, or any of the API and the Raw Materials, or the sale, use or other disposition of any Finished Product made in accordance with the Specifications; and  
 10.3.3 On or before the commercial launch of the Finished Product in the Territory, the Specifications shall have been approved by all applicable Government Authorities.  
 10.4 Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THIS AGREEMENT, THE PARTIES MAKE NO REPRESENTATIONS OR WARRANTIES OF ANY KIND WHATSOEVER, EITHER EXPRESS OR IMPLIED, WRITTEN OR ORAL, INCLUDING, WITHOUT LIMITATION, ANY IMPLIED WARRANTY OF MERCHANTABILITY, WARRANTY OF FITNESS FOR A PARTICULAR PURPOSE, OR WARRANTY OF NON-INFRINGEMENT.  
ARTICLE 11  
TERM AND TERMINATION  
 11.1 Term. This Agreement shall commence as of the Effective Date and shall continue in full force until August 19, 2009, unless earlier terminated in accordance with the terms and conditions of this Article 11 (the “Initial Term”). After the Initial Term, this Agreement shall continue in force for an indefinite duration (the “Renewal Term”); provided that either Party may terminate this Agreement at any time during the Renewal Term beginning on August 19, 2009, by providing the other Party with eighteen (18) months prior written notice of termination.  
 11.2 Termination for Cause. In the event that either party has failed to remedy a material breach of any of its representations, warranties or other obligations under this Agreement within ninety (90) days (the “Remediation Period”) following receipt of a written notice thereof (the “Breach Notice”) from the other party that expressly states that it is a notice under this Section 11.2, the non-breaching party may terminate this Agreement upon written notice to the other party (the “Termination Notice”). The Termination Notice may provide for a termination date that is as of any date within eighteen (18) months following the date of the Termination Notice. If the non-breaching party does not provide a Termination Notice within one hundred eighty (180) days after the receipt of the Breach Notice by the breaching party, then the non-breaching party shall be deemed to have waived its right to terminate the Agreement for such breach (but shall not have waived any other rights that may have accrued as a result of such breach). For the avoidance of doubt, a material breach of the Quality Agreement or the Capital Agreement shall be deemed to be a breach of this Agreement for the purpose of determining the rights of the Parties to terminate this Agreement.  
 11.3 Termination for Bankruptcy. Either Party may terminate this Agreement immediately if the other Party becomes insolvent, makes a general assignment for the benefit of creditors, suffers or permits the appointment of a receiver for its business or assets, avails itself of  
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 or becomes subject to any petition or proceeding under any statute of any state or country relating to insolvency or the protection of the rights of creditors.  
 11.4 Regulatory Proceedings. Santarus may terminate this Agreement effective immediately upon written notice to Patheon should the FDA or a Foreign Regulatory Authority having jurisdiction impose on the Facility an import ban in respect of the Finished Product or withdraw any license required by Patheon to manufacture the Finished Product at the Facility or take other action that is reasonably likely to have a material adverse impact on Patheon’s ability to perform hereunder.  
 11.5 Government Action. Santarus may terminate this Agreement upon thirty (30) days’ written notice to Patheon in the event that any governmental agency (including without limitation, the FDA or a Foreign Regulatory Authority) takes any action, or raises any objection, that prevents Santarus from importing, exporting, purchasing, or selling the Finished Product or otherwise makes such activity unlawful.  
 11.6 Termination for Discontinuation. Santarus may terminate this Agreement if at any time it decides to no longer market the Finished Product by giving Patheon six (6) months advance written notice of termination.  
