Exhibit 2.4  
 Form of  
 MANUFACTURING AND SUPPLY AGREEMENT  
 by and between  
 BIOGEN INC.  
 and  
 BIOVERATIV INC.  
 Dated as of [·],[·]  
   
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 MANUFACTURING AND SUPPLY AGREEMENT  
 This Manufacturing and Supply Agreement (the “Agreement”) is made and entered into as of [·], [·], by and between Biogen Inc., a Delaware corporation (“Biogen”), and Bioverativ Inc., a Delaware corporation (“Bioverativ”). Each of the parties hereto are referred to collectively as the “Parties” and individually as a “Party”.  
 WHEREAS, Biogen is pursuing a plan to separate (the “Separation”) into two separate, publicly traded companies and, in furtherance thereof, Biogen and its subsidiary, Bioverativ, propose to enter into a Separation Agreement (the “Separation Agreement”) and the other Transaction Agreements (as defined in the Separation Agreement), including the IP License Agreement (as defined in the Separation Agreement), that will govern and provide a framework for the Separation;  
 WHEREAS, pursuant to the Transaction Agreements the Parties have agreed that Biogen will manufacture and supply certain products, including drug substance, active drug product and finished goods to Bioverativ in accordance with the terms and conditions of this Agreement;  
 WHEREAS, pursuant to the IP License Agreement, Biogen has licensed to Bioverativ intellectual property rights controlled by Biogen and used in the manufacture of the products hereunder and Bioverativ has licensed to Biogen intellectual property rights controlled by Bioverativ and used in the manufacture of products hereunder.  
 NOW, THEREFORE, in consideration of the promises and the mutual covenants and agreements herein contained, and for other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Parties, intending to be legally bound, agree as follows:  
 ARTICLE 1  
 DEFINITIONS  
 Capitalized terms used herein have the definitions given in this Article 1 or elsewhere in this Agreement; provided that if any capitalized term used herein is not listed in Article 1 or defined elsewhere in this Agreement, such term shall have the definition provided in the Separation Agreement, as it may be amended from time to time.  
 “Active Drug Product” means drug product manufactured using the Drug Substance.  
 “Additional Cure Period” is defined in Section 13.3(b).  
 “ADP Certificate of Analysis” is defined in Section 6.1.  
 “ADP Certificate of Conformance” is defined in Section 6.1.  
 “ADP Certificates” means the ADP Certificate of Analysis and ADP Certificate of Conformance collectively.  
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 “ADP Lot” means the Active Drug Product output for one Active Drug Product manufacturing unit operation.  
 “Advisory Forecast” is defined in Section 5.2(a)(iii).  
 “Affiliate” has the meaning set forth in the Separation Agreement.  
 “Agreement” is defined in the Preamble.  
 “Alliance” will mean the relationship of the Parties as established by this Agreement.  
 “Applicable Law” means the applicable laws, rules and regulations, including any rules, regulations, guidelines or other requirements of the applicable supra-national, federal, national, regional, state, provincial or local regulatory agencies, departments, bureaus, commissions, councils or other governmental authority regulating or otherwise exercising authority, that may be in effect from time to time and applicable to the Parties in relation to the activities and products hereunder. For the avoidance of doubt, cGMPs shall be considered to be a part of Applicable Laws.  
 “Audited Party” is defined in Section 8.3.  
 “Auditing Party” is defined in Section 8.3.  
 “Batch Documentation” means all batch specific information included in a release decision, including but not limited to executed batch records, testing results and deviation investigations, in each instance based on Biogen’s applicable standard operating procedures.  
 “Binding Forecast” is defined in Section 5.2(a)(i).  
 “Binding Purchase Order” is defined in Section 5.2(b).  
 “Biogen” is defined in the Preamble.  
 “Biogen Background IP” is defined in Section 14.1.  
 “Biogen Broader Change” is defined in Section 11.3(d).  
 “Biogen Indemnified Parties” means Biogen and its Indemnified Parties.  
 “Biogen Marks” is defined in Section 4.2(b).  
 “Bioverativ” is defined in the Preamble.  
 “Bioverativ Background IP” is defined in Section 14.1.  
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 “Bioverativ Indemnified Parties” means Bioverativ and its Indemnified Parties.  
 “Breaching Party” is defined in Section 13.3(a).  
 “Campaign” means a series of batches or lots of the same product that are produced in parallel or consecutively at the same manufacturing site.  
 “cGMP Consultant” is defined in Section 9.1(c)(ii)(C).  
 “cGMPs” means current good manufacturing practices as provided for (and as amended from time to time) in European Community Directive 91/356/EEC (Principles and Guidelines of Good Manufacturing Practice for Medicinal Products) and in the Current Good Manufacturing Practice Regulations of the United States Code of Federal Regulations Title 21 (21 CFR Parts 210-211) in relation to the production of pharmaceutical intermediates and active pharmaceutical ingredients, as interpreted by ICH Harmonized Tripartite Guideline, Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients.  
 “Compliance Issue” means an issue as to whether Finished Goods, Drug Product or Drug Substance was manufactured in accordance with cGMPs in effect when such product is shipped to Bioverativ or upon the applicable product release.  
 “Confidential Information” has the meaning set forth in the Separation Agreement.  
 “Diluent” means the pre-filled syringe of sterile water for injection used to reconstitute the Active Drug Product or Finished Goods for intravenous delivery.  
 “Diluent Certificate of Analysis” is defined in Section 6.1.  
 “Diluent Certificate of Conformance” is defined in Section 6.1.  
 “Diluent Certificates” means the Diluent Certificate of Analysis and Diluent Certificate of Conformance collectively.  
 “Diluent Lots” means the quantity of Diluent prepared or required for one unit operation.  
 “Distribution Date” has the meaning set forth in the Separation Agreement.  
 “Distribution Effective Time” has the meaning set forth in the Separation Agreement.  
 “DP Release” means, with respect to Active Drug Product, the date on which Bioverativ receives the ADP Certificate of Analysis and the ADP Certificate of Conformance, and with respect to Diluent, the date on which Bioverativ receives the Diluent Certificate of Analysis and the Diluent Certificate of Conformance.  
 “DP/FG Testing Laboratory” is defined in Section 9.2(c)(i)(B).  
 “Drug Product” means Active Drug Product and Diluent, whether separately or collectively.  
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 “Drug Product Specifications” means the Specifications for the Active Drug Product or Diluent, as applicable, the current versions of which (as of the Effective Date) are set forth in Schedule 2B attached hereto.  
 “Drug Substance” (or “DS”) means, as applicable, the bulk drug substance containing (i) that certain Factor VIII: Fc Construct that is the subject of BLA 125487, or (ii) that certain Factor IX Fc Construct that is the subject of BLA 125444, in each case as such biologics license application may be amended or revised from time to time, or (iii) those certain clinical products that are specified on Schedule 1 attached hereto or as agreed to by the parties from time to time.  
 “Drug Substance Specifications” means the Specifications for the Drug Substance, the current version of which (as of the Effective Date) is set forth in Schedule 2A attached hereto.  
 “DS Batch” means the quantity of Drug Substance from a single formulation operation produced under cGMP and in accordance with a defined set of release criteria, using 1,000 liter, 2,000 liter, 15,000 liter or 18,000 liter working volume bioreactor, and as a result of a series of sequential inoculation cell culture, harvest and purification steps for manufacture of Drug Substance for inclusion in (i) products intended for commercial sale and (ii) products intended for use in clinical development.  
 “DS Certificate of Analysis” is defined in Section 6.1.  
 “DS Certificate of Conformance” is defined in Section 6.1.  
 “DS Certificates” means the DS Certificate of Analysis and DS Certificate of Conformance collectively.  
 “DS Release” is defined in Section 9.1(a).  
 “DS Testing Laboratory” is defined in Section 9.1(c)(i)(B).  
 “Effective Date” is means the Distribution Date (as defined in the Separation Agreement).  
 “Engineering Batch” shall mean one (1) test batch or lot, as applicable, of product manufactured at scale in accordance with its applicable Specifications, excluding completion of all release test results.  
