Exhibit 10.33  
 Execution Copy  
 \*\*\*TEXT OMITTED AND SUBMITTED SEPARATELY  
PURSUANT TO CONFIDENTIAL TREATMENT REQUEST  
UNDER 17 C.F.R. SECTIONS 200.80(b)(4) AND 230.406  
 MANUFACTURING AGREEMENT  
 BY AND BETWEEN  
 BAYER HEALTHCARE LLC  
 BIOLOGICAL PRODUCTS DIVISION  
 BERKELEY, CALIFORNIA  
 AND  
 TALECRIS BIOTHERAPEUTICS, INC.  
 RALEIGH, NORTH CAROLINA  
   
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 MANUFACTURING AGREEMENT  
 This MANUFACTURING AGREEMENT (this “Agreement”) is entered into as of March 31, 2005 (the “Effective Date”) by and between Talecris Biotherapeutics, Inc. (f/k/a NPS BioTherapeutics, Inc.) (“Purchaser”) and Bayer HealthCare LLC, Biological Products Division (“Bayer,” along with Purchaser, the “Parties”).  
 WHEREAS, Bayer, Talecris Holdings, LLC (f/k/a NPS Bio Holdings, LLC), Talecris Biotherapeutics Holdings Corp. and Purchaser have entered into that certain Amended and Restated Joint Contribution Agreement, dated as of March 30, 2005 (the “Contribution Agreement”);  
 WHEREAS, Purchaser desires to engage Bayer as a custom manufacturer of Column Eluate and ATM (the “Products”) at its facility located at Berkeley, California (“Bayer Facility”) processing Fraction IV-I and PEG Paste (the “Inputs”) supplied by Purchaser;  
 WHEREAS, Purchaser will, upon receipt of Column Eluate from Bayer, further process and purify the Column Eluate into an injectable therapeutic product (“Prolastin”);  
 WHEREAS, Purchaser will engage in the marketing, sale, storage, and distribution of ATIII and Prolastin; and  
 WHEREAS, Purchaser and Bayer wish to set forth their mutual agreements and understandings regarding the manufacture of the Products by Bayer on behalf of Purchaser. -  
 NOW, THEREFORE; for and in consideration of the premises and the mutual covenants contained herein, and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties hereto do hereby agree as follows:  
 ARTICLE 1 TERM  
This Agreement shall have an initial term commencing on the Effective Date and terminating on December 31, 2006 (“Initial Term”) unless earlier terminated as provided in Article 4 below. The Initial Term may be renewed for two one (1) year periods at the option of Purchaser (each, an “Extended Term”), and thereafter for one additional one (1) year period upon the terms and conditions set forth below (“Final Term”). Purchaser shall give Bayer at least nine (9) months’ written notice prior to the end of the then expiring term as to each of the Extended Terms, and shall give Bayer at least twelve (12) months’ written notice prior to the end of the second Extended Term as to a proposed Final Term. The Initial Term, each Extended Term and the Final Term shall collectively constitute the “Term”. As promptly as practicable after Purchaser gives notice of the Final Term, Bayer shall within ninety (90) days of such notice advise Purchaser of the price calculation, subject to adjustment under Article 3 and subject to reflecting the full costs of operating the facility solely for the purpose of manufacturing the Products. The Parties shall then engage in good faith negotiations for a period of three (3) months. If the Parties cannot reach an agreement to adjust the Price within such three (3) month period, then Purchaser shall not have the option to extend for such Final Term.  
   