 11.7 Effect of Termination. Except as otherwise provided in this Section 11.7 or elsewhere in this Agreement, in the event this Agreement is terminated for any reason, (a) subject to Section 11.8, all rights and obligations of the Parties under this Agreement shall terminate; (b) Santarus shall surrender to Patheon, or, at Patheon’s sole option and expense, Santarus shall destroy and provide Patheon with a certificate signed by a Responsible Executive of Santarus attesting to the destruction of, all copies of any Confidential Information of Patheon in its possession (excluding all of the foregoing assigned to Santarus under Article 9 above); (c) Patheon shall surrender to Santarus, or, at Santarus’ sole option and expense, Patheon shall destroy and provide Santarus with a certificate signed by a Responsible Executive of Patheon attesting to the destruction of, all copies of any Confidential Information provided by Santarus hereunder (except to the extent required to be maintained by Patheon pursuant to Applicable Laws or this Agreement); (d) Santarus shall pay for any Finished Product manufactured at any time before the date of termination pursuant to any Firm Purchase Order delivered to Patheon prior to such termination, and (e) Patheon shall return to Santarus all unused API (with shipping and related expenses, if any, to be borne by Santarus). Further, in the event of termination by Patheon pursuant to Section 11.2 or pursuant to Section 11.3, or in the event of termination by Santarus pursuant to Sections 11.4, 11.5 or 11.6, Santarus shall reimburse Patheon for: (x) Raw Materials applicable to the Finished Product, at Patheon’s cost (including all costs incurred by Patheon in connection with the purchase and handling of such Raw Materials), which were ordered, purchased, produced or maintained by Patheon in contemplation of filling Firm Purchase Orders prior to notice of termination being given in accordance with the provisions of Article 7, in particular Section 7.3.1.; and (y) satisfaction of the purchase price payable pursuant to Patheon’s orders with suppliers of Raw Materials, provided such orders were made by Patheon in reliance on Firm Purchase Orders; but in each case subject to Patheon’s obligation to cover as set forth in Section 7.3.3 and subject to the limitations on Santarus’ liability set forth in Section 7.3.2. Patheon shall cooperate with Santarus and assist in the transfer to Santarus of all legal and technical documents concerning API and Finished Products, including master batch records,  
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 validation reports, stability reports and relevant manufacturer authorizations, existing retention samples and all such other documents and materials as may be reasonably necessary or useful for Santarus to source Finished Products from other qualified Third Parties.  
 11.8 Accrued Rights. Termination, relinquishment, or expiration of this Agreement for any reason shall be without prejudice to any right which shall have accrued to the benefit of either Party prior to such termination, relinquishment, or expiration. Such termination, relinquishment or expiration shall not relieve either Party from obligations which are expressly indicated to survive termination or expiration of this Agreement. The provisions of this Article shall not limit or restrict the rights of any Party to seek remedies or take measures that may be otherwise available to it at law or equity in connection with the enforcement and performance of obligations under this Agreement. Any provision of this Agreement intended by their specific terms or by necessary implication to survive the expiration or termination of this Agreement, including without limitation, Articles, 8, 9, 12 and 13, shall so survive.  
ARTICLE 12  
INDEMNIFICATION; INSURANCE; LIMITATION OF LIABILITY  
 12.1 Indemnification by Santarus. Santarus hereby agrees to defend, at its expense, indemnify, and hold harmless Patheon, its directors, officers, employees, agents, and Affiliates, against all Third Party claims, demands, damages, liabilities, losses, costs and expenses, including, without limitation, attorney’s fees (collectively, “Claims”) resulting from or arising out of: (a) the negligence or willful misconduct of Santarus, its Affiliates, or their directors, officers, agents, employees or consultants in the performance of their obligations under this Agreement; (b) a material breach by Santarus of any provision of this Agreement, the Quality Agreement or the Capital Agreement; or (c) a breach by Santarus of any of its representations or warranties set forth in this Agreement, the Quality Agreement or the Capital Agreement; provided, however, that Santarus shall not be obligated to indemnify Patheon under this Section 12.1 to the extent that such Claim results from or arises out of any act or omission for which Patheon is obligated to indemnify Santarus pursuant to Section 12.3 below.  