 “Facility” shall mean a Biogen manufacturing facility and/or any other facility operated by Biogen or a Third Party Manufacturer in connection with the manufacture of the product.  
 “Finished Goods” means Drug Product in finished dosage form, packaged and labeled for distribution or sale, for donation or for use in clinical trials.  
 “Finished Goods Certificate of Analysis” is defined in Section 6.1.  
 “Finished Goods Certificate of Conformance” is defined in Section 6.1.  
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 “Finished Goods Certificates” means the Finished Goods Certificate of Analysis and Finished Goods Certificate of Conformance collectively.  
 “Finished Goods Release” means the date on which Bioverativ receives the Finished Goods Certificates.  
 “Finished Goods Specifications” means the Specifications for the Finished Goods, the current versions of which (as of the Effective Date) are set forth in Schedule 2C attached hereto.  
 “First Phase” means, with respect to a particular jurisdiction, the period from the Effective Date until the date that Bioverativ has obtained appropriate licenses in such jurisdiction such that Bioverativ is enabled under Applicable Law to take title to, and sell, Finished Goods and Drug Product.  
 “Force Majeure Event” is defined in Section 21.2.  
 “Forecast” means the Binding Forecast, the Semi-Binding Forecast or the Advisory Forecast.  
 “FTE Rate” means, with respect to Biogen’s employees, the full-time equivalent rate then used by Biogen for its internal accounting purposes, prorated on an hourly basis based on a total of one thousand six hundred (1,600) hours worked per year.  
 “Indemnified Parties” means, with respect to a Party, such Party and such Party’s Affiliates and licensors of intellectual property sublicensed under this Agreement, and its and their respective officers, directors, shareholders, successors, assigns, agents, employees and insurers to the extent the same become subject to a claim in such capacity.  
 “Initial Cure Period” is defined in Section 13.3(a).  
 “Initial Term” is defined in Section 13.1(a).  
 “Joint IP” is defined in Section 14.3.  
 “Joint Manufacturing and Supply Committee” or “JMSC” is defined in Section 10.1.  
 “Latent Defect” means (i) with respect to Drug Substance, a Non-Conformity or a Compliance Issue that was not reasonably discoverable within the forty-five (45) day period referenced in Section 9.1(c)(i)(A)) and which failure is confirmed by the procedure set forth on Schedule 7 attached hereto; and (ii) with respect to Drug Product or Finished Goods, a Non-Conformity or a Compliance Issue that was not reasonably discoverable within the forty-five (45) day period referenced in Section 9.2(c)(i)(A) and which failure is confirmed by the procedure set forth on Schedule 7 attached hereto.  
 “Lot” shall refer to a Drug Product lot or a Diluent lot.  
 “Manufacture” or “Manufacturing” means, with respect to a product for which an Order is made under this Agreement, the process scale-up, validation, clinical and commercial  
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 manufacturing (including bulk manufacturing, finished pharmaceutical product manufacturing, and label-pack); provided, that Manufacturing excludes development and commercialization of such product.  
 “MFC” means projected months forward coverage of inventory calculated against the most recent unit demand Forecasts by stage of Manufacture. Finished Goods will be calculated as independent demand and drug product and drug substance will be calculated as dependent demand.  
 “NDC” means National Drug Code.  
 “Non-Conformity” means (i) with respect to any Drug Substance, a failure of such Drug Substance to conform to the Drug Substance Specifications in effect at the time of the DS Release, (ii) with respect to any Drug Product or Finished Goods, a failure of such Drug Product or Finished Goods, or the Drug Substance used to Manufacture such Drug Product or Finished Goods, to conform to the Drug Product Specifications or Finished Goods Specifications in effect at the time of the DP Release; and (iii) with respect to any Finished Goods, a failure of such Finished Goods to comply with the Finished Goods Specifications in effect at the time of Finished Goods Release, and the adjective “Non-Conforming” shall have the correlative meaning.  
 “Notifying Party” is defined in Section 13.3(a).  
 “Order” means (i) a Purchase Order or (ii) a service order for commitment of Finished Goods as transacted in the First Phase.  
 “Party” and “Parties” are defined in the first paragraph of this Agreement.  
 “Presentation” means the presentations set forth in Schedule 3 attached hereto, as it may be updated from time to time by the JMSC.  
 “Process” shall mean a process for the manufacture of product in accordance with the terms of this Agreement, comprising all intellectual property and other technical information relating to the process of manufacture and testing reasonably required to produce a product including, without limitation, any associated documentation, as set forth in the applicable Specification for such product.  
 “Proposed Change” is defined in Section 11.3(a).  
 “Purchase Order” is defined in Section 5.2(b).  
 “Quality Agreement” means the quality agreement between the Parties relating to Drug Substance, Drug Product and Finished Goods, as such agreement is amended from time to time. As of the Effective Date, the Parties anticipate that the Quality Agreement will be executed within 60 days of the Effective Date.  
 “Regulatory Approval” means, with respect to a product and a country, any and all approvals (including any applicable governmental price and reimbursement approvals), licenses,  
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 registrations or authorizations of the applicable Regulatory Authority necessary for the use, storage, import, promotion, marketing and sale of such product in such country, including approval of all relevant regulatory filings.  
 “Regulatory Authority” means, with respect to a country, any governmental authority (whether federal, state, provincial, municipal or other) regulating the exportation, importation, use, manufacture, distribution, marketing and/or sale of pharmaceuticals, which, in the U.S., shall include the U.S. Food and Drug Administration (or any successor agency thereto) and, in Europe, shall include the European Medicines Agency (or any successor agency thereto).  
 “Renewal Term” is defined in Section 13.1(b).  
 “Representing Party” is defined in Section 16.1(a).  
 “Required Change” is defined in Section 11.2.  
 “Second Phase” means, with respect to a particular jurisdiction, the period from the end of the First Phase until the date that is 18 months after the date of this Agreement, or as may be mutually agreed by the parties.  
 “Semi-Binding Forecast” is defined in Section 5.2(a)(ii).  
 “Senior Executives” means, with respect to Biogen, [ ], and with respect to Bioverativ, [ ].  
 “Separation” is defined in the Recitals.  
 “Separation Agreement” is defined in the Recitals.  
 “Severed Clause” is defined in Section 21.7.  
 “Specifications” shall mean, with respect to any product, all specifications for the Process of manufacture of product, including required materials, approved suppliers, manufacturing, analytical and testing procedures, release, packaging, labeling, storage and other processes relating to the manufacture, shipping and handling of the product, all as set forth in the applicable Appendix, in each case including the Quality Agreement and test methods referred to therein.  
 “Term” means collectively the Initial Term and (if any) the Renewal Term(s).  
 “Third Party” means any Person other than Biogen, Bioverativ or their respective Affiliates.  
 “Third Party Carrier” means any carrier selected or approved by Bioverativ or its Affiliates to (i) transport Drug Substance (pursuant to Section 9.1(e)), or (ii) transport Drug Product or Finished Goods from the Manufacturing Facility to Bioverativ or Bioverativ’s designee.  
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 “Third Party Manufacturer” is defined in Section 2.3.  
 “Third Phase” means, with respect to a particular jurisdiction, the period from the end of the Second Phase to the end of the Term.  
 “Transaction Agreements” is defined in the Separation Agreement.  
 “Transferred Agreements” means that certain amended and restated FVIII: FC Lead Product Commercial Manufacturing and Supply Agreement between Swedish Orphan Biovitrum AB (Publ) and Biogen Hemophilia Inc., dated as of 20 November 2014, and that certain amended and restated FIX: Fc Lead Product Commercial Manufacturing and Supply Agreement between Swedish Orphan Biovitrum AB (Publ) and Biogen Hemophilia Inc., dated as of December 22, 2014, in each case, as the same may be amended or supplemented from time to time.  
 ARTICLE 2  
 MANUFACTURING — GENERAL PROVISIONS  
 2.1 Manufacturing Authority. Except as otherwise expressly set forth in this Agreement, Biogen shall retain full decision-making authority with respect to Drug Substance, Drug Product and Finished Goods manufacturing operations.  