 ARTICLE 2 CUSTOM MANUFACTURING SERVICES  
2.1 Volume Requirements. With respect to each calendar year during the Initial Term, Bayer shall make available to Purchaser, and Purchaser may purchase from Bayer, Column Eluate and ATIII in the quantities set forth in Exhibit A, attached hereto and incorporated herein by reference (which conform to the Product Specifications (as defined in Section 2.2 below)) (as adjusted herein, the “Column Eluate Required Quantity” and the “ATIII Required Quantity”, respectively, and collectively, the “Required Quantity”). Upon providing a notice of renewal for the Extended Term in accordance with Article 1, Purchaser shall amend Exhibit A to set forth the amount of Products that Bayer shall make available to Purchaser and that Purchaser may purchase from Bayer during the Extended Term; provided that, the Column Eluate Required Quantity cannot exceed one hundred twenty percent (120%) of that amount shown on Exhibit A then in effect on the date the notice of renewal is provided and the ATIII Required Quantity cannot exceed that amount set forth on Exhibit A in effect as of the Effective Date. Subject to the other provisions contained herein, including without limitation, Section 2.4 below, in each. calendar year during the Term of this Agreement, Purchaser may request in its sole discretion, and Bayer shall supply, (a) a minimum of seventy-five percent (75%) of the Column Eluate Required Quantity and a maximum of one hundred fifteen percent (115%) of the Column Eluate Required Quantity; and (b) a maximum of [\*\*\*] vials of ATIII (each as determined after deducting quantities representing Nonconforming Product (as defined in Section 6.1 below)). Subject to the foregoing, on or prior to October 1 of each calendar year, the Required Quantity applicable for the immediately following calendar year shall be reviewed and may be revised by mutual agreement of the Parties. For each calendar year during the Term, Purchaser shall make available to Bayer that quantity of Inputs meeting the Input Specifications (each as defined in Section 2.3 below) necessary for Bayer-to manufacture each Binding Production Forecast as set forth .in Section 2.4 (“Required Inputs”). In the event that Purchaser provides less than one hundred percent (100%) of the Required Inputs, then the Binding Production Forecast shall be adjusted to reflect the supply of Inputs provided by Purchaser to Bayer. Notwithstanding the foregoing, in no event shall Purchaser provide in each calendar year of the Term (other than the Final Term) (a) less than seventy-five percent (75%) of the Required Inputs and (b) less than [\*\*\*] kilograms of Fraction IV-I Paste manufactured by Purchaser at the Purchaser’s Facility (the “Minimum Bayer IV-I Paste Requirement”) (each as determined after deducting quantities representing Nonconforming Inputs (as defined in Section 6.1 below)).  
 2.2 Manufacturing Services. During the Term of this Agreement, Bayer shall process the Inputs provided by Purchaser into the Products (the “Manufacturing Services”). The Column Eluate supplied by Bayer shall meet the specifications set forth in Exhibit B and the ATIII supplied by Bayer shall meet the specifications set forth in Exhibit C, each such exhibit as attached hereto and incorporated herein by reference, and each of which may be amended from time-to-time by mutual written agreement of the Parties (the “Product Specifications”). The Product Specifications in effect as of the date hereof are those that were in effect as of the date of execution of the Contribution Agreement.  
 2.3 Supply of Inputs. Subject to the terms and conditions of this Agreement, during the Term, Purchaser shall supply to Bayer Fraction IV-I Paste meeting the specifications set forth in Exhibit D and PEG Paste meeting the specifications set forth in Exhibit E each such exhibit as attached hereto and incorporated herein by reference, and each of which may be amended from  
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 time-to-time by mutual written agreement of the Parties, and such other specifications and requirements as set forth in the Manufacturing Agreements attached hereto as Exhibits F and G, as applicable (collectively, the “Input Specifications”), at such times and in such amounts, as is required for Bayer to process and supply the Products in accordance with the Binding Production Forecasts (as defined in Section 2.4 below). In providing that volume of Required Inputs meeting those requirements set forth in Section 2.1 above, unless otherwise agreed in writing by the Parties, Purchaser shall during each calendar. year of the Term of this Agreement supply Bayer with Inputs (including the Minimum Bayer IV-I Paste Requirement) in such amounts as is necessary for Bayer to process amounts of ATIII and Column Eluate reflected in the Binding Production Forecasts, Purchaser shall maintain at the Bayer Facility an inventory of Fraction IV-I Paste manufactured by Purchaser at Purchaser’s Facility, and meeting the Input Specifications, equal to [\*\*\*] kilograms, to be used by Bayer in the production of the Products. The Inputs supplied by Purchaser shall be deemed at all times to be the property of Purchaser. Bayer shall be responsible for all Inputs while such Inputs are in Bayer’s possession at the Bayer Facility. Purchaser shall be responsible for arranging the shipment of the Inputs from the facility located in Clayton, North Carolina (“Purchaser’s Facility”).  
 2.4 Product Supply Forecasts. Upon the Effective Date, Purchaser shall provide Bayer with a twelve (12) month rolling forecast of Purchaser’s estimated production and supply needs for each of the Products by calendar month (the “Production Forecast”). Such Production Forecast of Purchaser’s future requirements, as may be revised from time to time, shall be attached hereto as Exhibit A, and incorporated herein by reference. Purchaser shall provide an updated twelve (12) month rolling Production Forecast on or about the commencement of each calendar month. The first six (6) months of each rolling twelve (12) month forecast for Column Eluate shall be binding (the “Column Eluate Binding Production Forecast”), and the last six (6) months of the Column Eluate rolling, forecast shall be good faith estimates and shall not be binding on the Parties. The first six (6) months of each rolling twelve (12) month forecast for ATIII shall be binding (the “ATIII Binding Production Forecast” and together with the Column Eluate Binding Production Forecast, the “Binding Production Forecast”), and the last six (6) months of ATIII rolling forecast shall be good faith estimates and shall not be binding on the Parties. In each calendar year, the aggregate Binding Production Forecasts for such period shall equal at least seventy-five percent (75%) of the Column Eluate Required Quantity and at least one hundred percent (100%) of the ATIII Required Quantity. In the event that the actual Products requested by Purchaser (as determined based on Orders (as defined in Section 2.9 below) placed by Purchaser for Products meeting the Product Specifications in accordance with Section 2.9 below) are less than those set forth in a Binding Production Forecast, the Parties agree and acknowledge that Purchaser nonetheless shall be obligated to pay for the Products set forth in such Binding Production Forecast at the prices set forth in Section 3.1, as may be revised from time to time.  
 2.5 Manufacturing of the Products. Bayer shall manufacture, process, store, distribute, test, transport, dispose, deliver and otherwise handle the Products and the Inputs at all times in full compliance with, as applicable, cGMPs (as defined in Section 5.1), other Regulations (as defined in Section 5.1), the Product Specifications, the Manufacturing Agreement (for manufacturing Fraction IV-I/PEG Paste into the Column Eluate), attached hereto as Exhibit F and incorporated herein by reference, the Manufacturing Agreement (for manufacturing Fraction IV-I Paste into ATIII), attached hereto as Exhibit G and incorporated herein by reference, and the SOPs (as  
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 defined in Section 2.13). The Manufacturing Agreements for manufacturing Fraction IV-I/PEG Paste into the Column Eluate and Fraction IV-I Paste into ATM shall be renewed annually, consistent with the Term of this Agreement, with each such renewal deemed attached hereto as Exhibit F and Exhibit G, respectively, and incorporated herein by reference. In the event of a conflict between the provisions of this Agreement and the provisions of either of the Manufacturing Agreements, the provisions of this Agreement shall prevail. Bayer shall maintain all records as are necessary and appropriate to demonstrate compliance with cGMPs and the Regulations. In no event shall any change to the batch production records be implemented until Bayer has received written approval from Purchaser which approval will not be unreasonably withheld. Bayer shall make no changes in the production equipment, production procedures, or testing methods existing as of the date of this Agreement. without providing reasonable notice to Purchaser in advance of the change and obtaining Purchaser’s prior written consent which consent will not be unreasonably withheld.  
 2.6 Yield. The standard expected yield of Products based on kilograms and potency of the Inputs and alpha-1 potency (“Expected Yield”), and the calculation method used to determine such Expected Yield, shall be set forth on Exhibit H, which shall be attached hereto and incorporated herein by reference (the “Yield Calculation”). The actual yield of Column Eluate (“Actual Yield”) and the Expected Yield shall be reconciled by Bayer quarterly within thirty (30) days of each January 1, April 1, July 1 and October 1, and the results thereof shall be promptly reported to Purchaser. Upon mutual agreement of the Parties, the Expected Yield shall be appropriately adjusted. As soon as practicable following the Effective Date, the Parties shall mutually agree upon, in writing, the effect that any variance between Expected Yield and Yield Calculation may have on price.  
 During any rolling four quarter period of the Term, if the Actual Yield fails to meet the Expected Yield, then Bayer shall compensate Purchaser for that amount of Inputs used in the processing attributable to the lower yield, and if the Actual Yield exceeds the Expected Yield, then Purchaser shall compensate Bayer for that amount of Inputs used in processing attributable to the higher yield, in each case at a rate of one hundred fifteen percent (115%) of the Input Replacement Value (as defined in Section 2.13) per kilogram of Inputs.  
 [\*\*\*]  
 Without limiting the foregoing, Purchaser may at its election provide additional Inputs to Bayer to compensate for any variance between Expected Yield and Actual Yield so that Products may be processed in amounts meeting the quantity specified in the Binding Production Forecast; provided, however, that any election by Purchaser not to provide such additional Inputs shall operate to waive Purchaser’s rights under Section 9.4.  
 If Purchaser fails to provide Inputs which constitute Required Inputs and which meet the Input Specifications for any reason (including Force Majeure), then Bayer shall not be responsible for meeting the Expected Yield computed pursuant to this Section 2.6 for as long as such failure continues and for a period of forty-five (45) days after Purchaser resumes providing Inputs which constitute Required Inputs and which meet Input Specifications. If Purchaser does not provide Inputs which  
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 constitute Required Inputs and which meet the Input Specifications for any reason, including Force Majeure, for a consecutive period of six (6) months, then the Parties shall negotiate in good faith for a period of three (3) months to amend this Agreement as to direct costs of Bayer as a result of Inputs that do not constitute Required Inputs or do not meet Input Specifications. If the Parties are unable to reach agreement to amend this Agreement during the Initial Term, then the matter shall be resolved in accordance with Section 12.9. If the Parties are unable to reach agreement to amend this Agreement during any term after the Initial Term, then Bayer may, at its sole option, terminate this Agreement for cause pursuant to Section 4.1 hereof.  
 2.7 Samples. Bayer shall provide to Purchaser adequate samples of ATIII prior to the shipment of ATIII (“Product Samples”) and Purchaser shall provide to Bayer adequate samples of the Inputs along with the shipment of Inputs (“Input Samples,” together with the ‘Product Samples, the “Samples”) for testing by Purchaser and Bayer, respectively, to determine the Samples’ compliance with the Product Specifications or Input Specifications, as applicable. Bayer and Purchaser shall supply the other Party with Samples according to a schedule (as may be amended from time to time) to be mutually agreed upon by the Parties in writing. Each of Purchaser and Bayer shall use its commercially reasonable efforts to test the Samples within a period of twenty (20) days. from such Party’s receipt of such Samples. The Parties shall use commercially reasonable efforts to expedite the testing of such Samples. Notwithstanding the foregoing, if after accepting a shipment of Products or Inputs, Purchaser or Bayer, respectively, subsequently discovers latent defects (including without limitation, nonconformance with Product Specifications or Input Specifications, as applicable) attributable to the other Party’s performance under this Agreement not reasonably discoverable at the time of delivery, such Party may revoke its acceptance of such shipment of Products or Inputs, respectively, by giving written notice to the other Party as soon as practicable after discovering such defects, and in such event, such Products or Inputs shall be considered Nonconforming Products or Nonconforming Inputs, as the case may be, and the provisions of Section 6.1 below shall apply.  
 2.8 Testing. With respect to each shipment of Products to be shipped to Purchaser, Bayer shall test such Products to ensure compliance with the Product Specifications. Bayer shall include a certificate of analyses with each shipment of Products disclosing the results of such testing and showing conformance with the Product Specifications.  
 2.9 Order and Availability. Purchaser shall place an order for Products reflecting the aggregate amount of Products in the initial Binding Production Forecast once Purchaser has determined, based on applicable test results obtained by it, that the relevant Product Samples have met the Product Specifications. With each subsequent Binding Production Forecast, Purchaser shall deliver an order reflecting the aggregate Column Eluate ordered for the sixth month of the Column Eluate Binding Production Forecast and the aggregate ATIII ordered for the sixth month of the ATIII Binding Production Forecast (in each case, an “Order”). The Orders shall specify delivery dates for the Products. Shipments of Products shall be scheduled by the Parties consistent with the Orders and the Binding Production Forecasts. The Parties shall cooperate to ensure that the Products to be purchased by Purchaser are ordered, and the Inputs to be provided by Purchaser are provided, in a manner so as to allow Bayer to produce such Products efficiently, without material swings in volume over. the course of any twelve (12) month period. The Parties shall cooperate to match the batch size of the Orders with the Inputs  
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 provided by Purchaser, taking into consideration, without limitation, Bayer’s normal production lot size.  
 2.10 Shipments. Subject to an adequate supply of Required Inputs being supplied by Purchaser (pursuant to Sections 2.1 and 2.3 herein), Bayer agrees that it shall provide Products in conformity with the delivery schedule provided by Purchaser to meet those Orders issued by Purchaser, provided that in no event shall Bayer be required to provide Products in excess of any Binding Production Forecast. Unless otherwise agreed by the Parties, provided that Purchaser timely provides the Inputs and places the Orders, time is of the essence for the delivery of Products in accordance with the Orders. Bayer shall include copies of production records with each shipment. Purchaser shall be responsible for making all necessary shipping arrangements for Inputs and Products. Risk of loss for the Inputs and Products in transit shall lie with Purchaser. All Inputs and Products shall be delivered F.O.B. Bayer Facility. All financial arrangements for shipping and handling of Inputs and Products shall be the responsibility of Purchaser.  
 2.11 Contract Review and Onsite Personnel. Commencing as soon as practicable following the Effective Date and thereafter on or about the first day of each month during the Term, the manufacturing representative of each Party shall hold contract review meetings, in person or via telephone, to discuss yields, Product delivery schedules, quality issues, and other issues pertinent to this Agreement. At least three (3) business days prior to each monthly meeting, each Party shall deliver to the other Party a written report regarding the issues to be discussed at such meeting. In addition to the monthly meetings, a senior manager of each Party shall meet (either in person or via telephone) on a quarterly basis and hold informal discussions on a weekly basis regarding each Party’s progress with respect to this Agreement. At the expense of Purchaser, Purchaser shall be entitled, in its sole discretion, to have a designated employee (which designated employee may be different persons from time to time) of Purchaser present at the Bayer Facility for the purposes of monitoring the Manufacturing Services and quality control of the Products. Such designated employee shall (a) have access to all areas of the Bayer Facility relating to Manufacturing Services, (b) comply with all safety and health laws, regulations, policies and procedures applicable to personnel of Bayer at the Bayer Facility and (c) remain an employee of Purchaser and continue to receive all compensation and benefits directly from Purchaser or its affiliates. Notwithstanding anything to the contrary in the foregoing, the presence of a Purchaser designated employee at the Bayer Facility and any action taken by such employee in no way impairs or waives any right or remedy Purchaser may otherwise have pursuant to the terms of this Agreement.  
 2.12 Bayer Processing. Bayer shall process the Inputs on a first in-first out basis to the extent possible.  
 2.13 Risk of Loss. The Parties agree that Purchaser shall bear the risk of loss for Inputs until the shipment is received in acceptable condition in accordance with Purchaser’s Standard Operating Procedures (as in effect as of the Effective Date and amended from time to time upon mutual agreement, and any replacements or successors thereto, “SOPs”) from the common carrier at the Bayer Facility. The risk of loss for the Inputs shall be borne by Bayer after the shipment of the Inputs is delivered to Bayer’s Facility by the common carrier and until delivery of Products is tendered to Purchaser through the placement of the Products in the care, custody  
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 and control of a common carrier under contract to Purchaser for transporting to the Purchaser’s Facility or such other location designated by Purchaser. Unless the Parties enter into a separate agreement obligating Bayer to provide storage for the Products, Purchaser shall bear the risk of loss for the Products after the Products are placed in the custody of the common carrier at the Bayer Facility. In the event of the loss of any Inputs provided by Purchaser for the production of the Products while in Bayer’s possession, which is non-recoverable by rework or which results in the loss of the Products in process or to be processed from such lost Inputs (a “Catastrophic Loss”), Bayer shall compensate Purchaser for the damages attributable to the Catastrophic Loss equal to [\*\*\*] per kilogram as adjusted pursuant to Section 3.2 hereof (the “Input Replacement Value”) of the Inputs, for the Inputs so lost. Any Catastrophic Loss shall not be used in the determination of Actual Yields.  
 2.14 Debarment. Bayer certifies it will not use in any capacity the services of any person, including any firm or individual, that has been debarred or is subject to debarment under the Generic Drug Enforcement Act of 1992, amending the Food Drug and Cosmetic Act at 21 USC 335a(a) or (b). Bayer agrees to notify Purchaser promptly in the event any person providing services to Bayer under the scope of this Agreement is debarred or becomes subject to debarment.  
 2.15 Cooperation of the Parties. Purchaser shall inform Bayer promptly of any problems that could reasonably be expected to prevent Purchaser from providing timely deliveries of the Inputs to Bayer for process in accordance with this Article 2. Similarly, Bayer shall inform Purchaser promptly of any problems that could reasonably be expected to prevent Bayer from processing the Inputs for the production of the Products. The Parties shall cooperate in resolving such problems relating to the manufacture and supply of the Products under this Agreement. In recognition of the fact that Purchaser’s business is dynamic and evolving based on market demand, regulatory approvals and other factors, Bayer shall in good faith, but subject to the terms of this Agreement, use commercially reasonable efforts to seek to accommodate any reasonable request by Purchaser to manufacture quantities of Products in excess of Bayer’s obligations hereunder; provided, however, that Bayer shall have no liability as a result of any failure to accommodate such requests despite such efforts. The Parties shall use their commercially reasonable efforts to coordinate maintenance outages and shut-downs of the Bayer Facility and the Purchaser’s Facility, which coordination could include making temporary changes to the Binding Production Forecast. For purposes of clarification, this Section 2.15 does not diminish or expand the Parties’ respective obligations to supply and purchase Products in accordance with any Binding Production Forecast set forth in Section 2.4.  
 2.16 Records. Bayer shall maintain production records and other records required by cGMPs and the Regulations for such time periods referenced thereby. Bayer shall make such records available to Purchaser for Purchaser’s inspection promptly following a written request by Purchaser.  
 ARTICLE 3 PRICE AND PAYMENT  
3.1 Charge for Manufacturing Services. During the Term of this Agreement, Purchaser shall pay the applicable price for the Products set forth in Exhibit I, attached hereto and incorporated herein by reference, as may be adjusted from time to time pursuant to Section 3.2. The price of  
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 the Products shall be F.O.B. Bayer Facility. All payments hereunder shall be made in U.S. dollars.  
 3.2 Adjustment to Prices. (i) The prices for the Products provided by Bayer to Purchaser shall be adjusted annually on October 1 or as soon thereafter as possible with respect to the Products to be provided in each immediately following calendar year during the Term based on the assumption that the Term commences during calendar year 2004. In each case, such adjustment to the prices (“Price Adjustments”) shall reflect the change in the CPI-U. For purposes of the foregoing, “CPI-U” shall mean the unadjusted percentage change for the previous twelve-month period ending on September 30 of each calendar year, as published in the Consumer Price Index for all urban consumers by the U.S. Department of Labor, Bureau of Labor Statistics. For the avoidance of doubt, the first such Price Adjustment shall become effective January 1, 2005.  
 (ii) The price shall be further subject to adjustment in accordance with Sections 5.4 and 8.1.  
 3.3 Price Adjustment Calculation. On October 1st of each calendar year or as soon thereafter as possible, Bayer shall provide for Purchaser’s review and approval the computation of the Price Adjustment (as determined in accordance with Section 3.2(i) above) to be applied in the following calendar year, and the methodology used in making such computation. Such adjustment shall be final and binding in the absence of manifest error.  
 3.4 Payments. Bayer shall deliver to Purchaser at the address set forth in Section 12.3 an invoice for shipments of Products to Purchaser as, the same is shipped. Each invoice shall reflect the actual quantity of the Products shipped and the price thereof as computed in accordance with Section 3.1, The amount invoiced by Bayer and payable by Purchaser during each Binding Production Forecast period will not be less than that charge associated with the Binding Production Forecast as computed in accordance with Section 3.1, unless the actual amount of Products delivered is less than the Binding Production Forecast due to Bayer’s failure to perform its obligations under this Agreement. Within thirty (30) days following receipt of each invoice, Purchaser shall pay to Bayer the amount specified in such invoice.  
 3.5 Payment Disputes. All billing and payment disputes between the Parties shall be resolved in accordance with Section 12.9 below.  
 ARTICLE 4 EARLY TERMINATION  
4.1 Termination for Cause. If either Party commits a substantial violation of any material provision of the Agreement (which means (i) in the case of Purchaser, nonpayment of amounts owing to Bayer in accordance with Section 3.4, failure to supply Inputs as provided in Section 2.6, or any other material breach by Purchaser of any representation, warranty, covenant or performance obligation under this Agreement and (ii) in the case of Bayer, any material breach of any representation, warranty, covenant or performance obligation under this Agreement (other than breach of its obligation to deliver Products under this Agreement, any such breach to be governed exclusively under Section 9.4 hereof)), the other Party may, without prejudice to any other right or remedy, and after giving the breaching Party sixty (60) days’ written notice of the  
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 breach, terminate the Agreement. This Agreement shall not be so terminated if the breaching Party has cured the breach, or submitted a plan for curing breach reasonably acceptable to the non-breaching Party within sixty (60) days after the non-breaching Party’s notice. If the breaching Party fails to cure the breach as set forth in the aforementioned plan in accordance with the deadlines set forth therein, the non-breaching Party may terminate this Agreement without further notice. The non-breaching Party shall have the right to recover all direct damages and losses arising as a result of any such material breach, including lost profits but not including consequential damages, provided that any such recovery shall be reduced by the amount that such non-breaching Party actually recovers under any insurance it maintains.  
 Other Termination Provisions. By Bayer if Purchaser or by Purchaser if Bayer:  
 (i) admits in writing that it is unable to pay its debts as they become due;  
(ii) starts a proceeding, or indicates its acquiescence to a proceeding started by another, relating to it under any bankruptcy, reorganization, rearrangement, insolvency, readjustment of debt, dissolution, liquidation or similar law;  
(iii) makes an assignment for the benefit of creditors;  
(iv) consents to the appointment of a receiver, trustee or liquidator for a substantial part of its property;  
(v) files, or has filed against it, a petition in bankruptcy, reorganization, rearrangement or insolvency which, if filed against it, is not dissolved or dismissed within ninety (90) days after filing; or  
(vi) has entered against it an order by a court of competent jurisdiction appointing a receiver, trustee or liquidator for it or a substantial part of its property, or approving its dissolution or termination, and if not consented to or acquiesced in by such Party, such order is not vacated or set aside or stayed within ninety (90) days.  
Notwithstanding anything to the contrary in the foregoing, no Party shall take or cause to be taken any action relating to the voluntary liquidation or dissolution of such Party.  
 4.2 Effect of Termination. In the event of termination of this Agreement, (i) Purchaser shall immediately cease delivery of all Inputs under this Agreement, (ii) Bayer shall promptly cease production of the Products and shall deliver any Products manufactured prior to the effective date of termination but not yet delivered, (iii) Bayer shall prepare and submit to Purchaser an invoice for all Products shipped by Bayer to Purchaser which at the time of the effective date of termination were not paid for by Purchaser, and (iv) Bayer shall return to Purchaser all Inputs that are in Bayer’s possession or en route to Bayer at the time of such termination which return shall be at the sole cost and expense of the Party whose breach of this Agreement resulted in the termination of the Agreement. Purchaser shall within thirty (30) days following receipt of the invoice referred to in subclause (iii) of this Section 4.3 pay the full amount of such invoice and all other sums owed to Bayer; provided, however, that if the aggregate total of the Orders placed by Purchaser prior to the effective date of such termination does not meet the Required Quantity for the then current calendar year and in the event that Bayer terminates this Agreement in  
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 accordance with Section 4.1 due to Purchaser’s breach hereof, Purchaser shall be obligated to pay amounts associated with the Products to be delivered under the then current Binding Production Forecast and, at Purchaser’s sole discretion, Bayer shall be obligated to deliver such Products.  
 4.3 Remedies. The rights of a Party to this Agreement to recover monetary damages from the other Party to this Agreement with respect to termination of this Agreement are exclusively set forth in this Article 4. Each Party shall have such non-monetary rights and remedies provided under this Agreement or under law or in equity for breaches of this Agreement, but limited to the remedy of specific performance.  
 4.4 Survival. In the event of any termination or expiration of this Agreement, each of the provisions of Articles 6, 7, 8, 9, 10, 11, 12 and Sections 2.5, 2.6, 2.7, 2.8, 2.10, 2.13, 2.14, 2.16, 3.5, 4.1, 4.3, 4.4, 4.5, 5.1, 5.3 and 5.4 shall survive as long as any such provision remains applicable, provided that Article 9 shall survive indefinitely, unless a shorter period for survival is provided in any such Article or Section.  
 ARTICLE 5 COMPLIANCE  
5.1 Compliance with Regulations. In the performance of its obligations under this Agreement, each Party shall comply in all material respects with all applicable laws, requirements, regulations, guidelines, licenses and directives, including those in any Regulatory Approval of any Regulatory Authority (including without limitation, current Good Manufacturing Practices (“cGMPs”) as defined in national and international accepted GMP compendia including PIC/C and WHO GMP Guide) including all specifications and procedures for plasma sourcing, plasma testing, and in process testing and all regulations, specifications, and procedures contained therein (collectively, the “Regulations”). Each Party shall comply with all Regulations that become effective after the Effective Date within the timeframes required by such Regulation or applicable Regulatory Authority. Bayer shall not amend or replace any SOPs related to the Manufacturing Services without providing reasonable notice to Purchaser in advance of the change and obtaining Purchaser’s prior written consent. Purchaser shall not amend or replace any SOPs related to the Inputs without providing reasonable notice to Bayer in advance of the change and obtaining Bayer’s prior written consent. Each Party shall use commercially reasonable efforts to provide such consent as soon as reasonably practicable with -the understanding that Bayer is under no obligation to provide any such consent if Purchaser’s proposed change would adversely affect Bayer’s performance of the Manufacturing Services. Notwithstanding the foregoing, until the second anniversary of the Effective Date, Purchaser shall not be liable to Bayer for, or considered in breach of this Agreement as a result of, any noncompliance or failure to comply with any Regulations to the extent such noncompliance or failure was in existence at the time of Closing (as defined in the Contribution Agreement); provided, however, that all other obligations of Purchaser contained herein shall remain in full force and effect at all times from and after the Effective Date. For purposes of this Agreement (i) “Regulatory Approvals” shall mean all licenses, approvals, permissions, or consents required for the manufacture, processing, distribution or sale of the Products and (ii) “Regulatory Authority and Regulatory Authorities” shall mean the FDA and any successor agency and all other local, state, federal, or foreign governmental authorities with authority to grant or deny the  
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 necessary Regulatory Approvals or to regulate the manner of means by which the Products are manufactured, processed, distributed, or sold.  
 5.2 Audit. (i) Each Party shall have the right, on reasonable written advance notice (to the extent practicable, not less than one (1) week advance notice), and during normal business hours, to inspect and audit the other Party’s facilities, SOPs, production, operations, testing, storage and books and records to confirm compliance with Section 5.1 and the other Party’s compliance with the terms and conditions of this Agreement, provided that such inspection or audit does not unreasonably interfere with the conduct of business of such other Party. Each Party shall use its commercially reasonable efforts to accommodate any reasonable request made by the other Party to inspect such facility. Each Party shall respond in writing to the other Party regarding any items of noncompliance identified by the other Party during such inspections or audits within fifteen (15) days of the other Party’s notice thereof and shall develop a plan, reasonably satisfactory to the other Party, to remedy any such items of noncompliance within sixty (60) days of notice thereof, and shall remedy such items of noncompliance as set forth in such plan, the failure of which shall entitle the other Party to terminate this Agreement in accordance with Section 4.1 hereof.  
 5.3 Regulatory Filings. Each Party shall promptly accommodate all requests made by any Regulatory Authority (as defined in Section 5.1) to audit such Party’s facilities. Both Parties shall have the right to review, during the Term and for a period of five (5) years thereafter, all audit findings or notices of Regulatory Authorities as such may, directly or indirectly, bear upon the Inputs, the Products or each Party’s obligations under this Agreement. Each Party shall develop. and provide to the other Party a plan, reasonably satisfactory to the other Party, to remedy, and shall remedy, any deficiencies identified as a result of a regulatory inspection in the timeframes provided in the applicable inspection report or the applicable Regulations. Bayer shall promptly notify Purchaser (i) after Bayer becomes aware of any Regulatory Authority inspection of the Bayer Facility and (ii) after Bayer receives notice from a Regulatory Authority of any observation or regulatory action, such as a warning letter. Bayer shall promptly provide a copy of any audit finding with Bayer’s corrective action response to Purchaser for items that, directly or indirectly, relate to the Manufacturing Services or any of Bayer’s obligations under this Agreement. Purchaser shall notify Bayer (i) at the time Purchaser becomes aware of any Regulatory Authority inspection of the Purchaser’s Facility and (ii) at the time Purchaser receives notice from any Regulatory Authority of any observation or regulatory action, such as a warning letter. Purchaser shall promptly provide a copy of any audit finding with Purchaser’s corrective action response to Bayer for items that, directly or indirectly, relate to the Inputs or the Products or any of Purchaser’s obligations under this Agreement.  
 5.4 Regulatory Approvals. Bayer is solely responsible for obtaining and maintaining all necessary Regulatory Approvals from all Regulatory Authorities necessary for the performance of the Manufacturing Services at the Bayer Facility. Purchaser is solely responsible for obtaining and maintaining all Regulatory Approvals necessary to further process, distribute or sell the Products. Each Party shall upon request and as reasonably necessary provide all documents or information requested by the other Party to support the other Party’s efforts to obtain, maintain, or defend Regulatory Approvals to manufacture, further  
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 process, distribute or sell the Products and/or will modify its operations or facilities as required to permit the other Party to obtain, maintain, or defend necessary Regulatory Approvals to manufacture, further process, distribute and sell the Products; provided if the modifications to operations or facilities requested by a Party are modifications which would require the other Party to change the manner of operations existing as of the date of this Agreement or to add facilities not in place as of the date of this Agreement, such Party will reimburse the other Party’s reasonable direct costs in making such modifications and the Parties shall engage in good faith negotiations to adjust the price set forth in Section 3.1 to reflect the increase or decrease of ongoing costs of processing the Products hereunder resulting from any such modifications; provided further that if the Parties cannot reach an agreement to adjust the price pursuant to this Section 5.4 despite such good faith negotiations, (i) if the requested modifications will affect only the Product operations of such Party at either the Bayer Facility or the Purchaser’s Facility, as applicable, the matter shall be resolved in accordance with Section 12.9, or (ii) if the requested modifications will, in the sole discretion of the affected Party, adversely affect in any material manner other operations of such Party at either the Bayer Facility or the Purchaser’s Facility, as applicable, separate from the Product operations of such Party at either the Bayer Facility or the Purchaser’s Facility, as applicable, such Party shall not be required to make any such modifications until the Parties reach such agreement; provided further such Party will have no obligation to reimburse the other Party for any maintenance, repair or replacement of existing facilities or for the substitution of their equivalent or for any increases in costs associated with the other Party’s conduct of operations in a fashion similar to or equivalent to the manner in which those operations were being conducted in the absence of such request as of the date of this Agreement.  
 ARTICLE 6 NONCONFORMING PRODUCT AND RECALLS  
6.1 Nonconforming Product. (i) Purchaser shall provide Bayer with the identification number of any plasma unit that was pooled and manufactured into a batch or lot of Nonconforming Inputs delivered to Bayer. In the event that Purchaser provides Inputs that do not meet the Regulations or do not conform to the Input Specifications, or contain latent defects, or that have not been manufactured, processed, distributed, transported, disposed, stored, tested or otherwise handled in accordance with applicable SOPs, the Input Specifications, cGMPs and the Regulations (“Nonconforming Inputs”), Purchaser shall remain obligated to pay Bayer for those Manufacturing Services performed by Bayer with such Nonconforming Inputs prior to such later time, if any, as Purchaser notifies Bayer that such Inputs are Nonconforming Inputs or Purchaser achieves the Required Quantity. To the extent Nonconforming Inputs have been processed, then Purchaser will reimburse Bayer based on the percentage of processing completed. Nonconforming Inputs shall, at the option of Purchaser, be destroyed by Bayer (and a certificate of destruction shall be promptly provided by Bayer to Purchaser) or returned to Purchaser. Purchaser shall reimburse Bayer for the reasonable costs of destruction or return of all Nonconforming Inputs. At Purchaser’s sole election, Purchaser may provide additional Inputs to Bayer for processing into Products to replace Non-Conforming Inputs so as to achieve the Required Quantity.  
 (ii) In the event that Bayer supplies Products that do not meet the Regulations or do not conform to the Product Specifications, or contain latent defects, or that have not been manufactured, processed, distributed, transported, disposed, stored, tested or otherwise handled in accordance with applicable SOPs, the Product Specifications, cGMPs and the Regulations, (“Nonconforming Products”) and such Nonconforming Products are not attributable to Nonconforming Inputs, then (i) Bayer shall, at no cost to Purchaser, and as soon as reasonably  
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 feasible, replace such Nonconforming Product with an equivalent amount of conforming Product to the extent Purchaser elects to provide additional Inputs to Bayer and (ii) such Nonconforming Products shall at the option of Purchaser be destroyed by Bayer (and a certificate of destruction shall be promptly provided by Bayer to Purchaser) or returned to Purchaser. Bayer shall reimburse Purchaser for the reasonable costs of destruction or return of all Nonconforming Products plus the Input Replacement Value of any additional Inputs provided by Purchaser.  
 (iii) In the event that the Parties are unable to agree as to whether Nonconforming Inputs resulted in a Nonconforming Product, then a mutually selected independent third party laboratory shall perform testing and provide results thereof to the Parties within thirty (30) days of receiving the Inputs and Products for testing for purposes of making such determination. The Parties shall share equally the costs of such testing.  
 6.2 General Requirements. Purchaser shall maintain accurate records of the quantities of the Inputs shipped to Bayer and Bayer shall maintain accurate records of all Products derived from such Inputs.  
 6.3 Distribution and Use Records.  
(i) Purchaser shall maintain and give Bayer access upon advance notice and at reasonable times, to, for a period of not less than fifteen (15) years from production, donor records and test results with respect to each unit of the Inputs delivered to Bayer. Such records and results shall be maintained such that they can rapidly and unequivocally be accounted for and made available to Bayer within fourteen (14) days from the date of request.  
(ii) Records of the use of each lot of the Inputs delivered to Bayer shall be maintained by Bayer for a period of not less than fifteen (15) years from the date of delivery. Such records shall be maintained such that the use of each lot of the Inputs can be rapidly and unequivocally accounted for and the Products into which such Inputs were processed, identified and made available to Purchaser within fourteen (14) days from the date of request. Purchaser shall assist Bayer in identifying, tracking and controlling the use of any Inputs identified in post-donation information as contaminated or otherwise unsuitable for processing into Products.  
(iii) Records regarding the testing, storage, distribution and disposal of the Products shall be maintained by Purchaser for such period required by the Regulations.  
6.4 Adverse Events. Purchaser shall record and investigate all reports of adverse events in which Products manufactured from the Inputs have been implicated. If Purchaser determines that a Product has caused adverse reactions as a result of such Product being manufactured from Inputs, Purchaser shall immediately notify all Regulatory Authorities as required by the Regulations. Purchaser shall promptly notify Bayer of any such adverse events and shall provide Bayer with copies of all documents provided by Purchaser to Regulatory Authorities with respect thereto.  
 6.5 Customer Notification of Adverse Reactions. In the event that during the course of a preliminary investigation related. to a report of any serious adverse reaction associated with the Products, Purchaser obtains preliminary evidence indicating that, according to indications and dosage, the Inputs used in the manufacture of the Products may have caused such specific  
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 adverse reaction, each Purchaser customer that received any such Products shall be notified by Purchaser and cautioned that any unused containers of the suspect lots should be withheld from use, pending the outcome of more definitive investigations and evaluations, with a copy of such notice to the applicable Regulatory Authority, if required. Purchaser shall promptly provide Bayer with a copy of such notice. Any and all of the foregoing actions will be executed with the concurrence of all relevant Regulatory Authority, to the extent required by law.  
 6.6 Withdrawals and Recalls. Purchaser shall make all contacts with relevant Regulatory Authority and shall be responsible for coordinating all activities in connection with any recall or withdrawal of any Product. In the event that Bayer believes a recall or withdrawal of a Product may be necessary or appropriate, Bayer shall promptly notify Purchaser in writing. In the event that Purchaser initiates a recall or Product withdrawal, Purchaser shall promptly notify Bayer.  
 6.7 Customer Complaints. Bayer and Purchaser will cooperate, according to policies mutually determined by the Parties in writing, in the reporting, investigation and evaluation of customer complaints.  
 6.8 Responsibility. In the event that any market withdrawal, recall or third party return of any Product results from Bayer’s supply of Nonconforming Product, then Bayer shall assume the claims and costs associated with such withdrawal, recall or return and the destruction of implicated Products to the extent attributable to Bayer’s Nonconforming Product. Notwithstanding the foregoing, Bayer shall not be liable for any market withdrawals, recalls or third party returns caused by Nonconforming Inputs supplied by Purchaser.  
 6.9 Deviation Report. (i) If during the manufacture, processing, storage, distribution, testing, transport, disposal or other handling of the Products by Bayer there arises a result that is classified as either a Type I Incident or a Type II Incident (as defined below), then Bayer shall prepare within seven (7) days following the discovery of such deviation a written report detailing such deviation (a “Deviation Report”) and promptly send to Purchaser such Deviation Report prior to Bayer’s delivery of the Products which is the subject of such report. If Purchaser rejects a shipment of the Products based on a Deviation Report, it shall promptly notify Bayer, such Products shall be considered Nonconforming Products and the provisions of Section 6.1 shall apply. For purposes of this Agreement, a “Type I Incident” shall be defined as an unexpected result that has potential serious impact on product safety, identity, strength, quality, purity, efficacy or manufacturing/testing process. Examples of Type I Incidents include final product sterility and stability failure, media fill failure, pyrogen specification exceeded for bulk or final container and inadequate viral inactivation process. For purposes of this Agreement, a “Type II Incident” shall be defined as an unexpected result that has the potential to affect product safety, identity, strength, quality, purity, efficacy, or manufacturing/testing process. Examples of Type II Incidents include clean steam exceeding action level for LAL and Presterile in-process bioburden exceeding action level.  
 (ii) If during the manufacture, processing, storage, distribution, testing, transport, disposal or other handling of the Inputs by Purchaser there arises a result that is classified as either a Type I Incident or a Type II Incident, then Purchaser shall prepare within seven (7) days following the discovery of such deviation a Deviation Report and promptly send to Bayer such Deviation Report prior to Purchaser’s delivery of the Inputs which is the subject of such report. If Bayer  
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 rejects a shipment of the Inputs based on a Deviation Report, it shall promptly notify Purchaser, such Inputs shall be considered Nonconforming Inputs and the provisions of Section 6.1 shall apply.  
 ARTICLE 7 CONFIDENTIALITY  
7.1 Confidentiality Obligations. All information provided by one Party to the other Party in connection with this Agreement (including without limitation, the Product Specifications and Input Specifications and forecasts provided by Purchaser) shall be maintained in strict confidence by the receiving Party. Such information shall remain the property of the providing Party, and the receiving Party shall not make use of any such information except for the purposes for which it was provided. At the termination of this Agreement, the receiving Party shall promptly return to the providing Party any physical embodiments (including copies) of any such information. Each Party agrees to keep confidential the existence of this Agreement, as well as all of its terms and conditions; provided that if a public announcement or disclosure is required by law, rule, regulation, court order, subpoena, interrogatory or other discovery request (including without limitation applicable securities laws or stock exchange regulations), and subject to Section 7.2(v), the Party required to make the public announcement or disclosure shall be permitted to make such disclosure and shall provide prompt prior written notice of such requirement to the other Party, and the Parties shall thereafter negotiate in good faith, to the extent appropriate and feasible, the contents of the public announcement or disclosure.  
 7.2 Exceptions. The covenants of the receiving Party contained in Section 7.1 shall not apply to information which: (i) is already in the public domain at the time of disclosure; (ii) becomes part of the public domain through no action or omission of the receiving Party after disclosure to the receiving Party; (iii) is already known to the receiving Party on a non-confidential basis at the time of disclosure, as evidenced by the receiving Party’s written records, except for information that was known to Bayer prior to the Effective Date; (iv) has been or is disclosed to the receiving Party in good faith by a third party who was or is not, at the time of disclosure, under any obligation of confidence to the other Party hereto at the time the third party disclosed such information; or (v) is required to be disclosed by law, provided that the receiving Party shall cooperate with the disclosing Party (at the disclosing Party’s expense) in obtaining any available protection for such information to be disclosed.  
 7.3 Term of Obligations. This Article 7 shall survive termination of this Agreement for a period of five (5) years.  
 ARTICLE 8 WARRANTIES AND COVENANTS  
8.1 General. (i) Bayer represents and warrants as of the time immediately prior to the Closing (as defined in the Contribution Agreement) that the manufacture, processing, testing, distribution, transport, storage, disposal and other handling of the Inputs by Bayer until delivery to and processing at the Bayer Facility (i) conformed to the SOPs relating to the Inputs, the Input Specifications, cGMPs and the Regulations and (ii) were free from defects in materials and  
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 workmanship and were not adulterated or misbranded within the meaning of applicable Regulations.  
 (ii) Purchaser represents and warrants that the manufacture, processing, testing, distribution, transport, storage, disposal and other handling of the Inputs by Purchaser until delivery to and processing by Bayer shall (i) conform to the SOPs relating to the Inputs, the Input Specifications, cGMPs and the Regulations and (ii) be free from defects in materials and workmanship and shall not be adulterated or misbranded within the meaning of applicable Regulations. Purchaser shall deliver a certificate of analyses with each shipment of the Inputs specifying the results of its testing and analysis to show conformance with the Input Specifications. Similarly, Bayer represents and warrants that the Manufacturing Services until the Products are delivered to and processed by Purchaser shall (i) conform to the SOPs relating to the Manufacturing Services, the Product Specifications, cGMPs and other Regulations and (ii) be free from defects in materials and workmanship and shall not be. adulterated or misbranded within the meaning of applicable Regulations. Either Party shall be entitled to request the other Party to change the Input Specifications or Product Specifications, as applicable, or SOPs where, in such Party’s sole discretion, such change would benefit the production of the Products and the other Party shall use commercially reasonable efforts to accommodate such change; provided that the Party making such request will reimburse the other Party the reasonable direct costs the other Party incurs in making any such change; provided further that the Parties shall engage in good faith negotiations to adjust the price set forth in Section 3.1 to reflect the increase or decrease of ongoing costs of processing the Products hereunder resulting from any such change; provided further that if the Parties cannot reach agreement to adjust the price pursuant to this Section 8.1 despite such good faith negotiations, then (i) if the requested modifications will affect only the Product operations of such Party at either the Bayer Facility or the Purchaser’s Facility, as applicable, the matter shall be resolved in accordance with Section 12.9, or (ii) if the requested modifications will, in the sole discretion of the affected Party, adversely affect in any material manner other operations of such Party at either the Bayer Facility or the Purchaser’s Facility, as applicable, separate from the Product operations of such Party at either the Bayer Facility or the Purchaser’s Facility, as applicable, such Party shall not be required to make any such modifications until the Parties reach such agreement.  
 8.2 Intellectual Property. (i) Bayer represents and warrants as of the time immediately prior to the Closing (as defined in the Contribution Agreement) that the manufacture, processing, testing, distribution, transport, storage, disposal and other handling of the Inputs did not infringe the intellectual property rights of any third party and that Bayer validly possessed all licenses to third party intellectual property necessary or appropriate for the manufacture, processing, testing, distribution, transport, storage disposal and other handling of the Inputs.  
 (ii) During the Term of this Agreement, Purchaser represents and warrants that the manufacture, processing, testing, distribution, transport, storage, disposal and other handling of the Inputs pursuant to this Agreement will not infringe the intellectual property rights of any third party; provided that for purposes of making this representation and warranty Purchaser is entitled to rely to the extent applicable on the representations and warranties made by Bayer as of the Closing Date (as defined in the Contribution Agreement) pursuant to the Contribution Agreement for so long as such representations and warranties survive in the Contribution Agreement. During the Term of this Agreement, Purchaser agrees to maintain at its sole cost and  
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 expense all licenses to third party intellectual property necessary or appropriate for the manufacture, processing, testing, distribution, transport, storage, disposal and other handling of the Inputs. Purchaser grants to Bayer a fully paid, non-exclusive right and license to use Purchaser’s intellectual property listed on Exhibit J attached hereto and incorporated herein by reference solely for the purpose of performing the Manufacturing Services, during the term of this Agreement. The grant of this license in such intellectual property in no way provides Bayer any rights in or authorization to use any other intellectual property of Purchaser.  
 8.3 Representations and Warranties.  
(a) Bayer hereby represents and warrants to Purchaser that:  
(i) Due Organization, Good Standing and Power. Bayer is a limited liability company duly organized, validly existing and in good standing under the laws of the state of Delaware. Bayer has all requisite corporate or other power and authority to own or lease and to operate its assets and to conduct the business now being conducted by it. Bayer is duly authorized, qualified or licensed to do business as a foreign corporation or other organization in good standing in each of the jurisdictions in which its ownership of property or the conduct of its business requires such authorization, qualification or licensing, except where the failure to have such authorization, qualification or licensing could not reasonably be expected to have a material adverse effect on Bayer or on the consummation of the transactions contemplated hereunder. Bayer has all requisite corporate power and authority under Applicable Law and its Charter Documents to enter into this Agreement and to perform its obligations hereunder and to consummate the transactions contemplated hereby.  
(ii) Authorization and Validity of Agreement. The execution and delivery of this Agreement by Bayer and the consummation by it of the transactions contemplated hereby have been duly authorized and approved by all necessary corporate action under Applicable Law and the relevant Charter Documents on the part of Bayer and do not require the approval of the stockholders of Bayer. This Agreement has been duly executed and delivered by Bayer and constitutes the legal, valid and binding obligation of Bayer enforceable against it in accordance with its terms, except as that enforceability may be (i) limited by any applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors’ rights generally, (ii) subject to general principles of equity (regardless of whether that enforceability is considered in a proceeding in equity or at law) and (iii) limited by general principles of Applicable Law regarding the enforceability of arbitral awards and judicial decisions.  
(iii) Lack of Conflicts. Neither the execution and delivery of this Agreement by Bayer or the consummation by it of the transactions contemplated hereby, does or will (i) conflict with, or result in the breach of any provision of, the Charter Documents of Bayer or (ii) violate any Applicable Law or any permit, order, award, injunction, decree or judgment of any Governmental Authority applicable to or binding upon Bayer or to which any of its properties or assets is subject.  
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(iv) No Consents. The execution, delivery and performance of this Agreement by Bayer and the consummation of the transactions contemplated by this Agreement do not require any Governmental Approval. No consent (other than Governmental Approvals) will be required to he obtained by Bayer for the consummation of the transactions contemplated by this Agreement.  
 (b) Purchaser hereby represents and warrants to Bayer that:  
(i) Due Organization, Good Standing and Power. Purchaser is a corporation duly organized, validly existing and in good standing under the laws of the state of Delaware. Purchaser has all requisite corporate or other power and authority to own or lease and to operate its assets and to conduct the business now being conducted by it. Purchaser is duly authorized, qualified or licensed to do business as a foreign corporation or other organization in good standing in each of the jurisdictions in which its ownership of property or the conduct of its business requires such authorization, qualification or licensing, except where the failure to have such authorization, qualification or licensing could not reasonably be expected to have a material adverse effect on Purchaser or on the consummation of the transactions contemplated hereunder. Purchaser has all requisite corporate power and authority under Applicable Law and its Charter Documents to enter into this Agreement and to perform its obligations hereunder and to consummate the transactions contemplated hereby.  
(ii) Authorization and Validity of Agreement. The execution and delivery of this Agreement by Purchaser and the consummation by it of the transactions contemplated hereby have been duly authorized and approved by all necessary corporate action under Applicable Law and the relevant Charter Documents on the part of Purchaser and do not require the approval of the stockholders of Purchaser. This Agreement has been duly executed and delivered by Purchaser and constitutes the legal, valid and binding obligation of Purchaser enforceable against it in accordance with its terms, except as that enforceability may be (i) limited by any applicable bankruptcy, insolvency, reorganization, moratorium or similar laws affecting the enforcement of creditors’ rights generally, (ii) subject to general principles of equity. (regardless of whether that enforceability is considered in a proceeding in equity or at law) and (iii) limited by general principles of Applicable Law regarding the enforceability of arbitral awards and judicial decisions.  
(iii) Lack of Conflicts. Neither the execution and delivery of this Agreement by Purchaser or the consummation by it of the transactions contemplated hereby, does or will (i) conflict with, or result in the breach of any provision of, the Charter Documents of Purchaser or (ii) violate any Applicable Law or any permit, order, award, injunction, decree or judgment of any Governmental Authority applicable to or binding upon Purchaser or to which any of its properties or assets is subject.  
(iv) No Consents. The execution, delivery and performance of this Agreement by Purchaser and the consummation of the transactions contemplated by this Agreement do not require any Governmental Approval. No consent (other than Governmental  
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 Approvals) will be required to be obtained by Purchaser for the consummation of the transactions contemplated by this Agreement.  
ARTICLE 9 INDEMNITIES AND DAMAGES  
9.1 Indemnifications. Purchaser hereby agrees to save, defend and hold Bayer and its affiliates and its or their directors, officers, managers, employees, representatives, consultants, stockholders, controlling persons and agents and each of the heirs, executors, successors and assigns of any of the foregoing (together, the “Bayer Group”) harmless from and against any and all claims, suits, actions, liabilities, expenses and/or losses, including punitive or exemplary damages and reasonable attorneys’ fees and expenses (“Claims”) asserted by a person or entity other than a member of the Bayer Group arising from any material breach of obligations under this Agreement by the Purchaser Group (as defined below); provided that any Claims for failure to deliver Inputs in accordance with the terms of this Agreement shall be deemed a material breach. Bayer hereby agrees to save, defend and hold Purchaser and its affiliates and its or their directors, officers, managers, employees, representatives, consultants, stockholders, controlling persons and agents and each of the heirs, executors, successors and assigns of any of the foregoing (together, the “Purchaser Group”) harmless from and against any and all Claims asserted by a person or entity other than a member of the Purchaser Group arising from any material breach of obligations under this Agreement by the Bayer Group; provided that failure to deliver Products in accordance with the terms of this Agreement shall be governed exclusively under Section 9.4 hereof Where a Claim arises directly or indirectly from acts or omissions of both (i) the Purchaser Group and (ii) the Bayer Group, the obligation of the Purchaser or Bayer to indemnify the other shall not exceed the extent of the indemnifying party’s contribution to the harm giving rise to the Claim.  
 9.2 Indemnification Process. Each party indemnified under the provisions of this Agreement, upon receipt of written notice of any Claim or the service of a summons or other initial legal process upon it in any action instituted against it for which it may be entitled to indemnification pursuant to this Agreement, shall promptly give written notice of such Claim, or the commencement of such action, or threat thereof, to the Party from whom indemnity shall be sought hereunder; provided, however, that the failure to provide such notice within a reasonable period of time shall not relieve the indemnifying party of any of its obligations hereunder except to the extent the indemnifying party is prejudiced by such failure. Each indemnifying party shall be entitled at its own expense to participate in the defense of such Claim or action, or, if it shall elect, so long as it has acknowledged in writing to the indemnified party its indemnification obligations hereunder, by written notice to the indemnified party within twenty (20) days of receipt of notice of the Claim or action from the indemnified party to assume such defense, in which event such defense shall be conducted by counsel chosen by such indemnifying party (without prejudice to the right of the indemnified party to fully participate at its own expense through counsel of its own choosing) which counsel may be any counsel reasonably satisfactory to the indemnified party against whom such Claim is asserted or who shall be the defendant in such action, and such indemnified party shall bear all fees and expenses of any additional counsel retained by it or them, provided that the indemnifying party shall obtain the consent of the indemnified party (which consent may be withheld in its sole discretion) before entering into any settlement, adjustment or compromise of such Claims, provided further that the indemnifying party may, without the consent of the indemnified party, settle or compromise or  
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 consent to the entry of any judgment in any action involving only the payment of money which includes as an unconditional term thereof the delivery by the claimant or plaintiff to the indemnified party of a duly executed written release of the indemnified party from all liability in respect of such Claim or action which written release shall be reasonably satisfactory in form and substance to the indemnified party. Notwithstanding the immediately preceding sentence, if the named parties in such action (including impleaded parties) include the indemnified and the indemnifying parties, and the indemnified party shall have been advised by counsel that there may be a conflict between the positions of the indemnifying party and the indemnified party in conducting the defense of such action or that there are legal defenses available to such indemnified party different from or in addition to those available to the indemnifying party, then counsel for the indemnified party, shall be entitled, if the indemnified party so elects, to conduct the defense to the extent reasonably determined by such counsel to be necessary to protect the interests of the indemnified party, at the expense of the indemnifying party. If the indemnifying party shall elect not to assume the defense of such Claim or action, such indemnifying party shall reimburse such indemnified party for the reasonable fees and expenses of any counsel retained by it, and shall be bound by the results obtained by the indemnified party in respect of such Claim or action; provided, however, that no such Claim or action shall be settled without the written consent of the indemnifying party (which consent shall not be unreasonably withheld or delayed).  
 9.3 Insurance. During the Term of this Agreement and for a period of at least two (2) years following the expiration or earlier termination of this Agreement, each Party shall maintain, at its sole cost and expense, general liability insurance, including product liability coverage, with bodily injury, death and property damage limits, in such amounts and with such scope of coverage as is consistent with plasma industry standards. Each Party shall have its insurance carrier furnish to the other Party certificates stating that all insurance required under this Agreement is in force. Such certificates shall indicate any deductible and self-insured retention and the effective expiration dates of the policies. All certificates are to stipulate that the other Party shall be given thirty (30) days written notice of all cancellation, non-renewal or material changes in policy. Each Party shall be named as an additional insured on all insurance policies obtained by the other Party in accordance with this Section 9.3. Each Party also agrees to waive and will require its insurers to waive all rights of subrogation against the other Party, its directors, officers and employees on all of the foregoing coverages.  
 9.4 Liquidated Damages For Failure To Deliver Products. (a) The Parties acknowledge that the anticipated damages to Purchaser in the event of a failure by Bayer to deliver the Products to Purchaser for a prolonged period of time is incapable of accurate estimation as of the Effective Date.  
 (b) Subject to the last sentence of this subsection (b), in the event at the conclusion of any month Bayer has failed to deliver during the immediately preceding rolling twelve (12) months an amount of Column Eluate which conforms to the Product Specifications aggregating at least seventy-five percent (75%) of the Orders for the immediately preceding rolling twelve (12) months (“Column Eluate Threshold Deliveries”) and such failure is not the result of Force Majeure or Purchaser’s failure to deliver Inputs meeting the Input Specifications to Bayer in accordance with this Agreement (each, a “Column Eluate Triggering Event”), then Bayer shall promptly pay Purchaser liquidated damages as follows:  
 20  
  