 12.2 Further Indemnification by Santarus. Further, Santarus hereby agrees to defend, at its expense, indemnify and hold harmless Patheon, its directors, officers, employees, agents and Affiliates against all Third Party Claims resulting from or arising out of actions or proceedings where the claimant has alleged that:  
 (a) the use by Patheon, in connection with its performance under this Agreement, of the Specifications infringes any Invention or any other intellectual property rights (including patent rights or trade secret rights) of any Third Party;  
 (b) the provision of the services by Patheon in respect to the Finished Product pursuant to this Agreement, or use or disposition of any Finished Product by Patheon as required to perform its obligations under this Agreement infringes any Invention or any other intellectual property rights (including patent rights or trade secret rights) of any Third Party;  
 (c) the sale or distribution by Santarus in any country of Finished Product violates any law in such country;  
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 (d) the Finished Product marketed in any given country by Santarus is not suitable for the indication for which it has been approved in such country or is unsafe for human use; or  
 (e) the Finished Product contains a defect in the API that was not reasonably discoverable by Patheon utilizing the test methods set forth in the Specifications,  
provided, however, that Santarus shall not be obligated to indemnify Patheon under this Section 12.2 to the extent such claim resulted from or arose out of any act or omission for which Patheon is obligated to indemnify Santarus pursuant to Section 12.3 below.  
 12.3 Indemnification by Patheon. Patheon hereby agrees to defend, at its expense, indemnify, and hold harmless Santarus, its directors, officers, employees, agents, and Affiliates against all Third Party Claims resulting from or arising out of (a) the failure to manufacture, package and test the Finished Product in accordance with the Specifications, GMP, Applicable Laws and the Patheon Manufacturing Responsibilities; (b) the failure to store the Finished Product, Bulk API or Raw Materials in accordance with the Specifications, GMP and Applicable Laws; (c) the negligence or willful misconduct of Patheon, its Affiliates, or their directors, officers, agents, employees or consultants in the performance of their obligations under this Agreement, (d) a material breach by Patheon of any provision of this Agreement, the Quality Agreement or the Capital Agreement; or (e) a breach of any of Patheon’s representations, warranties, or covenants set forth in this Agreement, the Quality Agreement or the Capital Agreement; provided, however, that Patheon shall not be obligated to indemnify Santarus under this Section 12.3 to the extent that such Claim results from or arises out of any act or omission for which Santarus is obligated to indemnify Patheon pursuant to Sections 12.1or 12.2 above.  
 12.4 Indemnification Procedure. Each indemnified Party (the “Indemnitee”) agrees to give the indemnifying Party (the “Indemnitor”) prompt written notice of any Claims or discovery of fact upon which the Indemnitee intends to base a request for indemnification. Notwithstanding the foregoing, the failure to give timely notice to the Indemnitor shall not release the Indemnitor from any liability to the Indemnitee to the extent the Indemnitor is not materially prejudiced thereby.  
 12.4.1 The Indemnitee shall furnish promptly to the Indemnitor copies of all papers and official documents in the Indemnitee’s possession or control which relate to any Claims; provided, however, that if the Indemnitee defends or participates in the defense of any Claims, then the Indemnitor shall also provide such papers and documents to the Indemnitee. The Indemnitee shall reasonably cooperate with the Indemnitor in defending against any Claims.  
 12.4.2 The Indemnitor shall have the right, by prompt written notice to the Indemnitee, to assume direction and control of the defense of any Claim, with counsel reasonably satisfactory to the Indemnitee and at the sole cost of the Indemnitor, so long as (a) the Indemnitor shall promptly notify the Indemnitee in writing (but in no event more than thirty (30) days after the Indemnitor’s receipt of notice of the Claim) that the Indemnitor intends to indemnify the Indemnitee pursuant to this Article absent the development of facts that give the Indemnitor the right to claim indemnification from the Indemnitee, and (b) the Indemnitor diligently pursues the defense of the Claim.  