 2.2 Exclusivity. Except as expressly contemplated by this Agreement, Biogen shall not manufacture or supply the Drug Substance, Drug Product or Finished Goods contemplated by this Agreement, or any biosimilar of any of the foregoing, to any Person other than Bioverativ until the date that is one year after the expiration or termination of this Agreement.  
 2.3 Affiliates and Third Party Manufacturers. Notwithstanding anything to the contrary in this Agreement, Biogen may use one or more Third Party manufacturers (each a “Third Party Manufacturer”) or Affiliates to (a) manufacture the Drug Substance, Active Drug Product and/or Diluent and/or to (b) pack and label and perform other activities necessary for the provision of the Finished Goods, in each case solely to the extent Bioverativ, in its reasonable judgment, has consented in writing to the use of such Third Party Manufacturers; provided that Bioverativ shall be deemed to be have consented hereunder to the continued use of Third Party Manufacturers used by Biogen prior to the date of this Agreement.  
 2.4 Technology Transfer. Either Party may request during the Term a technology transfer from the Facility to another facility in accordance with this Section 2.4. Biogen may request, and Bioverativ may approve (such approval not to be unreasonably withheld, conditioned or delayed; for the avoidance of doubt, a material increase in the resulting cost of goods to Bioverativ shall be a reasonable basis for objection) a technology transfer from a Facility to another Biogen Facility, provided that Biogen shall bear all costs associated therewith. Bioverativ may request a technology transfer to its own facility or that of a Third Party, provided that Bioverativ shall bear all costs associated therewith, including any costs set forth on the cost schedule included in Schedule 8 attached hereto. Scale technology transfers requested by Biogen shall be approved by Bioverativ (with such approval not to be unreasonably withheld, conditioned or delayed) and Biogen shall bear all costs associated therewith. Scale  
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 technology transfers requested by Bioverativ shall adhere to the technology transfer cost schedule included in Schedule 8 attached hereto.  
 2.5 Invoicing by Biogen’s Affiliates. Where this Agreement refers to invoices being issued by Biogen to Bioverativ, Biogen may, at its discretion, have one or more of its Affiliates issue such invoices. If an Affiliate of Biogen issues such an invoice to Bioverativ, Bioverativ shall pay such Affiliate in accordance with the payment instructions on such invoice, and Bioverativ’s payment of a given amount against such invoice shall be deemed to satisfy its obligation hereunder to pay such amount to Biogen.  
 2.6 IRC Section 199. The Parties agree that the mutual intent is for Bioverativ to be considered as having the IRC Section 199 benefits and burdens, pursuant to Treasury Regulation 1.199-3(f)(1), of any Drug Substance manufacturing activity occurring within the United States on or after the Effective Date.  
 ARTICLE 3  
 [RESERVED]  
 ARTICLE 4  
 PHASES  
 4.1 First Phase. During the First Phase, with respect to a particular jurisdiction, Bioverativ shall forecast Drug Substance, Drug Product and Finished Goods that are packaged and labelled for sale by Biogen or by a Third Party designated by Biogen as agreed by the Parties. Biogen or such designated Third Party will distribute, sell and have sold such Finished Goods under Biogen’s or such Third Party’s necessary authorizations and licenses for the marketing of prescription biopharmaceutical products in any applicable territory. For the avoidance of doubt, during the First Phase, title to such Finished Goods shall not transfer from Biogen to Bioverativ.  
 4.2 Second Phase.  
 (a) During the Second Phase, with respect to a particular jurisdiction, Bioverativ shall forecast Drug Substance, Drug Product and Finished Goods and order Drug Product or Finished Goods that are packaged and labelled for sale by Bioverativ or by a Third Party designated by Bioverativ, which shall include, for the avoidance of doubt, any product remaining unsold following the end of the First Phase that was forecasted by Bioverativ during the First Phase and that bears Biogen’s or a Biogen designated Third Party’s NDC numbers (or any equivalent non-U.S. designation of responsible party). Bioverativ shall take title to all such Drug Product or Finished Goods in accordance with Section 9.2(d) in order to enable Bioverativ or such designated Third Party to distribute, sell and have sold such products under Bioverativ’s or such Third Party’s necessary authorizations  
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 and licenses for the marketing of prescription biopharmaceutical products in any applicable territory.  
 (b) Effective as of the beginning of the Second Phase on a territory-by-territory basis, Biogen, on behalf of itself and its Affiliates, hereby grants to Bioverativ and its Affiliates, until the earlier of (i) the sale of the last Finished Goods bearing the trade marks and trade dress of Biogen as provided on Finished Goods manufactured by Biogen for Bioverativ (the “Biogen Marks”) in the applicable territory or (ii) the expiration of the usable shelf life of the last Finished Goods in such territory bearing the Biogen Marks, a non-exclusive, sublicenseable, worldwide, and royalty-free license to use the Biogen Marks to facilitate the transition by Bioverativ and its Affiliates to the sale of Finished Goods bearing new names and marks. All goodwill associated with the Biogen Marks generated by Bioverativ or its Affiliates’ use of the Biogen Marks pursuant to the foregoing license in this Section 4.2(b) shall inure to the benefit of Biogen and its Affiliates. Bioverativ and its Affiliates shall use the Biogen Marks at a level of quality equivalent in all material respects to that in effect as of the beginning of the Second Phase in the applicable territory. For purposes of clarity, nothing in this Section 4.2(b) shall preclude any uses of the Biogen Marks by Bioverativ and its Affiliates that are required or otherwise not prohibited under Applicable Law, including uses of the Biogen Marks not in commerce, uses that would not cause confusion as to the origin of a good or service, and references to the Biogen Marks in historical, tax, and similar records.  
 4.3 Third Phase. During the Third Phase, with respect to a particular jurisdiction, Bioverativ shall forecast and order Drug Substance from Biogen. Bioverativ shall take title to all such Drug Substance and arrange shipments in accordance with Sections 9.1(d) and 9.1(e), respectively. The parties shall in good faith work together to determine the duration and terms for storage of any Drug Substance in a Biogen Facility. For the avoidance of doubt, the Parties intend that Bioverativ enter the Third Phase in each jurisdiction as expeditiously as possible and and not later than eighteen (18) months from the Distribution Effective Time unless otherwise agreed. The Parties agree to cooperate in good faith to enable Bioverativ to further such objective.  
 4.4 Phase Timeline. The Parties currently intend that the timeline for the applicability of the First Phase, Second Phase and Third Phase to certain jurisdictions shall be as set forth on Schedule 4.4 attached hereto. For the avoidance of doubt, upon execution of this Agreement, Japan and jurisdictions included in the Transferred Agreements shall begin in the Second Phase and the United States and Canada shall begin in the First Phase. The Parties will work together in good faith to address supply for the humanitarian aid program and other jurisdictions to adjust the timeline as appropriate in response to circumstances to achieve the aims of this Agreement.  
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 ARTICLE 5  
 MANUFACTURING, FORECASTS, ORDERS AND INVENTORY  
 5.1 Manufacture and Supply. Subject to the terms of this Agreement, Biogen shall manufacture (or cause to be manufactured) and/or supply, as applicable, Drug Substance, Active Drug Product, Diluent and Finished Goods, in each case in accordance with the Binding Forecast.  
 5.2 Forecasting, Planning, Ordering, and Inventory.  
 (a) Forecast and Planning. Bioverativ shall submit to Biogen written, rolling forecasts for planning and purchase of Drug Substance, Drug Product and Finished Goods supply needs, in accordance with the template attached on Schedule 5 attached hereto, itemized as follows:  
 FORECAST  
 “Binding  
Forecast”  
Months  
 “Semi-  
Binding  
Forecast”  
Months  
 “Advisory  
Forecast”  
Months  
 Minimum Update  
Frequency  
Clinical Drug Substance  
 1-7  
 8-19  
 20–60  
 Quarterly  
Commercial Drug Substance  
 1-13  
 14-25  
 26-60  
 Quarterly  
Clinical and Commercial Active Drug Product & Diluent  
 1-7  
 8-16  
 17-60  
 Monthly  
Finished Goods  
 1-4  
 N/A  
 5-24  
 Monthly  
 (i) The “Binding Forecast” shall be binding per the terms noted above for the quantities of clinical and commercial DS Batches or Active Drug Product and Diluent or Finished Goods, respectively, by Presentation forecasted for future orders by Bioverativ for release in the months specified above, with “month-one” of such Binding Forecast representing the month during which such Forecast is submitted.  