 For each month following a Column Eluate Triggering Event Bayer fails to make Column Eluate Threshold Deliveries, Bayer shall initially pay $250,000;  
 After Bayer has failed to make Column Eluate Threshold Deliveries for two consecutive months following a Column Eluate Triggering Event, Bayer shall thereafter pay $500,000 per month for each following consecutive month in which Bayer fails to make Column Eluate Threshold Deliveries; and  
 After Bayer has failed to make Column Eluate Threshold Deliveries for five consecutive months following a Column Eluate Triggering Event, Bayer shall pay $1 million per month for each additional consecutive month in which Bayer fails to make Column Eluate Threshold Deliveries.  
 The first rolling twelve (12) months shall commence on the first day of the calendar month immediately following the Effective Date (the “Commencement Date”). Any liability for payment of damages specifically under this Section 9.4(b) shall not arise before the first day of the thirteenth month after the Commencement Date.  
 (c) In no event shall the aggregate amount of liquidated damages payable by Bayer for all such incidences to Purchaser pursuant to subsection (b) above exceed $15 million (the “Column Eluate Cap”). From January 1, 2007 through December 31, 2008, the Column Eluate Cap shall be reduced to an amount equal to $7.5 million minus the aggregate liquidated damages payable by Bayer pursuant to subsection (b) above from the Effective Date through December 31, 2006, but not less than zero. No liquidated damages shall be payable by Bayer pursuant to subsection (b) after December 31, 2008.  
 (d) Subject to the last sentence of this subsection (d), in the event at the conclusion of any month Bayer has failed to deliver during the immediately preceding rolling twelve (12) months an amount of ATIII which conforms to the Product Specifications aggregating at least seventy-five percent (75%) of the Orders for the immediately preceding rolling twelve (12) months (“ATIII Threshold Deliveries” and together with the Column Eluate Threshold Deliveries, the “Threshold Deliveries”) and such failure is not the result of Force Majeure or Purchaser’s failure to deliver Inputs meeting the Input Specifications to Bayer in accordance with this Agreement (each, a “ATIII Triggering Event”), Bayer shall pay Purchaser liquidated damages as follows:  
 For each month following an ATIII Triggering Event Bayer fails to make ATIII Threshold Deliveries, Bayer shall initially pay $37,500;  
 After Bayer has failed to make ATIII Threshold Deliveries for two consecutive months following an ATIII Triggering Event, Bayer shall thereafter pay $75,000 per month for each following consecutive month in which Bayer fails to make ATIII Threshold Deliveries; and  
 After Bayer has failed to make ATIII Threshold Deliveries for five consecutive months following an ATIII Triggering Event, Bayer shall pay $150,000 per month for each additional consecutive month in which Bayer fails to make ATIII Threshold Deliveries.  
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 The first rolling twelve (12) months shall commence on the Commencement Date. Any liability for payment of damages specifically under this Section 9.4(d) shall not arise before the first day of the thirteenth month after the Commencement Date.  
 (e) In no event shall the. aggregate amount of liquidated damages payable by Bayer for all such incidences to Purchaser pursuant to subsection (d) above exceed $1.75 million (the “ATIII Cap”). From January 1, 2007 through December 31, 2008, the ATIII Cap shall be reduced to an amount equal to $875,000 minus the aggregate liquidated damages payable by Bayer pursuant to subsection (d) above from the Effective Date through December 31, 2006, but not less than zero. No liquidated damages shall be payable by Bayer pursuant to subsection (d) after December 31, 2008.  
 (f) If the liquidated damages provision provided for in this Section 9.4 is deemed unenforceable for any reason by a court of competent jurisdiction, Bayer shall pay an amount to Purchaser equal to the direct damages or losses incurred by Purchaser, including without limitation all lost profits, costs of cover and delivery penalties but excluding consequential damages as a result of Bayer’s failure to deliver Products, subject to the Column Eluate Cap and the ATIII Cap, as applicable.  
 (g) For the avoidance of doubt, the requirement to pay liquidated damages in this Section 9.4 only applies where there has been a failure of Bayer to make Threshold Deliveries and nothing in this Section 9.4 shall be construed as relieving Bayer of liability for its failure to deliver Products which conform to the Product Specifications in the amounts required by Sections 2.1, 2.4 or 2.9 and/or meeting the requirements set forth in Section 2.5 in circumstances (other than Force Majeure) where Bayer has made Threshold Deliveries, but has not made full deliveries of the Products in full compliance with an Order presented in accordance with Section 2.9 (“Circumstance of Under-Delivery”) to the extent provided in this Section 9.4(g). In the event at the conclusion of any month Bayer has failed to deliver during the immediately preceding rolling three (3) months Products which conform to the Product Specifications in an amount aggregating one hundred percent (100%) of the Orders for the immediately preceding. rolling three (3) months and Purchaser suffers direct damages as a result thereof, Purchaser may notify Bayer to that effect, in which case Bayer shall have three additional months within which to deliver such Products. If Bayer does in fact deliver such Products within such period, then no damages shall apply for such Circumstances of Under-Delivery. If Bayer does not deliver such Products within such period, then Bayer shall be liable to Purchaser for all direct damages or losses Purchaser suffers, including without limitation all lost profits, cost of cover and delivery penalties but excluding consequential damages for each Circumstance of Under-Delivery in an amount not exceeding, for that calendar year twice the amount of all revenues to Bayer from this Agreement for such calendar year (calculated as though it had complied with its delivery obligations in such calendar year based on actual Orders plus the rolling forecast issued the month prior to the 3-month period of underdelivery, as to those months for which Orders had not yet been issued), provided that any such recovery shall be reduced by (i) any amounts previously paid pursuant to Section 9.4(b) and (d) and (ii) any amount that Purchaser actually recovers under any insurance it maintains.  
 The first rolling three (3) months shall commence on the date that is four (4) months following the Commencement Date.  
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 (h) The rights and remedies of Purchaser provided in this Section 9.4 shall be Purchaser’s exclusive remedy for recovery of monetary damages with respect to Bayer’s failure to deliver Products in amounts required by this Agreement. Purchaser shall have such non-monetary rights and remedies provided under this Agreement or under law or in equity for Bayer’s failure to deliver Products in amounts required by this Agreement, but only limited to the remedy of specific performance.  
 9.5 Insurance Recoveries. If and to the extent the indemnifying party has acquired insurance in compliance with Section 9.3, and to the extent such coverage is inadequate to cover all Claims asserted against Purchaser and Bayer and if and to the extent Purchaser or Bayer, as the case may be, has its own policy of insurance purporting to provide coverage for Claims against Purchaser or Bayer, as the case may be, Purchaser or Bayer, as the case may be, shall not be entitled to indemnification from the indemnifying party for such Claims under Section 9.1 until Purchaser or Bayer, as the case may be, has utilized all commercially reasonable means to recover such loss under its policy of insurance.  
 9.6 Aggregate Caps. In no event shall Bayer have liability under this Section 9.4 for non-delivery of Products greater than $11 million in the case of ATM or $23 million in the case of Column Eluate.  
 ARTICLE 10 DISCLAIMER  
EACH PARTY MAKES NO REPRESENTATIONS OR WARRANTIES, EXPRESS OR IMPLIED, OTHER THAN THOSE EXPRESSLY MADE IN THIS AGREEMENT. ALL OTHER WARRANTIES, EXPRESS OR IMPLIED, INCLUDING, WITHOUT LIMITATION, THE IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE, ARE HEREBY DISCLAIMED.  
 ARTICLE 11 FORCE MAJEURE  
For the purpose of this Agreement, “Force Majeure” shall mean only (i) acts of God, acts of the public enemy, insurrections, riots, sabotage, strike, work-stoppage or other labor dispute and natural disasters; (ii) explosions, fires, flood damage, or loss of electric power not resulting from the negligence of the Party invoking Force Majeure; (iii) regulatory actions not attributable to any violation of law after the date hereof on the part of Purchaser or Bayer, as the case may be, unless, in the case of Purchaser, Purchaser is required as a result of any statute, law; regulation, ordinance, rule, judgment, code, order, decree or other requirement of a Regulatory Authority (“Applicable Law”), not initiated by Purchaser, to cease or materially curtail production primarily based upon (x) violation of any Applicable Law which violation was in existence on the Effective Date or (y) any condition in existence on the Effective Date or any condition alleged in writing to have been in existence on or prior to the Effective Date by a Regulatory Authority which condition remained outstanding on the Effective Date and which condition constituted a violation or alleged violation of Applicable Law or impacts the safety or efficacy of the Products; and (iv) in the case of Purchaser, events, circumstances, conditions and actions outside of the control of Purchaser that materially and adversely affect the plasma-derived products industry generally, including interruptions of supply of raw plasma due to viral outbreaks, eruption of new viruses and similar events, that are reasonably likely to be subject to  
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 action by any Regulatory Authority; any of (i), (ii), (iii) or (iv) of which, in the case of the Purchaser, prevents the Purchaser from performing its obligations under this Agreement, or, any of (i), (ii) or (iii) of which, in the case of Bayer, prevents Bayer from performing its obligations under this Agreement; provided that nothing in clause (iii) or (iv) shall excuse Purchaser from complying with cGMPs or excuse Purchaser from remedying those matters which were capable of remedy by Purchaser through the application of commercially reasonable efforts prior to the occurrence of the events identified in (iii) or (iv) preventing Purchaser from performing under the Agreement. Notwithstanding anything in this Agreement to the contrary, except Article 7 and Article 12, the Party experiencing the Force Majeure shall be excused from the performance of each of its obligations under this Agreement upon a Force Majeure, but only to the extent performance of any such obligation is necessarily prevented, hindered or delayed thereby and only during the continuance of any such Force Majeure, and shall have no liability for damages arising from non-performance of any obligation excused by a Force Majeure. The Party suffering such Force Majeure shall invoke this provision by promptly notifying the other Party in writing of the nature and estimated duration of the suspension period, as well as the extent to which it will be unable to fulfill its obligations under this Agreement. Each Party shall be relieved of performance of its obligations under this Agreement during the time when it is prevented from performing by the failure of the other Party to perform its obligations or because of any event of Force Majeure.  
 ARTICLE 12 MISCELLANEOUS  
12.1 Consent to Assignment. This Agreement and all of the provisions hereof shall be binding upon and inure to the benefit of the Parties hereto and their respective successors and assigns, and it is not intended to confer upon any other person any rights or remedies hereunder. Neither this Agreement nor any of the rights, interests or obligations hereunder may be assigned by any of the Parties without the prior written consent of the other Party hereto, except that each Party may at any time assign any or all of its rights or obligations hereunder to one of its wholly owned subsidiaries (but no such assignment shall relieve such Party of any of its obligations under this Agreement). Notwithstanding the foregoing, Purchaser may assign this Agreement and any or all rights or obligations hereunder to (i) any affiliate of Purchaser provided that any such affiliate becomes a party to this Agreement, (ii) any lender of Purchaser as collateral security or (iii) any successor in interest to Purchaser, provided that any such successor becomes a party to this Agreement; provided that no assignment under (i), (ii) or (iii) above shall relieve Purchaser from any obligation hereunder. Bayer may assign this Agreement and any or all rights or obligations hereunder to (i) any affiliate of Bayer provided that any such affiliate becomes a party to this Agreement or (ii) any successor in interest to the Bayer Facility provided that any such successor becomes a party to this Agreement; provided that no assignment under (i) or (ii) above shall relieve Bayer from any obligations hereunder. Any purported assignment in contravention of this Section 12.1 shall be void.  
 12.2 Entire Agreement and Amendments. This Agreement, together with the Exhibits, constitutes the entire agreement between the Parties, and merges and supersedes all previous agreements and understandings between Purchaser and Bayer, whether oral or written, relating to the subject matter hereof. No amendment, modification or interpretation of this Agreement will have any effect unless it is reduced to writing, makes specific reference to this Agreement and is  
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 signed by all of the Parties. In the event that this Agreement conflicts with any Order, invoice or other written document, the terms and conditions of this Agreement shall apply.  
 12.3 Notices. All notices, requests, demands and other communications required or permitted hereunder shall be in writing and if mailed by prepaid first class mail or certified mail, return receipt requested, at any time other than during a general discontinuance of postal service due to strike, lockout or otherwise, shall be deemed to have been received on the earlier of the date shown on the receipt or three (3) business days after the postmarked date thereof and, if telexed or telecopied, the original notice shall be mailed by prepaid first class mail within twenty-four (24) hours after sending such notice by telex or telecopy, and shall be deemed to have been received on the next business day following dispatch and acknowledgment of receipt by the recipient’s telex or telecopy machine. In addition, notices hereunder may be delivered by hand, in which event the notice shall be deemed effective when delivered, or by overnight courier, in which event the notice shall be deemed to have been received on the next business day following delivery to such courier. All notices and other communications under this Agreement shall be given to the parties hereto at the following addresses:  
 If to Bayer:  
 Bayer HealthCare LLC  
 Biological Products Division  
 000 Xxxxxx Xxx  
 X.X. Xxx 0000  
 Xxxxxxxx, XX 00000  
 Attention: Contracts Manager  
 With a copy to:  
 Bayer HealthCare LLC  
 000 Xxxxxx Xxxx  
 Xxxx Xxxxx, XX 00000-0000  
 Attention: General Counsel  
 Xxxxxxx Xxxxxx  
 Fulbright & Xxxxxxxx L.L.P.  
 000 Xxxxxxxxxxxx Xxxxxx, X.X.  
 Xxxxxxxxxx, X.X. 00000  
 If to Purchaser:  
 Talecris Biotherapeutics, Inc.  
 X.X. Xxx 00000  
 79 XX Xxxxxxxxx Drive  
 4101 Research Commons  
 Xxxxxxxx Xxxxxxxx Xxxx  
 Xxxxxxx, XX 00000  
 Fax: (000) 000-0000  
 25  
  