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 12.4.3 If the Indemnitor assumes the defense of the Claim as provided in this Section 12.4, the Indemnitee may participate in such defense with the Indemnitee’s own counsel who shall be retained, at the Indemnitee’s sole cost and expense; provided, however, that neither the Indemnitee nor the Indemnitor shall consent to the entry of any judgment or enter into any settlement with respect to the Claim without the prior written consent of the other Party, which consent shall not be unreasonably withheld or delayed. If the Indemnitee withholds consent in respect of a judgment or settlement involving only the payment of money by the Indemnitor and which would not involve any stipulation or admission of liability or result in the Indemnitee becoming subject to injunctive relief or other relief, the Indemnitor shall have the right, upon written notice to the Indemnitee within five (5) days after receipt of the Indemnitee’s written denial of consent, to pay to the Indemnitee, or to a trust for its or the applicable Third Party’s benefit, such amount established by such judgment or settlement in addition to all interest, costs or other charges relating thereto, together with all attorneys’ fees and expenses incurred to such date for which the Indemnitor is obligated under this Agreement, if any, at which time the Indemnitor’s rights and obligations with respect to such Claim shall cease.  
 12.4.4 The Indemnitor shall not be liable for any settlement or other disposition of a Claim by the Indemnitee which is reached without the written consent of the Indemnitor.  
 12.5 No Consequential Damages. UNDER NO CIRCUMSTANCES SHALL EITHER PARTY BE RESPONSIBLE OR LIABLE TO THE OTHER PARTY FOR ANY INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR OTHER LIKE DAMAGES, OR FOR ANY LOSS OF PROFITS, LOSS OF REVENUE, LOSS RESULTING FROM INTERRUPTION OF BUSINESS OR LOSS OF USE OR DATA , EVEN IF SUCH PARTY, OR ANY OF ITS DIRECTORS, OFFICERS, EMPLOYEES, OR AGENTS HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES AND NOTWITHSTANDING ANY FAILURE OF ESSENTIAL PURPOSE OF ANY LIMITED REMEDY OF ANY KIND, UNDER ANY CONTRACT, NEGLIGENCE, STRICT LIABILITY OR OTHER THEORY, ARISING OUT OF OR RELATING IN ANY WAY TO THIS AGREEMENT OR ITS IMPLEMENTATION. FOR THE AVOIDANCE OF DOUBT, NOTHING IN THIS SECTION 12.5 SHALL BE INTERPRETED TO LIMIT THE INDEMNIFICATION OBLIGATION OF EITHER PARTY IN CONNECTION WITH A PRODUCT LIABILITY CLAIM WITH RESPECT TO THE CHARACTERIZATION OF DAMAGES OR LOSSES CLAIMED BY A THIRD PARTY AS BEING INDIRECT, INCIDENTAL, CONSEQUENTIAL, SPECIAL, EXEMPLARY, PUNITIVE OR OTHER LIKE DAMAGES OR LOSSES.  
 12.6 Insurance. Each Party shall maintain commercial general liability and product liability insurance through the term of this Agreement and for a period of five (5) years thereafter, which insurance shall afford limits of not less than (i) $5,000,000 for each occurrence, and (ii) $5,000,000 annual aggregate. In addition, from time to time during the term of this Agreement, each Party shall increase their levels of insurance coverage if reasonably deemed prudent by such party in light of the overall activities under this Agreement. If requested 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 of liability. The insurance certificate shall further provide for a minimum of 30 days’ written notice to the insured of a cancellation of, or material change in, the insurance. If a Party is unable to maintain the  
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 insurance policies required under this Agreement through no fault on the part of such Party, then such Party shall forthwith notify the other Party in writing and the parties shall in good faith negotiate appropriate amendments to the insurance provision of this Agreement in order to provide adequate assurances.  
 12.7 Limitation of Liability.  
 12.7.1 Active Materials. Patheon’s maximum liability for loss or damage to any quantity of Bulk API for any reason whatsoever shall be determined in accordance with Section 2.11.  
 12.7.2 Recall Expenses. Patheon’s maximum liability to Santarus pursuant to Section 5.3 for expenses associated with a Recall shall not exceed $[\*\*\*] in a calendar year.  