 (1) Drug Substance: The aggregate quantities forecasted in a Binding Forecast for the months in any quarter may not be more than fifty percent (50%) above or fifty percent (50%) below the number of DS Batches for such quarter when it first appeared in the Semi-Binding Forecast, and the quantities forecasted for any month of the Binding Forecast may not be changed from the quantities forecasted for such month in the first Binding Forecast to include such month, without the prior written consent of Biogen on a case-by-case basis.  
 (2) Drug Product: The Binding Forecast for any month (i) may not be more than fifty percent (50%) above or fifty percent (50%) below the number of Lots respectively by Presentation for such month when it first appeared in the Semi-  
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 Binding Forecast and (ii) may not be changed from the quantities forecasted for such month in the first Binding Forecast to include such month, without the prior written consent of Biogen on a case-by-case basis.  
 (ii) The “Semi-Binding Forecast” shall specify the quantities of DS Batches or Active Drug Product and Diluent, respectively, by Presentation forecasted for future orders by Bioverativ for release in the months specified above, with “month-one” representing the month during which such Forecast is submitted.  
 (1) Drug Substance: The amounts forecasted by Bioverativ for each quarter within the Semi-Binding Forecast period may not be changed by Bioverativ to be more than fifty percent (50%) above or fifty percent (50%) below the number of DS Batches for such quarter when it first appeared in the Semi-Binding Forecast.  
 (2) Drug Product: The amounts forecasted by Bioverativ for each month within the Semi-Binding Forecast period may not be changed by Bioverativ to be more than fifty percent (50%) above or fifty percent (50%) below the number of Lots by Presentation for such month when it first appeared in the Semi-Binding Forecast.  
 (iii) The “Advisory Forecast” shall be non-binding and specify for each month noted above the quantities of DS Batches or Active Drug Product and Diluent or Finished Goods, respectively, by Presentation forecasted for future order by Bioverativ for release in the months specified above, with “month-one” representing the month during which such Forecast is submitted.  
 (iv) Biogen will provide Bioverativ a 24 month forecast of planned Facility outages and overall Facility utilization for Drug Substance Manufacture in conjunction with Bioverativ’s quarterly Drug Substance forecast.  
 (b) Orders. Bioverativ shall place Orders for the number of batches or units of Drug Substance, Active Drug Product, Diluent and Finished Goods by Presentation (a “Purchase Order”), in accordance with the amounts, procedures and timelines set forth on Schedule 5 attached hereto. Such Purchase Order shall become binding in accordance with the procedures and timelines set forth on Schedule 5 attached hereto, and thereafter shall be deemed to be a “Binding Purchase Order.”  
 (c) Subject to the foregoing conditions, Biogen shall give such response of acceptance of the Purchase Order within ten (10) Business Days from receipt of a Purchase Order and such response shall include confirmation of the shipment date. Biogen shall be committed to use commercially reasonable efforts to produce and deliver the quantities of Drug Substance, Active Drug Product, Diluent and Finished Goods, by Presentation, set forth in such Binding Purchase  
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 Order; provided, however, that if Biogen conditionally agrees to supply any quantities of Drug Substance, Active Drug Product, Diluent and Finished Goods in excess of the quantities for such item set forth in the applicable Binding Forecast, Biogen’s efforts to supply such quantities shall be at its discretion. If Bioverativ does not place such a Purchase Order, or places a Purchase Order for a lesser quantity than the quantities specified in the Binding Forecast, in any case without Biogen’s prior written approval, then (i) Bioverativ shall nevertheless be deemed to have submitted such Purchase Order for the forecasted quantities of Drug Substance, Active Drug Product, Diluent and Finished Goods, (ii) Biogen may, but is not obligated to, produce the quantities of Drug Substance, Active Drug Product, Diluent or Finished Goods by Presentation that exceed the quantities in the applicable Binding Purchase Order if one was actually placed by Bioverativ, or any quantities of Drug Substance, Active Drug Product, Diluent or Finished Goods by Presentation if Bioverativ failed to timely place a Binding Purchase Order, (iii) Biogen shall be entitled to invoice Bioverativ for such Drug Substance, Active Drug Product, Diluent and Finished Goods pursuant to Section Article 7, (iv) Bioverativ shall be obligated to pay Biogen for such Drug Substance, Active Drug Product, Diluent and Finished Goods, and (v) such quantities of Drug Substance, Active Drug Product, Diluent and Finished Goods shall be deemed produced pursuant to a Binding Purchase Order. When scheduling Drug Substance production of Bioverativ Orders, and giving consideration to delivery schedules as per accepted Purchase Orders, Biogen will use commercially reasonable efforts to plan and conduct cost efficient manufacturing campaigns.  
 (d) Inventory. The Parties shall manage inventory levels, including minimum levels of critical materials and components and safety stock of Drug Substance, Drug Product and Finished Goods, in accordance with the following.  
 (i) Specifically, Biogen and Bioverativ, as appropriate depending on Phase, shall use commercially reasonable efforts to maintain safety stock (released and unreleased) inventories of twelve months Drug Substance MFCs, nine months Drug Product MFCs and 3 months Finished Goods MFCs.  
 (ii) Biogen will maintain all incoming materials including raw materials and components at safety stock levels appropriate to ensure uninterrupted market supply.  
 (iii) Inventory deemed excess or obsolete by Bioverativ due to any reason, including but not limited to changes in demand, inventory transitions, production scheduling, campaign and lot sizing or batch yield will be charged to Bioverativ per pricing schedule.  
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 5.3 Manufacturing Difficulties and Shortages.  
 (a) DS Batch Failure.  
 (i) During each calendar year, Biogen is expected to maintain the production success rates for commercial DS Batches as included in Schedule 6 attached hereto. If during such time less than 10 commercial batches are produced, then the time period will be extended until 10 or greater commercial batches have been produced. The costs of commercial batch failures will be borne by the parties based on the production success rates and as set forth on Schedule 6 attached hereto.  
 (ii) The cost of clinical batch failures will be borne by the parties as set forth in Schedule 6 attached hereto.  
 (iii) To the extent Bioverativ is responsible for any costs related to batch failures as set forth in Schedule 6, it will pay Biogen the cost incurred by Biogen, including the cost of raw materials. To the extent Biogen is responsible for any costs related to batch failures as set forth in Schedule 6, it will be responsible for its cost incurred, except for failures resulting from incoming raw materials which were properly inspected upon receipt or due to product process changes initiated at the request of Bioverativ.  
 (iv) Any batch failures resulting from incoming raw material or process failures due to product process changes initiated at the request of Bioverativ will not be factored into the success rate calculations and will be paid for according to Schedule 6, including raw materials, by Bioverativ. In the case of gross negligence, Biogen will be financially responsible for any costs related to batch failures, including raw materials.  
 (v) For batch failures, Bioverativ may elect to:  
 (1) not request replacement of the failed batches, with no impact to the requirements of the Binding Forecast or Semi-Binding Forecast and without financial impact to Bioverativ;  
 (2) cause Biogen to manufacture, at Biogen’s cost and expense, a new DS Batch that conforms to the Specifications as soon as practicable using commercially reasonable efforts, taking into account the availability of materials; or  
 (3) cause Biogen to reprocess, at a cost and expense per pre-defined success rate criteria set forth on Schedule 6 attached hereto, the DS Batch (if reasonably possible), with the goal that the reprocessed DS Batch conforms to the Specifications as soon as practicable using commercially reasonable efforts.  
 (vi) Notwithstanding any provision herein to the contrary: (i) Biogen will be responsible for any loss of resin or similar high value material resulting from gross negligence or willful misconduct by Biogen or its agents or contractors, and (ii) for any loss of resin or similar high value material at each production scale resulting from unrecoverable and assignable failure of Biogen or its agents or contractors that is not  
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 considered gross negligence or willful misconduct, Biogen will be responsible for 25% of the loss connected with the first occurrence, 75% of the loss connected with the second occurrence and 100% for the third and all subsequent loss occurrences; (iii) the number of resin and high value material losses described in this Section shall not be resin specific, and shall be reset on each fifth anniversary of the Effective Date; and (iv) in the event that resins or similar high value materials are not expected to be used in the manufacture of product within 12 months of the expected receipt date of such resins or high value materials.  