 With a copy to:  
 Xxxxxx X. Xxxxxxx, Esq.  
 Xxxxxxxx & Xxxxxxxx LLP  
 0000 Xxxxxxx Xxxx Xxxx  
 Xxxxx 0000  
 Xxx Xxxxxxx, XX 00000  
 Fax: (000) 000-0000  
 Xxxxxxx X. Xxxxxxxxxx, Esq.  
 Xxxxxx & Xxxxxxx LLP  
 000 00xx Xxxxxx, X.X.  
 Xxxxx 0000  
 Xxxxxxxxxx, X.X. 00000  
 Fax: (000) 000-0000  
 Any Party hereto may change its address specified for notices herein by designating a new address by notice in accordance with this Section 12.3.  
 12.4 Independent Contractor. This Agreement does not create an employer-employee. relationship between the Parties, and is not an agency, joint venture or partnership. Neither Party shall have the authority to act for the other or to bind the other in any way, nor to sign the name or to represent that the other is in any way responsible for the acts or omissions of the other. Bayer shall maintain its status as an independent contractor engaged in the selling of Products to Purchaser.  
 12.5 Non-Waiver. The waiver by either Party of any breach of any term, covenant, condition or agreement contained herein or any default in the performance of any obligations hereunder shall not be deemed to be a waiver of any other breach or default of the same or of any other term, covenant, condition, agreement or obligation.  
 12.6 Choice of Law. The rights and obligations of the Parties arising out of the Agreement shall be governed in all respects by the laws of the State of New York, without giving effect to its conflict of laws provisions.  
 12.7 Captions. All captions are inserted for convenience only, and will not affect any construction or interpretation of this Agreement.  
 12.8 Severability. Any provision of this Agreement which is or may become prohibited or unenforceable, as a matter of law or regulation, will be ineffective only to the extent of such prohibition or unenforceability and shall not invalidate the remaining provisions hereof if the essential purposes of this Agreement may be given effect despite the prohibition or unenforceability of the affected provision.  
 12.9 Dispute Resolution.  
(a) Resolution by the Parties. The Parties shall attempt to resolve any dispute, controversy, claim or difference arising out of or in connection with, this Agreement amicably and promptly by  
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 negotiations between executives who have authority to settle the controversy. Either Party may give(the other Party written notice of any dispute not resolved in the normal course of business (“Notice of Dispute”). Within seven (7) days after delivery of such Notice of Dispute, executives of the Parties shall agree to meet at a mutually acceptable time and place, and thereafter, as often as they reasonably deem necessary, to attempt to resolve the dispute. If the matter has not been resolved within ten (10) days of the first meeting of such executives (or, if the Parties are unable to mutually agree upon an acceptable time and place to meet, within ten (10) days of the disputing Party’s Notice of Dispute), either Party may, by notice to the other Party (“Dispute Escalation Notice”), refer the matter to the respective officers of the Parties designated below.  
 For Bayer: Executive Vice President, Bayer HealthCare LLC and President, Biological Product Division  
 With a copy to:  
 Bayer HealthCare LLC  
000 Xxxxxx Xxxx  
Xxxx Xxxxx, XX 00000-0000  
Attention: General Counsel  
 For Purchaser: Chief Executive Officer, Talecris Biotherapeutics, Inc.  
 Such officers shall negotiate in good faith to resolve the matter in an amicable manner within ten (10) days of the Dispute Escalation Notice. In the event the matter is not resolved within such ten (10) days, either Party may initiate arbitration of the dispute as provided for in this Section 12.9.  
 (b) Binding Arbitration. In any event, if the dispute, other than with respect to Section 3.2(ii) or Article 4, is not resolved in accordance with Section 12.9(a) within thirty (30) days of the date in which such dispute arose, either Party may submit the dispute to binding arbitration by giving the other Party notice (the “Arbitration Notice”). Such arbitration shall be conducted in accordance with the then valid Commercial Arbitration Rules, in effect as of the Effective Date, of the American Arbitration Association (the “Rules”). The arbitration shall be held in the English language in New York, New York (U.S.) in accordance with the substantive law of the State of New York, without giving effect to its conflict of laws provisions. The arbitration will be conducted by one (1) arbitrator knowledgeable in the subject matter that is at issue in the dispute and who is selected by mutual agreement of the Parties or, failing such agreement by thirty (30) days after the Arbitration Notice was given, will be selected according to the Rules. Either Party reserves the right to object to any individual arbitrator who shall be employed by or affiliated with a competing organization. The arbitrator shall render a decision no later than ninety (90) days from the date of such arbitrator’s selection. The award of the arbitrator shall be final and binding on both Parties. Each Party hereby submits itself to the jurisdiction of the courts of the place where arbitration is held, but only for the entry of judgment with respect to the decision of the arbitrator hereunder. Notwithstanding the foregoing, judgment upon the award may be entered in any court in the state where the arbitration takes place, or any court having jurisdiction over the Parties. In the event of any actual or threatened breach or default which could give rise to irreparable harm, nothing in this Agreement shall prevent either Party from seeking injunctive relief (or any other provisional remedy or equitable relief) from any court having jurisdiction over the Parties and the subject matter of this  
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 dispute to protect their respective rights pending the outcome of arbitration. The Parties bind themselves to carry out the awards of the arbitrator. The fees and expenses of the arbitrators, the fees and expenses of the court report and any expense for a hearing room, and reasonable attorney’s fees may be awarded to the prevailing party by the arbitrator, or if such award is not made, will be shared equally by the Parties. The Parties will otherwise bear their respective expenses of arbitration.  
 (c) Reviewing Accountant. If the Parties fail to resolve under Section 12.9(a) any dispute arising under Section 3.2(ii) within forty-five (45) days, the Parties shall select a firm of independent certified public accountants of national standing (the “Reviewing Accountant”) to resolve the areas of dispute or, if the Parties fail to agree upon a Reviewing Accountant within twenty (20) days after the 45-day period lapses, such firm shall be selected by lot from among all so-called “Big Four” firms not having (and not having announced a pending combination with another firm having) a disqualifying interest with respect to either Party. The performance of any such firm as the Reviewing Accountant under this Agreement shall not constitute a disqualifying interest. The Parties shall make available to the Reviewing Accountant all work papers and all other information and material in their possession relating to the matters in dispute. The Reviewing Accountant shall be instructed by the Parties to use its best efforts to deliver to the Parties its determination as promptly as practicable after such submission of the dispute to the Reviewing Accountant. The determination of the Reviewing Accountant shall be final and binding on the Parties. Each Party shall bear its own expenses and the fees and expenses of its own representatives and experts, including its independent accountant, in connection with the preparation, review, dispute (if any) and final resolution of the dispute. The Parties shall share equally in the costs, expenses and fees of the Reviewing Accountant.  
12.10 Defined Terms. Defined terms used but not otherwise defined in this Agreement shall have the meaning ascribed to those terms in the Contribution Agreement.  
 12.11 Set-Off. No Party to this Agreement shall have any right of set off with respect to amounts it has an obligation to pay hereunder.  
 (Remainder of this page has been intentionally left blank)  
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 IN WITNESS WHEREOF, the Parties have caused their duly authorized representatives to execute this Agreement as of the Effective Date.  
 BAYER HEALTHCARE LLC  
 Biological Products Division - Berkeley  
Facility  
 By:  
/s/ Xxxxxx X. Xxxxx  
 Name:  
Xxxxxx X. Xxxxx  
 Title:  
Executive Vice President  
 BAYER HEALTHCARE LLC  
 Biological Products Division – Berkeley  
Facility  
 By:  
/s/ Xxxxx X. Xxxxxx  
 Name:  
Xxxxx X. Xxxxxx  
 Title:  
Assistant Secretary  
 TALECRIS BIOTHERAPEUTICS, INC.  
 By:  
/s/ Xxxxxxxx X. Xxxxx  
 Name:  
Xxxxxxxx X. Xxxxx  
 Title:  
Executive Chairman. President and  
Chief Executive Officer  
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 Execution Copy  
 Exhibit Index  
to  
Manufacturing Agreement  
between  
Bayer HealthCare LLC and Talecris Biotherapeutics, Inc.  
 Exhibit A  
 Column Eluate Required Quantity and ATIII Required Quantity  
Exhibit B  
 Column Eluate Specifications  
Exhibit C  
 ATIII Specifications  
Exhibit D  
 Fraction IV-I Paste Specifications  
Exhibit E  
 PEG Paste Specifications  
Exhibit F  
 Manufacturing Agreement for Column Eluate  
Exhibit G  
 Manufacturing Agreement for ATIII  
Exhibit H  
 Expected Yield Calculation  
Exhibit I  
 Price  
Exhibit J  
 Purchaser Intellectual Property to be Licensed  
   