ARTICLE 13  
GOVERNING LAW; DISPUTE RESOLUTION  
 13.1 Governing Law. This Agreement shall be governed by and construed under the laws of the State of New York, without regard to the United Nations Convention on Contracts for the International Sale of Goods and without giving effect to any choice of laws rule that would cause the application of the laws of any jurisdiction other than the internal laws of the State of New York, to the rights and duties of the Parties.  
 13.2 Dispute Resolution/Injunctive Relief. Notwithstanding anything to the contrary contained in this Agreement, the parties specifically agree to the following dispute resolution procedure.  
 13.2.1 Negotiation Between Responsible Executives. In the event of any dispute between the Parties arising out of or related to this Agreement, the Parties shall refer such dispute to the Responsible Executive of Santarus and the Responsible Executive of Patheon for attempted resolution by good faith executive negotiations within thirty (30) days after such referral is made. In the event such officers are unable to resolve such dispute within such thirty (30) day period, then the Parties will subject themselves to the arbitration procedures set forth below before seeking any other means of resolving the dispute.  
 13.2.2 Arbitration. Any dispute arising out of or in connection with this Agreement including any question regarding its existence, validity or termination, that can not be resolved through negotiation between Responsible Executives, shall be finally resolved by arbitration under the Rules of the American Arbitration Association. The arbitration shall consist of a single arbitrator mutually agreed by the Parties, or, in the absence of such agreement, each Party shall select an arbitrator and those two arbitrators shall select a third arbitrator who shall arbitrate the dispute. Any arbitration shall take place in New York, New York, U.S.A. The award of the arbitrator shall be final and binding. The Parties waive any right to appeal the arbitration award, to the extent a right to appeal may be lawfully waived. Each Party retains the right to seek judicial assistance: (a) to compel arbitration; (b) to obtain interim measures of protection pending or during arbitration; and (c) to enforce any decision of the arbitrator, including the final award.  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
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 13.2.3 Exceptions. Notwithstanding the provision of this Section 13.2, the Parties agree that certain violations or threatened violations of this Agreement will result in irrevocable harm to other Party, for which damages would be an inadequate remedy. In addition to any rights and remedies otherwise available, either Party, before or during arbitration, may apply to a court having jurisdiction for a temporary restraining order, preliminary injunction or other interim or conservatory relief, where such relief is necessary to protect its interests pending completion of the arbitration proceedings without breach of this arbitration agreement and without any abridgment of the powers of the arbitrators.  
 13.2.4 Continuation of Performance. Except where such area of performance is the subject of dispute, each Party shall continue to perform its respective obligations under this Agreement while any dispute is being resolved in accordance with this Section 13.2 unless and until such obligations are terminated or expire in accordance with the provisions of this Agreement.  
ARTICLE 14  
CAPITAL CONTRIBUTIONS  
 14.1 Capital Reimbursement Agreement. Each Party’s capital contribution to the performance of this Agreement shall be as set forth in the Capital Reimbursement Agreement between the Parties and dated as of December 19, 2003 (the “Capital Agreement”).  
 14.2 Manufacturing Tools. Except as set forth in the Capital Agreement, Patheon shall be solely responsible for all costs associated with maintaining the equipment, tools, technology, and all other items necessary to manufacture, package, test, store and ship the Finished Product (“Manufacturing Tools”).  
 14.3 Personnel. Patheon shall be solely responsible for all costs associated with hiring personnel to maintain the Manufacturing Tools necessary to comply with its obligations pursuant to this Agreement.  