 (vii) No credit will be allowed and no relief from any payment obligation will result under Section 5.3(a) for any loss or production of any Engineering Batch.  
 (b) Shortages Allocation. In the case of a shortage of Drug Substance, Drug Product or components of Finished Goods or manufacturing capacity issues, including shortages due to a Force Majeure Event that is not caused by Biogen, Biogen shall produce and allocate to Bioverativ, with respect to each relevant Purchase Order, a portion of the product that is the subject of such shortage equal to the percentage of Bioverativ’s requirements for such product (based on the anticipated average annual production from the most recent twenty-four (24) month Forecast) bears to the overall product requirements of Biogen to produce all Biogen products, Third Party drug products and Bioverativ products, provided, however, that (i) unmet medical needs are prioritized first and foremost across all Biogen, Bioverativ and non-Biogen products manufactured; (ii) appropriate safety stock inventories (as set forth in Section 5.2(d) above) are adhered to; and (iii) unless (and only to the extent) not permitted by the terms of any agreements with Biogen’s other customers in effect on the date hereof (or any subsequent renewals on substantially the same terms), Biogen shall produce and allocate to Bioverativ the subject of the Purchase Order for which there is a shortage on an equal basis as Biogen products to the extent produced over all other non-Biogen products. Notwithstanding the foregoing, Biogen shall not prioritize the production of any Biogen products or any Third Party drug products that use the same materials or components that are subject to the shortage over the production of any Bioverativ products.  
 ARTICLE 6  
 TESTING AND QUALITY ASSURANCE  
 6.1 Finished Goods, Drug Product and Drug Substance Testing. Subject to the Quality Agreement and prior to the release and delivery of a DS Batch, a ADP Lot or a Diluent Lot, Biogen shall manage the testing and release of such Drug Substance, Active Drug Product, Diluent or Finished Goods, as applicable, and supply to Bioverativ the applicable certificates setting forth the analytical test results for such Drug Substance, Drug Product or Finished Goods, as applicable (the “DS Certificate of Analysis,” “ADP Certificate of Analysis,” “Diluent Certificate of Analysis” and “Finished Goods Certificate of Analysis” respectively) and (b)  
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 stating whether such Drug Substance, Drug Product or Finished Goods, as applicable, is manufactured in accordance with cGMPs and conforms with Drug Substance Specifications, Drug Product Specifications or Finished Goods Specifications, as applicable (the “DS Certificate of Conformance,” “ADP Certificate of Conformance,” “Diluent Certificate of Conformance” and “Finished Goods Certificate of Conformance” respectively).  
 ARTICLE 7  
 COST ALLOCATION, PRICING, AND PAYMENT  
 7.1 Pricing. Bioverativ shall pay Biogen for Drug Substance, Drug Product and Finished Goods on a cost-plus markup basis in accordance with Schedule 6 attached hereto.  
 7.2 Invoicing and Payment . Biogen will submit or cause to be submitted to Bioverativ for payment invoices of amounts due under this Agreement in accordance with Schedule 6 attached hereto.  
 7.3 Payment Denominations. All payments to be made under this Agreement shall be made in United States dollars.  
 7.4 Taxes.  
 (a) Bioverativ shall pay and otherwise be responsible for all applicable sales taxes, VAT, goods and services taxes and transfer taxes in connection with any payment made by Bioverativ pursuant to this Agreement.  
 (b) Any income or other tax that one Party hereunder is required to withhold and pay on behalf of the other Party hereunder with respect to amounts payable under this Agreement shall be deducted from and offset against said amounts prior to payment to the other Party; provided, however, that in regard to any tax so deducted, the Party making the withholding shall give or cause to be given to the other Party such reasonable assistance as may reasonably be necessary to enable that other Party to claim exemption therefrom or credit therefor, and in each case shall furnish the Party on whose behalf amounts were withheld, proper evidence of the taxes paid on its behalf. Each Party shall comply with reasonable requests of the other Party to take any proper actions that may minimize any withholding obligation.  
 ARTICLE 8  
 AUDITS  
 8.1 Drug Substance Facility. Subject to the terms of the Quality Agreement, reasonable advance notice to Biogen and confidentiality considerations, Bioverativ, at its cost (excluding, however, Biogen’s internal costs), shall have the right to audit Biogen’s Drug Substance manufacturing Facility one (1) time per every calendar year, unless legitimate quality concerns warrant additional visits or the Parties mutually agree otherwise, during normal business hours. The Parties agree that Biogen may refuse any Bioverativ employee or agent  
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 access to the Facility (or eject such person from the Facility) where it reasonably believes, and can reasonably demonstrate to Bioverativ that it has grounds for such belief, that such employee or agent is or may be a security risk to Biogen or does not meet Biogen’s safety or security requirements. Biogen shall have no liability under this Agreement for refusing access to or ejecting such individual(s). Bioverativ further agrees to protect, defend, indemnify, and hold harmless Biogen and its Affiliates from all demands, claims, actions, liability, loss, damage, costs and expenses, including reasonable attorneys’ fees arising out of any claims for personal injury or property damage caused by, or sustained by, a Bioverativ employee or agent while visiting Biogen’s Drug Substance manufacturing Facility.  
 8.2 Facilities for Manufacture of Drug Product and Finished Goods . Biogen shall, on its own and on Bioverativ’s behalf, audit the Third Party Manufacturer’s Facilities for the Manufacture of Drug Product and Finished Goods in accordance with the provisions of the agreement between Biogen and the Third Party Manufacturer and shall furnish to Bioverativ the reports from such audits. Bioverativ shall not accrue any costs for such audit.  
 8.3 Financial Audits. Each Party (the “Auditing Party”) shall have the right during the Term and for a period of three (3) years thereafter, to have an independent certified public accountant reasonably acceptable to the other Party (the “Audited Party”) examine the relevant books and records of the Audited Party and its Affiliates during normal business hours, not more than once each calendar year, to verify that appropriate accounting and payments have been made under this Agreement. In the event a determination is made that the Auditing Party has been underpaid or overcharged, the Audited Party shall promptly pay to the Auditing Party the amount by which the Auditing Party was underpaid or overcharged. The fees and expenses of the accountant performing any verification pursuant to this Section 8.3 shall be paid by the Auditing Party; provided, however, that, if a determination is made that the amount paid to the Auditing Party with respect to any calendar year was less than ninety-five percent (95%) of the amount properly due to the Auditing Party, the Audited Party shall promptly reimburse the Auditing Party for the costs of such verification. Any accountant who examines the books and records of the Audited Party pursuant to this Section 8.3 shall sign a confidentiality agreement reasonably satisfactory to the Audited Party.  
 ARTICLE 9  
 RELEASE, STORAGE AND SHIPMENT  
 9.1 Drug Substance. Subject to the Quality Agreement, this Section 9.1 shall apply to Drug Substance manufactured and supplied by Biogen under this Agreement in the Second Phase and the Third Phase. For the avoidance of doubt, this Section 9.1 shall not apply to the First Phase.  
 (a) Biogen Release. Biogen shall perform release testing in accordance with the Drug Substance Specifications of all DS Batches to ensure compliance with the Drug Substance Specifications and cGMPs. With respect to each DS Batch produced by Biogen under a Binding Purchase Order (or under Binding Forecast with respect to Drug Substance produced by Biogen under Section 5.2) and subject to Sections 5.2, 9.1(c) and 9.1(f), Biogen will release such Drug Substance  
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 to Bioverativ at the delivery date upon Biogen forwarding to Bioverativ by electronic transmission (as specified in the quality agreement) the DS Certificate of Analysis and the DS Certificate of Conformance (the “DS Release”). If Bioverativ submits to Biogen a written request for a copy of the related Batch Documentation, Biogen shall furnish a copy of such Batch Documentation to Bioverativ within five (5) Business Days.  