Execution Copy  
 EXHIBIT A  
 2005 Product Forecast  
 Intermediate  
 Final  
 Input IV1  
 Product  
 Product  
 Paste  
 Product  
 Eluate  
 ATIII  
 Month  
 (kgs)  
 Harvested  
 (kgs)  
 (vials)  
 Jan  
 [\*\*\*]  
 Eluate and ATIII  
 [\*\*\*]  
 [\*\*\*]  
 Feb  
 [\*\*\*]  
 Eluate and ATIII  
 [\*\*\*]  
 [\*\*\*]  
 Mar  
 [\*\*\*]  
 Eluate and ATIII  
 [\*\*\*]  
 [\*\*\*]  
 Apr  
 [\*\*\*]  
 Eluate only  
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 May  
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 Eluate and ATIII  
 [\*\*\*]  
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 Jun  
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 Eluate only  
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 [\*\*\*]  
 Jul  
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 Eluate only  
 [\*\*\*]  
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 Aug  
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 Eluate and ATIII  
 [\*\*\*]  
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 Sep  
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 Eluate and ATIII  
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 Oct  
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 Eluate only  
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 Nov  
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 Eluate only  
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 Dec  
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 Eluate only  
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 [\*\*\*]  
 Total  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
 Approved by  
 /s/ Authorized Signatory  
 Purchaser  
 Approved by  
 /s/ Authorized Signatory  
 Bayer  
 \* To be updated within 30 days of closing  
 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
Execution Copy  
 EXHIBIT A(Cont’d.)  
 2006 Product Forecast  
 Intermediate  
 Final  
 Input IV1  
 Product  
 Product  
 Paste  
 Product  
 Eluate  
 ATIII  
 Month  
 (kgs)  
 Harvested  
 (kgs)  
 (vials)  
 Jan  
 [\*\*\*]  
 Eluate only  
 [\*\*\*]  
 [\*\*\*]  
 Feb  
 [\*\*\*]  
 Eluate and ATIII  
 [\*\*\*]  
 [\*\*\*]  
 Mar  
 [\*\*\*]  
 Eluate and ATIII  
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 Apr  
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 Eluate and ATIII  
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 May  
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 Eluate and ATIII  
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 Jul  
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 Eluate only  
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 Aug  
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 Eluate and ATIII  
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 Sep  
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 Eluate only  
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 Nov  
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 Dec  
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 [\*\*\*]  
 [\*\*\*]  
 Total  
 [\*\*\*]  
 [\*\*\*]  
 [\*\*\*]  
 Approved by  
 /s/ Authorized Signatory  
 Purchaser  
 Approved by  
 /s/ Authorized Signatory  
 Bayer  
 \* To be updated within 30 days of closing  
 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
 Exhibit B  
 Execution Copy  
 BIOLOGICAL PRODUCTS PURCHASE SPECIFICATION  
SAP MATERIAL #:  
08633072  
08658989  
 REVISION: NEW  
 TITLE:  
ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 1 of 5  
 /s/ Authorized Signatory  
 11-16-04  
 /s/ Authorized Signatory  
 11-16-2004  
Document Owner  
 Date  
 Quality Manager  
 Date  
 Supercedes:  
 Date Effective:  
 Nov 16 2004  
 1. PURPOSE  
 1.1 [\*\*\*]  
 2. REFERENCE(S)  
 2.1. Guidance for Industry, “Cooperative Manufacturing Arrangements for Licensed Biologics” August 1999.  
 2.2. 21 CFR 600 and 200 (appropriate sections).  
 2.3. CS-000-BE-021, “Quality Review and Release of Intermediate Materials Processed at Bayer Berkeley and Shipped to Xxxxx Xxxxxxx.”  
 3. DEFINITIONS  
 3.1. Fraction IV-1 Paste – Refers to a paste fraction obtained by processing U.S. collected source plasma using an FDA approved method that conforms to the process flow specifications as stated in the Bayer PLA/BLA.  
 3.2. [\*\*\*] – Refers to a paste fraction obtained by further processing Fraction IV-1 Paste using an FDA approved method that conforms to the process flow specifications as stated in the Bayer PLA/BLA.  
 3.3. Alpha-1 Column Eluate – Refers to a solution obtained by applying PEG Paste to a chromatography column and subsequently eluting the purified protein from the column by an FDA approved method that conforms to the process flow specifications as stated in the Bayer PLA/BLA.  
 3.4. Date of separation – The date of separation is the date the fraction is separated from the other fractions, it is synonymous with the date of manufacture.  
 3.5. NLT – not less than.  
 3.6. NMT – not more than.  
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 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
 1 of 11  
  