ARTICLE 15  
MISCELLANEOUS  
 15.1 Assignment. Patheon may not assign this Agreement or any of its rights or obligations hereunder) without the written consent of Santarus, such consent not to be unreasonably withheld. Santarus may not assign this Agreement or any of its rights or obligations hereunder without the written consent of Patheon, such consent not to be unreasonably withheld; provided, however, that Patheon’s consent may be withheld if, in the opinion of Patheon, acting reasonably, the assignee is not a creditworthy substitute for Santarus. Notwithstanding the foregoing provisions of this Section 15.1, Santarus may assign this Agreement to any of its Affiliates or to a successor to or purchaser of all or substantially all of its business relating to this Agreement, provided that such assignee executes an agreement with Patheon whereby it agrees to be bound hereunder.  
 15.2 Force Majeure. With respect to this Agreement, neither Party shall lose any rights hereunder or be liable to the other Party for damages or losses on account of failure of performance by the defaulting Party if the failure is occasioned by war, fire, explosion, flood,  
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 xxxxxx, xxxxxxx, xxxxxxxxx xxxxxxx, xxxxxxx, xxx of God, or any other similar cause to the extent beyond the reasonable control of the defaulting Party, provided that the Party claiming force majeure shall promptly notify the other Party in writing setting forth the nature of such force majeure, shall use its best efforts to eliminate, remedy or overcome such force majeure and shall resume performance of its obligations hereunder as soon as reasonably practicable after such force majeure ceases. Notwithstanding the previous sentence, if any force majeure continues for more than ninety (90) days, the other Party may terminate this Agreement.  
 15.3 Further Actions. Each Party agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, as may be necessary or appropriate in order to carry out the purpose and intent of this Agreement.  
 15.4 Compliance With Laws. Each Party will comply with all Applicable Laws in such Party’s exercise of its rights and performance of its obligations under this Agreement.  
 15.5 Notices. All notices required or permitted to be given under this Agreement shall be in writing and shall be deemed given if delivered personally or by facsimile transmission receipt verified, mailed by registered or certified mail return receipt requested, postage prepaid, or sent by express courier service, to the Parties at the following addresses, or at such other address for a Party as shall be specified by like notice, provided that notices of a change of address shall be effective only upon receipt thereof.  
 If to Patheon: Patheon Inc.  
 0000 Xxxxxxxxxxx Xxxx, Xxxxx 000  
 Xxxxxxxxxxx, Xxxxxxx  
 Xxxxxx X0X 0X0  
 Attn: President  
 With a copy to: Patheon Inc.  
 0000 Xxxxxxxxxxx Xxxx, Xxxxx 000  
 Xxxxxxxxxxx, Xxxxxxx  
 Xxxxxx X0X 0X0  
 Attn: General Counsel  
 If to Santarus Santarus, Inc.  
 00000 Xxxx Xxxxx Xxx Xxxxx, Xxxxx 000  
 Xxx Xxxxx XX 00000  
 Phone: 000-000-0000  
 Fax: 000-000-0000  
 Attn: Sr. Vice President, Manufacturing and Product  
 Development  
 With a copy to: Santarus, Inc.  
 00000 Xxxx Xxxxx Xxx Xxxxx, Xxxxx 000  
 Xxx Xxxxx XX 00000  
34  
 Phone: 000-000-0000  
 Fax: 000-000-0000  
 Attn: Legal Affairs  
 Unless an earlier date can be proven by competent evidence, the date of receipt of any notice given under this Agreement, including, without limitation, any invoice provided by Patheon to Santarus, shall be deemed to be the date given if delivered personally or by facsimile transmission receipt verified, seven (7) days after the date mailed, if mailed by registered or certified mail return receipt requested, postage prepaid, and two (2) days after the date sent if sent by express courier service.  
 15.6 Waiver. No failure of either Party to exercise and no delay in exercising any right, power or remedy in connection with this Agreement (each a “Right”) will operate as a waiver thereof, nor will any single or partial exercise of any Right preclude any other or further exercise of such Right or the exercise of any other Right. No waiver shall be effective unless made in writing and signed by the waiving Party.  