 (b) Biogen Refusal to Release. Without limiting Biogen’s obligation to supply Drug Substance hereunder, Biogen has the right to disqualify any quantity of Drug Substance for failure to comply with the Drug Substance Specifications, cGMPs or with other requirements (as determined in Biogen’s sole discretion) and to decide not to release such Drug Substance.  
 (c) Bioverativ Rejection.  
 (i) Specifications.  
 (A) If, based on its review of the DS Certificates and/or Batch Documentation, Bioverativ claims that any Drug Substance released by Biogen does not meet the Drug Substance Specifications, then Bioverativ shall notify Biogen in writing of its intent to reject such Drug Substance within forty-five (45) days of its receipt of the DS Certificate of Analysis and DS Certificate of Conformance for such Drug Substance, which notice shall describe in reasonable detail the reasons for rejection (e.g., the specific Drug Substance Specification failure and the deviation of reported numbers from required Drug Substance Specifications).  
 (B) If the Parties, through the JMSC, are unable to agree as to whether such Drug Substance meets the Drug Substance Specifications, then (i) the Parties shall jointly select an independent testing laboratory to test such disputed Drug Substance (the “DS Testing Laboratory”), (ii) Biogen shall send a sample of the disputed Drug Substance, along with the DS Certificates, to the DS Testing Laboratory within ten (10) Business Days of joint selection of the DS Testing Laboratory, (iii) within a mutually agreed period after receipt of the test sample, the DS Testing Laboratory shall test such sample for compliance with the Drug Substance Specifications using methods validated and approved by Biogen, and shall forward such test results to Biogen and Bioverativ, and (iv) such test results shall be binding on Biogen and Bioverativ on the issue of compliance of the Drug Substance with the Drug Substance Specifications.  
 (C) If the parties agree, or if the DS Testing Laboratory concludes, that the disputed Drug Substance meets the Drug Substance Specifications, then (i) such Drug Substance shall be  
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 deemed to be accepted under this Agreement and the DS Release shall be deemed effective as of the original release date as determined pursuant to Section 9.1(a), (ii) all payment and other terms of this Agreement shall apply as of such effective date of the DS Release and (iii) Bioverativ shall bear the cost of such laboratory testing.  
 (D) If the parties agree, or the DS Testing Laboratory concludes, that the disputed Drug Substance does not meet the Drug Substance Specifications, then (i) such Drug Substance shall be deemed to have been rejected under this Agreement and no DS Release with respect to such rejected Drug Substance shall be deemed to have occurred, (ii) Biogen shall use commercially reasonable efforts to replace the rejected DS Batch as soon as reasonably practicable but in no event later than six (6) months from the conclusion of the DS Testing Laboratory, and Bioverativ shall pay for such replacement DS Batch only if it has not paid for the DS Batch being replaced and (iii) Biogen shall bear the cost of such laboratory testing.  
 (E) For the avoidance of doubt and without limiting other remedies provided hereunder for any Non-Conformity, Bioverativ shall not have a right to reject Drug Substance where it does not provide its rejection notice within the forty-five (45) day period referenced in Section 9.1(c)(i)(A); provided that if Bioverativ discovers, or otherwise becomes aware of, a Latent Defect relating to a Non-Conformity with respect to any Drug Substance, Bioverativ shall be entitled to the same remedies set forth above in this Section 9.1(c)(i) so long as Bioverativ notifies Biogen promptly after the discovery of such Latent Defect and in any event prior to the documented or labeled expiration date of the shelf life of the applicable quantity of Drug Substance.  
 (F) Without prejudice to Bioverativ’s rights pursuant to Sections 11.8, 11.10, 16.1(c) and 18.2, the remedies set forth in Section 9.1(c)(i) shall be the sole and exclusive remedies for Biogen’s failure to deliver Drug Substance in accordance with the Drug Substance Specifications.  
 (ii) Compliance.  
 (A) If, based on its review of the DS Certificates, Bioverativ claims that any Drug Substance released by Biogen is subject to a Compliance Issue, then Bioverativ shall notify Biogen in writing of its rejection of such Drug Substance within forty-five (45) days of its receipt of the DS Certificate of Analysis and DS Certificate of Conformance for such Drug Substance, which notice shall describe  
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 in reasonable detail the reasons for rejection (e.g., the specific Compliance Issue failure).  
 (B) If the Parties agree that a Compliance Issue exists with respect to such Drug Substance, then Biogen shall, at its election, replace such Drug Substance as soon as reasonably practicable, but in no event later than six (6) months from the conclusion of the DS Testing Laboratory, and Bioverativ shall pay for such replacement DS Batch only if it has not paid for the DS Batch being replaced.  
 (C) If the Parties, through the JMSC, are unable to agree as to whether a Compliance Issue exists with respect to such Drug Substance, then (i) the Parties shall jointly select an independent consultant with expertise in cGMPs applicable to the manufacturing of biological drug products to test such disputed Drug Substance (the “cGMP Consultant”), (ii) Biogen shall send a sample of the disputed Drug Substance, along with the applicable DS Certificate of Analysis, DS Certificate of Conformance, Batch Documentation and any other information requested by the cGMP Consultant, to the cGMP Consultant within ten (10) Business Days of joint selection of the cGMP Consultant, (iii) within a mutually agreed period after receipt of the test sample and the foregoing documentation, the cGMP Consultant shall assess and make a determination as to the existence and nature of the alleged Compliance Issue, and shall forward the results of its assessment and determination (along with a detailed statement of the basis for its determination) to Biogen and Bioverativ, and (iv) such determination shall be binding on Biogen and Bioverativ on the issue of the alleged Compliance Issue.  
 (D) If the parties agree, or if the cGMP Consultant concludes, that the disputed Drug Substance was manufactured in accordance with cGMPs in effect when such Drug Substance was released, then (i) such Drug Substance shall be deemed to be accepted under this Agreement and the DS Release shall be deemed effective as of the original release date as determined pursuant to Section 9.1(a), (ii) all payment and other terms of this Agreement shall apply as of such effective date of the DS Release and (iii) Bioverativ shall bear the cost of the cGMP Consultant’s assessment and determination.  
 (E) If the parties agree, or the cGMP Consultant concludes, that the disputed Drug Substance is subject to a Compliance Issue, then (i) such Drug Substance shall be deemed to have been rejected under this Agreement and no DS Release with respect to such rejected Drug Substance shall be deemed to have occurred, (ii) Biogen shall replace the rejected DS Batch as soon as reasonably practicable but in no event later than six (6) months from the  
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 conclusion of the DS Testing Laboratory, and Bioverativ shall pay for such replacement DS Batch, and (iii) Biogen shall bear the cost of the cGMP Consultant.  
 (F) For the avoidance of doubt and without limiting other remedies provided hereunder for any Compliance Issue, Bioverativ shall not have a right to reject Drug Substance where it does not provide its rejection notice within the forty-five (45) day period referenced in Section 9.1(c)(ii)(A); provided that if Bioverativ discovers, or otherwise becomes aware of, a Latent Defect relating to a Compliance Issue with respect to any Drug Substance, Bioverativ shall be entitled to the same remedies set forth above in this Section 9.1(c)(ii) so long as Bioverativ notifies Biogen promptly after the discovery of such Latent Defect and in any event prior to the documented or labeled expiration date of the shelf life of the applicable quantity of Drug Substance.  
 (G) Without prejudice to Bioverativ’s rights pursuant to Sections 11.8, 11.10, 16.1(c) and 18.2, the remedies set forth in Section 9.1(c)(ii) shall be the sole and exclusive remedies for any Compliance Issue.  
 (d) Delivery. Upon DS Release in the Third Phase, delivery of the corresponding Drug Substance to Bioverativ shall be deemed to have occurred and title and risk of loss with respect to such Drug Substance shall transfer to Bioverativ. Upon Bioverativ’s request, Biogen shall sign any reasonable documents and take such other actions required for Bioverativ to perfect its title in such Drug Substance and, to the fullest extent permitted by law, Biogen hereby expressly grants Bioverativ authority and a limited power of attorney to file financing statements and other documents to record and otherwise perfect such title.  