 Exhibit B  
 Execution Copy  
 BIOLOGICAL PRODUCTS PURCHASE SPECIFICATION  
SAP MATERIAL #:  
08633072  
08658989  
 REVISION: NEW  
 TITLE:  
ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 2 of 5  
 4. GENERAL REQUIREMENTS  
 4.1. Acceptable manufacturer/location: Bayer HealthCare, Berkeley, CA facility.  
 4.2. The Alpha-1 Column Eluate must be processed from IV-1 Paste or [\*\*\*] shipped to the Bayer Berkeley facility from approved fractionation facilities, currently the Bayer facility in NC and the Precision facility in Melville, NY.  
 4.3. Manufacturing documents for Column Eluate paste shall be maintained on file for NLT 15 years or the duration of the shelf life of the product plus one year, whichever is longer, and shall be made available upon request by Xxxxx Xxxxxxx during Berkeley escorted audits.  
 4.4. Bayer shall have the right to audit Berkeley’s manufacturing facility and receiving area on an annual basis provided a written request is given to Berkeley to make appropriate arrangement for the requested audit. Such audit will be contingent upon a mutually agreeable time for both parties. If a “for cause” audit is requested by Xxxxx, Xxxxxxx shall provide Berkeley a written request justifying Xxxxxxx’x cause and reason for said audit. Such audit will be contingent upon a mutually agreeable time for both parties and will be accomplished in a reasonable time period.  
 4.5. Berkeley shall notify Xxxxx Xxxxxxx QO Release Manager, Xxxxxxx in the event that as a result of a regulatory audit there are documented findings at Berkeley that would possibly impact product intended for sale to Xxxxxxx or already shipped to Xxxxxxx. In such event, Xxxxxxx would be notified in writing by Berkeley.  
 4.6. Any product already shipped to Xxxxxxx determined not to meet specifications (i. e. discrepant) requires phone notification to the Xxxxxxx QO Release Manager within 24 hours of detection, followed by written notification within 48 hours. Xxxxxxx requires a discrepancy investigation which must detail Berkeley’s “Cause and Corrective Action” information (sent within 30 working days).  
 4.7. Berkeley will notify Xxxxxxx upon submission to the FDA of licensure changes specific to testing laboratories, methodologies and test kits used to test product that is manufactured by Berkeley for Xxxxxxx. Accordingly, Berkeley will notify Xxxxxxx prior to any changes specific to the Column Eluate process that requires validation in the manufacturing process. All notifications must be in writing. Paste will not be shipped prior to Xxxxxxx’x written acknowledgement of the change.  
 4.8. Associated Berkeley documentation B-QAP 536A and either BS-000-AH-010 or BS-000-AH-051 will accompany the shipment.  
 4.9. The Column Eluate must be processed according to Bayer Berkeley, CA procedures, the Bayer PLA/BLA and CBER/FDA approved PLA/BLA Amendments. This includes conformance with all temperature requirements. Reprocessed Column Eluate or Column Eluate containing reprocessed material is not acceptable.  
 5. SPECIAL REQUIREMENTS  
 5.1. Manufacturer Certification – For each batch of Column Eluate shipped to the Xxxxxxx facility, the manufacturer shall provide, prior to shipment of released Column Eluate, a document that  
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PAGE 3 of 5  
 certifies the required criteria. See Attachment 1 for example. This certificate shall be mailed overnight and/or faxed to the QO Release Manager at the following address:  
 Bayer – Clayton  
Attn. QO Release Manager  
QO Plasma – E810  
0000 XX Xxx. 00 X  
Xxxxxxx XX 00000  
Fax: 000-000-0000  
 5.1.1. All Associated IV-1 Paste and [\*\*\*] was shipped and stored at temperatures of - 20° C or colder.  
 5.1.2. The requirements in Section 6, Testing Requirements, have been met.  
 5.1.3. The Column Eluate was processed according to the approved Bayer PLA/BLA. There were no manufacturing deviations or discrepancies for this batch that could adversely affect the safety, purity, quality or potency of the Column Eluate batch.  
 5.1.4. The Column Eluate was processed in a manner minimizing microbial load and endotoxin level. It is not acceptable to ship Column Eluate if any coliform is detected.  
 5.1.5. The Column Eluate certificate will contain the date of separation and the associated IV-1/PEG Paste batches that were combined to create the Column Eluate. Date of separation is the date of manufacture.  
 5.1.6. Statement indicating the actual manufacturing facility (i.e. Bayer HealthCare, Berkeley, CA).  
 5.1.7. The Column Eluate batch has not been reworked for any reason. Reprocessed paste or paste containing reprocessed material is not acceptable.  
 Note: The completed Column Eluate certification will accompany the shipment.  
 5.1.8. Viral inactivation certification. Any deviations to the viral inactivation process will be reported on the certification, along with final Berkeley disposition.  
 5.2. There should be a direct correlation to the amount of IV-1 Paste or PEG Paste shipped to the Berkeley facility and the amount of Column Eluate returned to the Xxxxxxx facility. No product should be destroyed without the written approval from Xxxxxxx’x Supply Chain Manager.  
 5.3. Dating Period – The product dating for Column Eluate is [\*\*\*] months from date of separation. At least 4 months of shelf life must remain at the time of receipt of Column Eluate by the Xxxxxxx facility. If two months do not remain on shelf life approval to ship must be obtained from Xxxxxxx’x Supply Chain Manager prior to shipment. Each container of Column Eluate must be labeled and documented with the required information. Reference (Attachment 2) for required information.  
 6. TESTING REQUIREMENTS  
 6.1. The Xxxxxxx facility will be responsible for all plasma unit and manufacturing pool testing.  
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ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 4 of 5  
 6.2. The Column Eluate will be tested at the Berkeley facility and certified for the following characteristics:  
 Process Step  
 Characteristic  
 Specification  
Concentrated Column Eluate  
 Potency  
 [\*\*\*]  
Concentrated Column Eluate  
 Purity:  
 Albumin  
 [\*\*\*]  
 Alpah-1 Globulin  
 [\*\*\*]  
Concentrated Column Eluate  
 Recovery of column process  
 [\*\*\*]  
 Microbial Load  
 [\*\*\*]  
 Note: If a discrete Concentrated Column Eluate batch has a bioburden level greater than [\*\*\*], written notification to the Xxxxxxx Supply Chain Mangaer must be made so that a Xxxxxxx Quality evaluation of the batch and investigation may be assessed to determine further suitability. Quality assessment will be documented.  
 6.3. Column Eluate samples – Berkeley must send by overnight courier in a manner designed to maintain proper temperature one 50 gram and two 100 gram samples of Column Eluate to:  
 Bayer – Clayton  
Attn. QO Plasma Manager  
QO Plasma – B543  
0000 XX Xxx. 00 X  
Xxxxxxx XX 00000  
Fax: 000-000-0000  
 The samples must be in Clayton QO approved containers, Xxxxxxx Healthcare product catalog number 000-000-0000.  
 7. STORAGE AND SHIPPING REQUIREMENTS  
 7.1. Berkeley should not ship the Column Eluate until receiving written authorization from Xxxxxxx Supply Chain. The authorization to ship Column Eluate should be sent via fax to Berkeley.  
 7.2. This authorization to ship should be within the dating period described in paragraph 5.3 and will be given to Berkeley’s Material Management.  
 7.3. Packaging – Column Eluate shall be packaged and double bagged using polyethylene tote liners. Each tote liner shall be securely closed with a cable tie. The liners shall be overpacked in plastic totes whose lid is secured with a cable tie. Each tote should be NMT 20 kg.  
 7.3.1. The polyethylene bag and plastic totes shall be labeled with the following information:  
 Material number  
Material name  
Batch number  
Gross weight  
Net weight  
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ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 5 of 5  
 Tare weight  
Date manufactured  
Expiration date  
Container Number  
 7.4. Storage and Shipping Temperature – The eluate must be stored and shipped at -20° C or colder. The temperature of each shipment must be monitored using a refrigerated truck equipped with a temperature-recording device. Xxxxx Xxxxxxx will retain the intermediate shipment temperature monitoring data.  
 7.5. Prior to shipment, Berkeley must assure that:  
 7.5.1. The packaging is as specified in paragraph 7.3.  
 7.5.2. All Column Eluate was stored at -20° C or colder.  
 7.5.3. The truck temperature is checked and confirmed to be -25° C or colder prior to loading.  
 7.5.4. The truck continuous recording device is operating properly.  
 7.5.5. Material stored to be shipped must maintain at -20° C or colder until actual loading of the truck.  
 8. INSPECTION  
 8.1. Xxxxxxx’x Bayer QO will be responsible for reviewing all incoming Column Eluate and associated paperwork to ensure that material has met all established guidelines and standards.  
 8.2. Physical inspection requires material to be free of foreign debris and packed/labeled as outlined in this purchase specification.  
 9. ATTACHMENTS  
 9.1. Attachment 1 – Example Certificate of Analysis  
 9.2. Attachment 2 – Example of Column Eluate Label  
 9.3. Attachment 3 – Berkeley Column Eluate flow diagram  
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SAP MATERIAL #:  
08633072  
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ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 1 of 4  
ATTACHMENT 1  
 EXAMPLE OF CERTIFICATE OF ANALYSIS  
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PAGE 2 of 4  
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ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA  
FACILITY  
PAGE 3 of 4  
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 Exhibit B  
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SAP MATERIAL #:  
08633072  
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 TITLE:  
ALPHA-1 COLUMN ELUATE PROCESSED AT  
BAYER HEALTHCARE’S BERKELEY, CA  
FACILITY  
PAGE 4 of 4  
ATTACHMENT 1  
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ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 1 of 1  
ATTACHMENT 2  
 EXAMPLE OF COLUMN ELUATE LABEL  
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ALPHA-1 COLUMN ELUATE PROCESSED AT BAYER HEALTHCARE’S BERKELEY, CA FACILITY  
PAGE 1 of 1  
ATTACHMENT 3  
 BERKELEY COLUMN ELUATE PROCESS FLOW DIAGRAM  
 [\*\*\*]  
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 Exhibit C  
 Execution Copy  
 Revised February 11, 1994  
 5-1  
AT-III (H)  
 SPECIFICATIONS FOR ANTITHROMBIN III (HUMAN)  
 Test  
 Specification  
 1.  
 AT-III  
 [\*\*\*]  
 2.  
 Protein  
 [\*\*\*]  
 3.  
 Specific Activity  
 [\*\*\*]  
 4.  
 Moisture  
 [\*\*\*]  
 5.  
 pH  
 [\*\*\*]  
 6.  
 Sodium  
 [\*\*\*]  
 7.  
 Chloride  
 [\*\*\*]  
 8.  
 Solubility  
 [\*\*\*]  
 9.  
 Visual  
 [\*\*\*]  
 10.  
 EIA for HBsAg  
 [\*\*\*]  
 11.  
 Xxxxxxx  
 00 XXX 610.13 Pass  
 12.  
 Safety  
 21 CFR 610.11 Pass  
 13.  
 Sterility  
 21 CFR 610.12 Pass  
 14.  
 Identity test for packaged final container, Immunoprecipitation method  
 [\*\*\*]  
 15.  
 Alanine  
 [\*\*\*]  
 16.  
 Heparin  
 [\*\*\*]  
 17.  
 Vacuum (for final container sealed under vacuum)  
 [\*\*\*]  
 18.  
 Molecular Weight Distribution  
 [\*\*\*]  
 DRAFT  
CONFIDENTIAL  
DRAFT  
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 1 of 1  
 Exhibit D  
Execution Copy  
 Bayer Corporation  
Pharmaceutical Division  
Xxxxxxxx, XX 00000  
Page 1 of 2  
 SPECIFICATION SHEET  
 Material No:  
08633498  
 (Legacy Catalog No. 19A601K)  
 DISTRIBUTION:  
 BERKELEY:  
X. Xxxxxxxx(3), X.Xxxxxx, X. Xxxx,  
 Title: FRACTION IV-1 PASTE (HUMAN)  
 X. Xxxxx, QA Compliance, QA Library  
 Rev. No.:  
002  
 CLAYTON:  
X. Xxxxxx  
 Date:  
NOV 26 2002  
 1. PURPOSE  
Fraction IV-1 paste is used for manufacturing Alpha1-Proteinase Inhibitor (Human). Berkeley QA will inspect and release the paste as they do for other raw materials.  
 2. DESCRIPITION  
2.1 Description: Fraction IV-1 Paste from the process used in the manufacture of Alpha1-Proteinase Inhibitor (Human)  
2.2 Manufacturer: Bayer Corp., Clayton, North Carolina  
 3. [\*\*\*]  
[\*\*\*]  
[\*\*\*]  
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 Exhibit D  
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Xxxxxxxx, XX 00000  
Page 2 of 2  
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 Material No:  
08633498  
 (Legacy Catalog No. 19A601K)  
 Title: FRACTION IV-1 PASTE (HUMAN)  
 Rev. No.:  
002  
 4. [\*\*\*]  
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 5. LABELING AND PACKAGING  
5.1 The paste shall be double bagged using polyethylene bags. Each poly bag shall be securely closed with a cable tie. The poly bags shall be overpacked in plastic totes whose lids are secured with a cable tie.  
5.2 The poly bags and plastic totes shall be identified with the following information:  
 Material Name  
Gross Weight  
Net Weight  
Tare Weight  
Lot No.  
Date Manufactured  
Expiration Date  
 6. [\*\*\*]  
[\*\*\*]  
 7. [\*\*\*]  
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 APPROVED BY:  
/s/ X. Xxxx  
11/21/02  
 APPROVED BY:  
/s/ X. Xxxxxxxx  
11/25/02  
 APPROVED BY:  
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11/26/02  
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 Exhibit D  
Execution Copy  
 Bayer HealthCare  
Biological Products Division  
Bayer Healthcare LLC  
Quality Assurance  
Berkeley, California  
Page 1 of 3  
 SPECIFICATION SHEET  
 Material No:  
08632688  
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X. Xxxxx, X. Xxxxxx, X. Xxxxxxx,  
 Title: Fraction IV-1 Paste (Human)  
 X. Xxxxxxxx, D. Iseyama (3),  
 (Processed by Precision Pharma Services, Inc.)  
 X. Xxxxxxxx, X. Xxx, X. Xxxxxxx,  
 QA Compliance, QA Library  
 Rev. No.:  
003  
 CLAYTON:  
X. Xxxxxx  
 Date:  
NOV 17 2004  
 1. PURPOSE  
To provide specifications for the receipt of Fraction IV-1 Paste manufactured by Precision Pharma Services, Inc. from plasma provided by Bayer. Fraction IV-1 paste is used for manufacturing Alpha1-Proteinase Inhibitor (Human). Berkeley Quality will inspect and release the paste as they do for other raw materials.  
 2. REFERENCE  
2.1 Bayer (Clayton) purchase specification 08633056, Fraction IV-1 Paste Processed by Precision Pharma Services, Inc. Melville, New York.  
 3. DESCRIPTION  
3.1 Fraction IV-1 Paste refers to a paste fraction obtained by processing plasma using the FDA approved method for by Precision Pharma Services, Inc, according to their approved PLA and the Process Flow Specification.  
3.2 The Fraction IV-1 paste is to be manufactured from source plasma initially received by Bayer and provided to by Precision Pharma Services, Inc.  
3.3 The Fraction IV-1 Paste shall be shipped to Clayton, NC upon Bayer QA approval and at the request of Bayer Materials Management. Bayer (Clayton) will ship portions of the IV-1 Paste to Bayer (Berkeley) to support manufacturing requirements.  
 4. [\*\*\*]  
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[\*\*\*]  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\* CONFIDENTIAL TREATMENT REQUESTED  
   