 15.7 Disclaimer of Agency. The relationship between Patheon and Santarus established by this Agreement is that of independent contractors, and nothing contained in herein shall be construed to (i) give either Party the power to direct or control the day-to-day activities of the other, (ii) constitute the Parties as the legal representative or agent of the other Party or as partners, joint venturers, co-owners or otherwise as participants in a joint or common undertaking, or (iii) allow either Party to create or assume any liability or obligation of any kind, express or implied, against or in the name of or on behalf of the other Party for any purpose whatsoever, except as expressly set forth in this Agreement.  
 15.8 Severability. If any term, covenant or condition of this Agreement or the application thereof to any Party or circumstance shall, to any extent, be held to be invalid or unenforceable by a court or administrative agency of competent jurisdiction, then the remainder of this Agreement, or the application of such term, covenant or condition to Parties or circumstances, other than those as to which it is held invalid or unenforceable, shall not be affected thereby and each term, covenant or condition shall be valid and be enforced to the fullest extent permitted by law.  
 15.9 Entire Agreement. This Agreement, including all schedules and exhibits attached hereto, the Quality Agreement and the Capital Agreement, which are hereby incorporated herein by reference, set forth all covenants, promises, agreements, warranties, representations, conditions and understandings between the Parties hereto with respect to the manufacture and supply of commercial quantities of Finished Product and supersedes and terminates all prior and contemporaneous agreements and understandings between the Parties with respect to such subject matter.  
 15.10 Modification. No subsequent alteration, amendment, change or addition to this Agreement shall be binding upon the Parties hereto unless reduced to writing and signed by the respective authorized officers of the Parties. In the event of a conflict between the terms of any Firm Purchase Order, order acknowledgement, packaging slip or other documentation, and the terms of this Agreement, the terms of this Agreement shall control, unless such documentation  
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 specifically states that it overrides conflicting terms of this Agreement and is signed by each of the Parties.  
 15.11 Trademarks and Trade names. The Parties hereby acknowledge that neither Party has, and shall not acquire, any interest in any of the other Party’s trademarks or trade names appearing on the labels or packaging materials for the Finished Product unless otherwise expressly agreed in writing.  
 15.12 Construction. This Agreement shall be deemed to have been drafted by all Parties and, in the event of a dispute, no Party hereto shall be entitled to claim that any provision should be construed against any other Party by reason of the fact that it was drafted by one particular Party. The headings used in this Agreement are for convenience of reference only and are not a part of the text hereof.  
 15.13 Counterparts. This Agreement may be executed in counterparts, by manual or facsimile signatures, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.  
 IN WITNESS WHEREOF, the Parties have executed this Agreement in duplicate originals by their proper officers as of the Effective Date.  
 Patheon Inc. Santarus, Inc.   
 By:  
 /s/ Xxxxxxxx Xxxxxxxx By: /s/ Xxxxxx X. Xxxxxx   
Name:  
 Xxxxxxxx Xxxxxxxx Name:   
 Xxxxxx X. Xxxxxx   
Title:  
 Chief Executive Officer Title: President and Chief Executive Officer   
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 EXHIBIT A  
MINIMUM RUN QUANTITY  
The “Minimum Run Quantity” or the minimum number of batches to be produced during one cycle of manufacturing shall be:  
– [\*\*\*].  
 – [\*\*\*].  
 – [\*\*\*].  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 EXHIBIT B  
Pricing Information for Finished Product  
Zegerid Powder for Oral Suspension  
20 mg and 40 mg  
[\*\*\*]  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 EXHIBIT C  
KEY PERFORMANCE INDICATORS  
[\*\*\*]  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 EXHIBIT D  
TARGET API YIELDS  
The “Target API Yields” are mutually agreed upon targets that are used for determining quarterly and annual average yields as specified in Section 2.11 API Yield.  
– Zegerid® Trade Product Target API Yield is [\*\*\*]%  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.  
 EXHIBIT E  
2007 Raw Material (including Packaging Components) Purchase Plan  
[\*\*\*]  
 \*\*\* Certain information on this page has been omitted and filed separately with the Securities and Exchange Commission. Confidential treatment has been requested with respect to the omitted portions.