 (e) Shipment. Unless otherwise agreed, delivery terms for Drug Substance shall be FCA (Incoterms 2010) to the applicable storage or manufacturing facility for the Drug Product and Finished Goods following receipt of a written authorization letter from Bioverativ in accordance with the reasonable shipping instructions provided therein and using a Third Party Carrier selected by Bioverativ for such the shipment. Bioverativ shall be responsible for all payments due to such Third Party Carrier with respect to such shipments of Drug Substance. Biogen shall be responsible for all packaging required for the proper shipment of Drug Substance, which shall be reimbursed by Bioverativ in accordance with Schedule 6.  
 (f) Drug Substance Shortfalls and Shelf Life. In the event that Biogen fails to deliver a DS Batch under a Binding Purchase Order, Biogen shall remedy such shortfall as soon as commercially reasonable, but in no event later than six (6)  
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 months after the delivery date under such Binding Purchase Order. Unless agreed in advance, DS Batches shall have no more than 18 months shelf life consumed.  
 9.2 Drug Product and Finished Goods. Subject to the Quality Agreement, this Section 9.2 shall apply to Drug Product and Finished Goods supplied by Biogen under this Agreement in the Second Phase. For the avoidance of doubt, this Section 9.2 shall not apply to the First Phase or the Third Phase.  
 (a) Biogen Release. With respect to each order of Drug Product or Finished Goods by Bioverativ under a Binding Purchase Order, Biogen shall perform manufacturer’s release of such order and provide Bioverativ by email the ADP Certificate of Analysis and the ADP Certificate of Conformance, Finished Goods Certificate of Analysis and the Finished Goods Certificate of Conformance, or the Diluent Certificate of Analysis and the Diluent Certificate of Conformance, as applicable. If Bioverativ submits to Biogen a written request for a copy of the related Batch Documentation, Biogen shall furnish a copy of such Batch Documentation to Bioverativ within three (3) Business Days.  
 (b) Biogen Refusal to Release. Biogen has the right to disqualify any quantity of Drug Product or Finished Goods for failure to comply with the Drug Product Specifications or Finished Goods Specifications, cGMPs or with other requirements (as determined in Biogen’s sole discretion) and to decide not to release such Drug Product or Finished Goods.  
 (c) Bioverativ Rejection.  
 (i) Specifications.  
 (A) If, based on its review of the ADP Certificates, Diluent Certificates and/or Batch Documentation, Bioverativ claims that any Drug Product or Finished Goods released by Biogen was not compliant with the Drug Product Specifications or Finished Goods Specifications at the time of DP Release by Biogen pursuant to Section 9.2(a), Bioverativ shall notify Biogen of its rejection of such Drug Product or Finished Goods within forty-five (45) days of its receipt of the ADP Certificates, Diluent Certificates or Finished Goods Certificates, as applicable, for such Drug Product or Finished Goods, which notice shall describe in reasonable detail the reasons for rejection (e.g., the specific Drug Product Specifications or Finished Goods Specification failure and the deviation of reported numbers from required Drug Product Specifications or Finished Goods Specifications).  
 (B) If the Parties, through the JMSC, are unable to agree as to whether such Drug Product or Finished Goods meets the Drug Product Specifications or Finished Goods Specifications, then (i) the Parties shall jointly select an independent testing laboratory to  
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 test such disputed Drug Product or Finished Goods (the “DP/FG Testing Laboratory”), (ii) Biogen shall send a sample of the disputed Drug Product or Finished Goods, along with the applicable ADP Certificates or Diluent Certificates, to the DP/FG Testing Laboratory within ten (10) Business Days of joint selection of the DP/FG Testing Laboratory, (iii) within a mutually agreed period after receipt of the test sample, the DP/FG Testing Laboratory shall test such sample for compliance with the Drug Product Specifications or Finished Goods Specifications using methods validated and approved by Biogen, and shall forward such test results to Biogen and Bioverativ and (iv) such test results shall be binding on Biogen and Bioverativ on the issue of compliance of the Drug Product or Finished Goods with the Drug Product Specifications or Finished Goods Specifications.  
 (C) If the Parties agree, or if the DP/FG Testing Laboratory concludes, that the disputed Drug Product or Finished Goods meets the Drug Product Specifications or Finished Goods Specifications, then (i) such Drug Product or Finished Goods shall be deemed to be accepted under this Agreement and the DP Release shall be deemed effective as of Biogen’s original issuance of the applicable ADP Certificates or Diluent Certificates to Bioverativ under Section 9.2(a), (ii) all payment and other terms of this Agreement shall apply as of such effective date of the DP Release and (iii) Bioverativ shall bear the cost of such laboratory testing.  
 (D) If the parties agree, or the DP/FG Testing Laboratory concludes, that the disputed Drug Product or Finished Goods does not meet the Drug Product Specifications or Finished Goods Specifications, then (i) such Drug Product or Finished Goods shall be deemed to have been rejected under this Agreement and no DP Release with respect to such rejected Drug Product or Finished Goods shall be deemed to have occurred, (ii) Biogen shall use commercially reasonable efforts to replace the rejected Drug Product or Finished Goods as soon as reasonably practicable but in no event later than six (6) months from the conclusion of the DP/FG Testing Laboratory, and Bioverativ shall pay for such replacement Drug Product or Finished Goods only to the extent it has not paid for the Drug Product or Finished Goods being replaced; provided that (1) to the extent that any such failure to meet the Drug Product Specifications or Finished Goods Specifications was caused by the Third Party Manufacturer, Bioverativ’s sole remedy from Biogen shall be limited to the same remedy to which Biogen is entitled from its Third Party Manufacturer as further specified under Section 11.7, and (2) Biogen shall have no obligation to replace rejected Drug Product or Finished Goods, nor any other liability to Bioverativ, if the  
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 failure to meet the Drug Product Specifications or Finished Goods Specifications was caused by the Third Party Carrier; and (iii) Biogen shall bear the cost of such laboratory testing.  
 (E) With respect to Drug Product or Finished Goods during Second Phase only, notwithstanding anything to the contrary in this Agreement, but except to the extent Biogen is entitled to compensation from its Third Party Manufacturer, Biogen shall not be required to replace Drug Substance (or to bear the cost of replacement of Drug Substance) contained in any rejected Drug Product or Finished Goods, which cost shall be borne by Bioverativ, and Biogen shall be relieved of any obligation to replace Drug Product or Finished Goods if Bioverativ fails to provide adequate replacement Drug Substance for use in manufacturing the replacement Drug Product or Finished Goods.  
 (F) For the avoidance of doubt, Bioverativ shall not have a right to reject Drug Product or Finished Goods where it does not provide its rejection notice within the forty-five (45) day period referenced in Section 9.2(c)(i)(A); provided that if Bioverativ discovers, or otherwise becomes aware of, a Latent Defect relating to Non-Conformity with respect to any Drug Product or Finished Goods, Bioverativ shall be entitled to the same remedies, subject to the same limitations, set forth above in this Section 9.2(c)(i) so long as Bioverativ notifies Biogen promptly after the discovery of such Latent Defect and in any event prior to the documented or labeled expiration date of the shelf life of the applicable quantity of Drug Product or Finished Goods.  
 (G) Without prejudice to Bioverativ’s rights pursuant to Sections 11.8, 11.10, 16.1(c) and 18.2, the remedies set forth in Section 9.2(c)(i) shall be the sole and exclusive remedies for Biogen’s failure to deliver Drug Product or Finished Goods in accordance with the Drug Product Specifications or Finished Goods Specifications.  
 (ii) Compliance.  
 (A) If, based on its review of the ADP Certificates, Diluent Certificates, Finished Goods Certificates and/or Batch Documentation, as applicable, Bioverativ claims that any Drug Product or Finished Goods released by Biogen is subject to a Compliance Issue, then Bioverativ shall notify Biogen in writing of its rejection of such Drug Product or Finished Goods within forty-five (45) days of its receipt of the ADP Certificate of Analysis and ADP Certificate of Conformance, or Diluent Certificate of Analysis and Diluent Certificate of Conformance, as applicable,  
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 which notice shall describe in reasonable detail the reasons for rejection (e.g., the specific Compliance Issue failure).  