 Exhibit D  
Execution Copy  
 Bayer HealthCare  
Biological Products Division  
Bayer Healthcare LLC  
Quality Assurance  
Berkeley, California  
Page 2 of 3  
 SPECIFICATION SHEET  
 Material No:  
08632688  
 Title: Fraction IV-1 Paste (Human)  
 (Processed by Precision Pharma Services, Inc.)  
 Rev. No.:  
003  
 [\*\*\*]  
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 5. [\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
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[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
 6. LABELING AND PACKAGING  
6.1 The Paste shall be double bagged using polyethylene bags. Each poly bag shall be securely closed with a cable tie. The poly bags shall be overpacked in plastic totes whose lids are secured with a cable tie.  
6.2 The Poly bags and plastic totes shall be identified with the following information:  
 Material Name  
Gross Weight  
Net Weight  
Tare Weight  
Batch No.  
Date Manufactured  
Expiration Date  
 7. [\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\* CONFIDENTIAL TREATMENT REQUESTED  
   
 Exhibit D  
Execution Copy  
 Bayer HealthCare  
Biological Products Division  
Bayer Healthcare LLC  
Quality Assurance  
Berkeley, California  
Page 3 of 3  
 SPECIFICATION SHEET  
 Material No:  
08632688  
 Title: Fraction IV-1 Paste (Human)  
 (Processed by Precision Pharma Services, Inc.)  
 Rev. No.:  
003  
 8. [\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
 APPROVED BY:  
 /s/ X.Xxxxxx  
DATE:  
9/17/04  
 APPROVED BY:  
 /s/ X. Xxxxx  
DATE:  
10-7-04  
 APPROVED BY:  
 /s/ Xxx Xxxxxxxx  
DATE:  
10-12-04  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\* CONFIDENTIAL TREATMENT REQUESTED  
   
 Exhibit E  
 Execution Copy  
 Bayer HealthCare  
Biological Products Division  
Bayer Healthcare LLC  
Quality Assurance  
Berkeley, California  
Page 1 of 3  
 SPECIFICATION SHEET  
 Catalog No.:  
08633501-19A601P  
 DISTRIBUTION:  
 BERKELEY:  
L. Cianeila (3), X. Xxxxx, X. Xxxxxx,  
 Title: ALPHA - 1 (PEG) INTERMEDIATE PASTE  
 X. Xxxxxxx, X. Xxxxxxxx, X. Xxxxxx,  
 (Manufactured from Bayer IV-1 Paste)  
 X. Xxxxxxxx, X. Xxxxxxx,  
 QA Compliance, QA Library  
 Rev. No.:  
002  
 CLAYTON:  
X. Xxxxxx  
 Date:  
 1. PURPOSE  
Alpha-1 Intermediate Paste is used for manufacturing Alpha1-Proteinase Inhibitor (Human). Berkeley QA will inspect and release the paste as they do for other raw materials.  
 2. DESCRIPTION  
2.1 Description: Alpha-1 Intermediate Paste is from the process used in the manufacture of Alpha1 Proteinase Inhibitor (Human)  
 2.2 Manufacturer: Bayer Corp., Clayton, North Carolina  
 3. [\*\*\*]  
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 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\* CONFIDENTIAL TREATMENT REQUESTED  
   
 Exhibit E  
 Execution Copy  
 Bayer HealthCare  
Biological Products Division  
Bayer Healthcare LLC  
Quality Assurance  
Berkeley, California  
Page 2 of 3  
 SPECIFICATION SHEET  
 Catalog No.:  
08633501-19A601P  
 Title: ALPHA - 1 (PEG) INTERMEDIATE PASTE  
 (Manufactured from Bayer IV-1 Paste)  
 Rev. No.:  
002  
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 4. [\*\*\*]  
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[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
 5. LABELING AND PACKAGING  
5.1 The paste shall be double bagged using polyethylene bags (tote box liner 08655114-850046000). Each poly bag shall be securely closed with a cable tie. The poly bags shall be overpacked in plastic totes whose lids are secured with a cable tie.  
5.2 The poly bags and plastic totes shall be identified with the following information:  
 Material Number  
Material Name  
Batch No.  
Gross Weight  
Net Weight  
Tare Weight  
Date Manufactured  
Expiration Date  
 6. [\*\*\*]  
 [\*\*\*]  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
   
 Exhibit E  
 Execution Copy  
 Bayer HealthCare  
Biological Products Division  
Bayer Healthcare LLC  
Quality Assurance  
Berkeley, California  
PAGE 3 of 3  
 SPECIFICATION SHEET  
 Catalog No.:  
08633501-19A601P  
 Title: ALPHA - 1 (PEG) INTERMEDIATE PASTE  
 (Manufactured from Bayer IV-1 Paste)  
 Rev. No.:  
002  
 7. [\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
[\*\*\*]  
 APPROVED BY:  
 /s/ X. Xxxxxx  
DATE:  
8/7/03  
 APPROVED BY:  
 /s/ X. Xxxxxxxx  
DATE:  
8/7/03  
 APPROVED BY:  
 /s/ X. Xxxx  
DATE:  
 8/7/03  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
   
 Exhibit F  
 Execution Copy  
 NewCo and Bayer HealthCare LLC, Berkeley  
Page 1 of 3  
Manufacturing Agreement (Paste to Column Eluate)  
 MANUFACTURING AGREEMENT  
 This Manufacturing Agreement (Agreement) is between Talecris Biotherapeutics, Inc. (f/k/a NPS BioTherapeutics, Inc.) (NewCo), located at 0000 XX Xxxxxxx 00 Xxxx, Xxxxxxx XX 00000, and Bayer Healthcare LLC (Bayer), Biological Products Division, located at 000 Xxxxxx Xxx, Xxxxxxxx, XX 00000. The “Effective Date” is March 31, 2005.  
 Whereas the United States Food and Drug Administration (FDA) regulations allow that a shipment or other delivery of a drug (biologic) which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction and movement in interstate commerce and the time of holding at such establishment, from compliance with the labeling and packaging requirements of Sections 501(b) and 502 (b), (e), (f) and (g) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 351(b) and 352 (b), (e), (f) and (g)], if the requirements of 21 CFR §201.150 are met.  
 NOW, THEREFORE, it is agreed as follows:  
 1. INTENT OF PARTIES  
 It is the express intent of the parties hereto to adhere to all of the requirements set forth at 21 CFR §201.150 and other applicable provisions of the CFR.  
 2. MAINTENANCE OF PROPER RECORDS  
 Each party agrees to maintain complete and adequate records, where applicable, pertaining to the methods used in and the facilities and controls used for the manufacture, processing, packing, labeling and holding of drugs and pertaining to the disposition of Fraction IV-1/PEG Paste (Paste) that is further manufactured into column eluate at Bayer and returned to NewCo, as may be required by applicable FDA regulations.  
 It is further agreed that each party will maintain a copy of this Agreement until two (2) years after the final shipment or delivery of the Paste hereunder from the NewCo Clayton manufacturing facility and/or the final shipment of column eluate from the Bayer Berkeley manufacturing facility, and shall make copies available for inspection at any reasonable hour to any authorized representative of the Department of Health and Human Services.  
 3. SPECIFICATIONS  
 NewCo will manufacture and ship bulk quantities of Paste, from the process used in the manufacture of Albumin (Human), to Bayer. Said material will be furnished as paste in bulk containers and will be labeled to indicate that further manufacturing, processing, or repacking is intended. Bayer will further manufacture the Paste into column eluate and return the column eluate to NewCo for further manufacturing, processing, or repacking into final container product. Paste will be fractionated by NewCo from U.S. Collected Source Plasma obtained in accordance with the provisions of 21 CFR §640, Subpart G, and other applicable FDA guidelines and regulations including but not limited to 21 CFR §610.46 regarding lookback requirements. Paste shall meet the specifications attached hereto as Exhibit A (Paste Specifications), which Paste Specifications may be amended from time-to-time by mutual written agreement of the parties.  
 Each unit of plasma used in the manufacture of this material will be certified by NewCo to have been tested and found nonreactive for Hepatitis B Surface Antigen (HBsAg),  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
 Exhibit F  
 Execution Copy  
 NewCo and Bayer HealthCare LLC, Berkeley  
Page 2 of 3  
Manufacturing Agreement (Paste to Column Eluate)  
 antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2), antibody to Hepatitis C virus (anti-HCV) and either HIV-1 p24 antigen or alternatively by a FDA licensed assay for HIV-1 by NAT that is approved as an alternative to licensed HIV-1 p24 antigen tests. Each unit of plasma used in the manufacture of Paste will also be certified by NewCo to have been NAT tested and found non-reactive for HCV, HIV and HBV and will also meet any other applicable FDA testing and screening requirements. In addition, all manufacturing plasma pools will be certified to be NMT 105 IU Parvo B19 DNA/mL. The fractionation procedure will be performed according to Current Good Manufacturing Practices and in accordance with the NewCo Biologics License Application (formerly known as the Establishment License and the Product License Application) for Albumin (Human). NewCo grants permission to Bayer to reference the NewCo Biologics License for the description of the manufacturing facility and the details for the Albumin (Human) manufacturing process as it relates to the manufacturing of Paste.  
 Bayer will receive and further manufacture Paste into column eluate. Manufacturing will be performed according to Current Good Manufacturing Practices and in accordance with the Bayer Biologics License Application (formerly known as the Establishment License and the Product License Application for Albumin (Human). Bayer grants permission to NewCo to reference the Bayer Biologics License for the description of the manufacturing facility and the details for the Albumin (Human) manufacturing process as it relates to the manufacturing of column eluate. Column eluate shall meet the specifications attached hereto as Exhibit B (Column Eluate Specifications), which Column Eluate Specifications may be amended from time-to-time by mutual written agreement of the parties.  
 The Paste and column eluate will be stored and shipped at -20ºC or colder. Shipping temperature will be verified for each shipment in accordance to the Paste Specifications or the Column Eluate Specifications, as applicable.  
 NewCo shall include a certificate of analyses with each shipment of Paste specifying the results of its testing and analyses to show conformance with the Paste Specifications. Bayer shall include a certificate of analyses with each shipment of column eluate disclosing the results of its testing and showing conformance with the Column Eluate Specifications.  
 NewCo represents and warrants that the Paste provided to Bayer hereunder is not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. Bayer represents and warrants that the column eluate provided to NewCo hereunder is not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.  
 4. TERM  
 This Agreement shall apply to all Paste from the process used by NewCo in the manufacture of Albumin (Human) shipped in bulk quantities to Bayer for further manufacture and to all column eluate from the process used by Bayer in the manufacture of Albumin (Human) shipped in bulk quantities to NewCo for further manufacture. This Agreement is effective from the Effective Date and will be renewed annually.  
 5. WARNING  
 Paste shall be prepared from large pools of human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. NewCo represents and warrants that the plasma of each donor used to manufacture Paste has been screened and found negative for prior exposure to certain viruses, and for the presence of certain current virus infections. Despite these measures, such products can  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 Exhibit F  
 Execution Copy  
 NewCo and Bayer HealthCare LLC, Berkeley  
 Manufacturing Agreement (Paste to Column Eluate)  
 Page 3 of 3  
 still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Appropriate care should be used in handling this material.  
 IN WITNESS THEREOF, the parties thereto have caused this Agreement to be executed by their duly authorized representatives.  
 TALECRIS BIOTHERAPEUTICS, INC.  
BAYER HEALTHCARE LLC  
 By  
 By  
 Responsible Head/Agent  
 Responsible Head/Agent  
 BAYER HEALTHCARE LLC  
 By  
 Responsible Head/Agent  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
 Exhibit G  
 Execution Copy  
 NewCo and Bayer HealthCare LLC, Berkeley  
 Manufacturing Agreement (Paste to Antithrombin-III)  
 Page 1 of 3  
 MANUFACTURING AGREEMENT  
 This Manufacturing Agreement (Agreement) is between Talecris Biotherapeutics, Inc. (f/k/a NPS Bio Therapeutics, Inc.) (NewCo), located at 0000 XX Xxxxxxx 00 Xxxx, Xxxxxxx XX 00000, and Bayer Healthcare LLC (Bayer), Biological Products Division, located at 000 Xxxxxx Xxx, Xxxxxxxx, XX 00000. The “Effective Date” is March 31, 2005.  
 Whereas the United States Food and Drug Administration (FDA) regulations allow that a shipment or other delivery of a drug (biologic) which is, in accordance with the practice of the trade, to be processed, labeled, or repacked in substantial quantity at an establishment other than that where originally processed or packed, shall be exempt, during the time of introduction and movement in interstate commerce and the time of holding at such establishment, from compliance with the labeling and packaging requirements of Sections 501(b) and 502 (b), (e), (f) and (g) of the Federal Food, Drug and Cosmetic Act [21 U.S.C. 351(b) and 352(b), (e), (f) and (g)], if the requirements of 21 CFR §201.150 are met.  
 NOW, THEREFORE, it is agreed as follows:  
 1. INTENT OF PARTIES  
 It is the express intent of the parties hereto to adhere to all of the requirements set forth at 21 CFR §201.150 and other applicable provisions of the CFR.  
 2. MAINTENANCE OF PROPER RECORDS  
 Each party agrees to maintain complete and adequate records, where applicable, pertaining to the methods used in and the facilities and controls used for the manufacture, processing, packing, labeling and holding of drugs and pertaining to the disposition of Fraction IV-1 Paste (Paste) that is further manufactured into Antithrombin-III (AT-III) at Bayer and returned to NewCo, as may be required by applicable FDA regulations.  
 It is further agreed that each party will maintain a copy of this Agreement until two (2) years after the final shipment or delivery of the Paste hereunder from the NewCo Clayton manufacturing facility and/or the final shipment of AT-III from the Bayer Berkeley manufacturing facility, and shall make copies available for inspection at any reasonable hour to any authorized representative of the Department of Health and Human Services.  
 3. SPECIFICATIONS  
 NewCo will manufacture and ship bulk quantities of Paste, from the process used in the manufacture of Albumin (Human), to Bayer. Said material will be furnished as paste in bulk containers and will be labeled to indicate that further manufacturing, processing, or repacking is intended. Bayer will further manufacture the Paste into AT-III and return the AT-III to NewCo for further manufacturing, processing or repacking into final container product. Paste will be fractionated by NewCo from U.S. Collected Source Plasma obtained in accordance with the provisions of 21 CFR §640, Subpart G, and other applicable FDA guidelines and regulations including but not limited to 21 CFR §610.46 regarding lookback requirements. Paste shall meet the specifications attached hereto as Exhibit A (Paste Specifications), which Paste Specifications may be amended from time-to-time by mutual written agreement of the parties.  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
 Exhibit G  
 Execution Copy  
 NewCo and Bayer HealthCare LLC, Berkeley  
 Manufacturing Agreement (Paste to Antithrombin-III)  
 Page 2 of 3  
 Each unit of plasma used in the manufacture of this material will be certified by NewCo to have been tested and found nonreactive for Hepatitis B Surface Antigen (HBsAg), antibodies to Human Immunodeficiency Virus (HIV-1/HIV-2), antibody to Hepatitis C virus (anti-HCV) and either HIV-1 p24 antigen or alternatively by a FDA licensed assay for HIV-1 by NAT that is approved as an alternative to licensed HIV-1 p24 antigen tests. Each unit of plasma used in the manufacture of Paste will also be certified by NewCo to have been NAT tested and found non-reactive for HCV, HIV and HBV and will also meet any other applicable FDA testing and screening requirements. In addition, all manufacturing plasma pools will be certified to be NMT 10(5) IU Parvo B19 DNA/mL. The fractionation procedure will be performed according to Current Good Manufacturing Practices and in accordance with the NewCo Biologics License Application (formerly known as the Establishment License and the Product License Application) for Albumin (Human). NewCo grants permission to Bayer to reference the NewCo Biologics License for the description of the manufacturing facility and the details for the Albumin (Human) manufacturing process as it relates to the manufacturing of Paste.  
 Bayer will receive and further manufacture Paste into AT-III. Manufacturing will be performed according to Current Good Manufacturing Practices and in accordance with the Bayer Biologics License Application (formerly known as the Establishment License and the Product License Application for AT-III (Human). Bayer grants permission to NewCo to reference the Bayer Biologics License for the description of the manufacturing facility and the details for the AT-III (Human) manufacturing process as it relates to the manufacturing of AT-III. AT-III shall meet the specifications attached hereto as Exhibit B (AT-III Specifications), which AT-III Specifications may be amended from time-to-time by mutual written agreement of the parties.  
 The Paste and AT-III will be stored and shipped at -20° or colder. Shipping temperature will be verified for each shipment in accordance to the Paste Specifications or the AT-III Specifications, as applicable.  
 NewCo shall include a certificate of analyses with each shipment of Paste specifying the results of its testing and analyses to show conformance with the Paste Specifications. Bayer shall include a certificate of analyses with each shipment of AT-III disclosing the results of its testing and showing conformance with the AT-III Specifications.  
 NewCo represents and warrants that the Paste provided to Bayer hereunder is not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act. Bayer represents and warrants that the AT-III provided to New Co hereunder is not adulterated or misbranded within the meaning of the Federal Food, Drug, and Cosmetic Act.  
 4. TERM  
 This Agreement shall apply to all Paste from the process used by NewCo in the manufacture of Albumin (Human) shipped in bulk quantities to Bayer for further manufacture and to all AT-III from the process used by Bayer in the manufacture of Albumin (Human) shipped in bulk quantities to NewCo for further manufacturing and/or labeling. This Agreement is effective from the Effective Date and will be renewed annually.  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
 Exhibit G  
 Execution Copy  
 NewCo and Bayer HealthCare LLC, Berkeley  
 Manufacturing Agreement (Paste to Antithrombin-III)  
 Page 3 of 3  
 5. WARNING  
 Paste shall be prepared from large pools of human plasma. Products made from human plasma may contain infectious agents, such as viruses, that can cause disease. NewCo represents and warrants that the plasma of each donor used to manufacture Paste has been screened and found negative for prior exposure to certain viruses, and for the presence of certain current virus infections. Despite these measures, such products can still potentially transmit disease. There is also the possibility that unknown infectious agents may be present in such products. Appropriate care should be used in handling this material.  
 IN WITNESS THEREOF, the parties thereto have caused this Agreement to be executed by their duly authorized representatives.  
 TALECRIS BIOTHERAPEUTICS, INC.  
BAYER HEALTHCARE LLC  
 By  
 By  
 Responsible Head/Agent  
 Responsible Head/Agent  
 BAYER HEALTHCARE LLC  
 By  
 Responsible Head/Agent  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
   
Execution Copy  
Exhibit H  
Expected Yield Calculation  
 Yields will be calculated based on two steps:  
 Step # 1: Absolute Weight  
For every 1KG of IV-I paste input from Clayton, target weight returned from Berkeley will equal [\*\*\*] Column Eluate.  
 Step # 2 Potency  
Target potency will be equal to [\*\*\*] of step yield of IV-I paste to column eluate.  
 Example:  
IV-I Paste Input from Clayton = [\*\*\*] of Plasma of Alpha 1 in IV-I Paste  
 Column Eluate Output =[\*\*\*] x [\*\*\*] = [\*\*\*] of Plasma in Column Eluate  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
 Page 1 of 1  
  
 Execution Copy  
 EXHIBIT I  
 PRICE  
 For calendar year 2004, [\*\*\*] of Intermediate Product Eluate and [\*\*\*] of ATIII.  
 \*\*\*CONFIDENTIAL TREATMENT REQUESTED  
   
 Execution Copy  
 Exhibit J  
 Purchaser’s Intellectual Property  
 Patent  
 Country Code  
 Patent   
Number  
 Application  
 Number  
 Expiration Date  
 METHOD OF PREPARING ALPHA-1-  
 US  
 4656254  
 803184  
 Expires 12/02/05  
 PROTEINASE INHIBITOR AND  
 AU  
 591734  
 65888/86  
 Expires 12/02/06  
 ANTITHROMBIN III -  
 CA  
 1298032  
 524266  
 Expires 03/24/09  
 PROLASTIN® Alpha-1 PI  
 EP  
 0224811  
 86116125.5  
 Expires 11/21/06  
 JP  
 2030723  
 284445/86  
 Expires 12/01/06  
 Patent  
 Country  
Code  
 Patent   
Number  
 Application   
Number  
 Expiration Date  
 VIRAL INACTIVATION AND  
 US  
 4749783  
 884446  
 Expires 07/11/06  
 PURIFICATION OF ACTIVE PROTEINS-  
 AU  
 589868  
 74975/87  
 Expires 06/30/07  
 THROMBATE® AT-III(1)  
 CA  
 1,341,269  
 541758  
 Expires 07/10/18  
 XX  
 000000  
 9790283-7  
 Expires 06/27/07  
 (1) Subject to the Retained Intellectual Property License per the Joint Contribution Agreement.  
 Confidential Evaluation Material Subject to Confidentiality Agreement  
 Page 1 of 1