 (B) If the Parties, through the JMSC, are unable to agree as to whether a Compliance Issue exists with respect to such Drug Product or Finished Goods, then (i) the Parties shall refer the issue to the cGMP Consultant, (ii) Biogen shall send a sample of the disputed Drug Product or Finished Goods, along with the applicable Finished Goods Certificates or ADP Certificates, Diluent Certificates, Batch Documentation and any other information requested by the cGMP Consultant, to the cGMP Consultant within ten (10) Business Days of joint selection of the cGMP Consultant, (iii) within a mutually agreed period after receipt of the test sample and the foregoing documentation, the cGMP Consultant shall assess and make a determination as to the existence and nature of the alleged Compliance Issue, and shall forward the results of its assessment and determination (along with a detailed statement of the basis for its determination) to Biogen and Bioverativ and (iv) such determination shall be binding on Biogen and Bioverativ on the issue of the alleged Compliance Issue.  
 (C) If the parties agree, or if the cGMP Consultant concludes, that the disputed Drug Product or Finished Goods was manufactured in accordance with cGMPs in effect when such Drug Product or Finished Goods was released, then (i) such Drug Product or Finished Goods shall be deemed to be accepted under this Agreement and the DP Release shall be deemed effective as of the original release date as determined pursuant to Section 9.2(a), (ii) all payment and other terms of this Agreement shall apply as of such effective date of such release and (iii) Bioverativ shall bear the cost of the cGMP Consultant’s assessment and determination.  
 (D) If the parties agree, or the cGMP Consultant concludes, that the disputed Drug Product or Finished Goods is subject to a Compliance Issue, then (i) such Drug Product or Finished Goods shall be deemed to have been rejected under this Agreement and no DP Release with respect to such rejected Drug Product or Finished Goods shall be deemed to have occurred, (ii) Biogen shall replace the rejected batch of Drug Product or Finished Goods as soon as reasonably practicable but in no event later than six (6) months from the determination by the cGMP Consultant, and Bioverativ shall pay for such replacement Batch; provided that (1) to the extent that any Compliance Issue was caused by the Third Party Manufacturer, Bioverativ’s sole remedy from Biogen shall be limited to the same remedy to which Biogen is entitled from its Third Party Manufacturer as further specified under Section 11.7,  
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 and (2) Biogen shall have no obligation to replace rejected Drug Product or Finished Goods, nor any other liability to Bioverativ, if the Compliance Issue was caused by the Third Party Carrier; and (iii) Biogen shall bear the cost of such laboratory testing.  
 (E) Notwithstanding anything to the contrary in this Agreement, but except to the extent Biogen is entitled to compensation from its Third Party Manufacturer, Biogen shall not be required to replace Drug Substance (or to bear the cost of replacement of Drug Substance) contained in any rejected Drug Product or Finished Goods, which cost shall be borne by Bioverativ, and Biogen shall be relieved of any obligation to replace Drug Product or Finished Goods if Bioverativ fails to provide adequate replacement Drug Substance for use in manufacturing the replacement Drug Product or Finished Goods.  
 (F) For the avoidance of doubt, Bioverativ shall not have a right to reject Drug Product or Finished Goods where it does not provide its rejection notice within the forty-five (45) day period referenced in this Section 9.2(c)(ii)(A); provided that if Bioverativ discovers, or otherwise becomes aware of, a Latent Defect relating to a Compliance Issue with respect to any Drug Product or Finished Goods, Bioverativ shall be entitled to the same remedies, subject to the same limitations, set forth above in this Section 9.2(c)(ii) so long as Bioverativ notifies Biogen promptly after the discovery of such Latent Defect and in any event prior to the documented or labeled expiration date of the shelf life of the applicable quantity of Drug Product or Finished Goods.  
 (G) Without prejudice to Bioverativ’s rights pursuant to Sections 11.8, 11.10, 16.1(c) and 18.2, the remedies set forth in this Section 9.2(c)(ii) shall be the sole and exclusive remedies for a Compliance Issue.  
 (d) Shipment and Delivery. Bioverativ shall arrange the shipment of each order of Drug Product or Finished Goods via a Third Party Carrier it selects to the location designated in the Binding Purchase Order no later than (i) upon the expiration of the forty-five (45) day review period set forth in Section 9.2(c)(ii)(A) if Bioverativ has not furnished to Biogen a rejection notice within such period, or (ii) in the case of disputed Drug Product or Finished Goods, the date the DP/FG Testing Laboratory determines that the Drug Product or Finished Goods complies with the Drug Product or Finished Goods Specifications. If Bioverativ fails to arrange for timely shipment, Biogen shall have the right to arrange for such shipment and invoice Bioverativ for the shipment costs. If Bioverativ fails to specify a delivery location in any Binding Purchase Order, Biogen shall be entitled to either ship to the location last specified in any Binding Purchase Order and invoice Bioverativ for the shipment costs or to store or  
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 arrange for a Third Party to store such Drug Product or Finished Goods at Bioverativ’s expense, which storage costs shall be invoiced to and payable by Bioverativ on a monthly basis within ten days after the date of invoice. Unless agreed prior, the delivery terms shall be FCA (Incoterms 2010) Facility for Drug Product or Finished Goods, as applicable. For clarity, title to and risk of loss in the Drug Product or Finished Goods (as distinct from title and risk of loss in the Drug Substance, which is governed by Section 9.1(d)) shall transfer to Bioverativ upon the Drug Product or Finished Goods being made available to the Third Party Carrier at the Facility for Drug Product or Finished Goods, as applicable, and Bioverativ shall be responsible for obtaining insurance for the Drug Product from that time onward. Bioverativ shall be responsible for all delivery charges, duties or other export or import fees or charges, and any other costs associated with the export, import or carriage of the Drug Product. Biogen shall comply with Bioverativ’s written specifications for packaging for the shipment of Drug Product.  
 (e) Drug Product Batch Size and Number Shortfalls. If any Lot of Drug Product or amount of Finished Goods produced for Bioverativ by the Third Party Manufacturer is of a quantity that is lower than the expected yield range but otherwise meets the Drug Product Specifications or Finished Goods Specifications, Bioverativ shall accept such Lot or amount and Bioverativ’s sole remedy from Biogen shall be limited to the same remedy to which Biogen is entitled from its Third Party Manufacturer for such Lot or amount size shortfall. If Biogen is unable to supply to Bioverativ the number of Lots of Drug Product or amount of Finished Goods properly ordered by Bioverativ under this Agreement, Bioverativ will be entitled to any remedy for a shortfall in the number of Lots or amount that Biogen may be entitled to under Biogen’s supply agreement with the Third Party Manufacturer. For clarity, Bioverativ shall not be entitled to recover from Biogen for any shortfall in Drug Product or Finished Goods quantity or size any more than Biogen is entitled to recover from its Third Party Manufacturer for such shortfall.  
 ARTICLE 10  
 MANAGEMENT OF THE ALLIANCE  
 10.1 In connection with managing the Alliance, including the management of the Parties’ efforts hereunder, the exchange of Forecasts and other communications and certain other related matters, Bioverativ and Biogen will establish a joint steering committee (the “Joint Manufacturing and Supply Committee” or “JMSC”) and certain procedures related to the operation thereto, in each case in accordance with Schedule 9 attached hereto.  
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 ARTICLE 11  
 MANUFACTURE SERVICES  
 11.1 General. Biogen shall manufacture or cause to be manufacture by a Third Party Manufacturer in accordance with the Specifications, cGMPs, Applicable Law and the Quality Agreement. Nothing in this Agreement shall be deemed to restrict in any way Biogen’s right to make changes in any Facility in its sole discretion, provided that such Facility remains in compliance with all requirements of this Agreement and the Parties shall discuss and reasonably agree upon a plan to provide Bioverativ with sufficient supply of product manufactured according to the then current Specifications and allow Biogen to implement such Facility changes within a commercially reasonable time. Biogen shall inform Bioverativ of any Facility changes impacting facility process equipment or infrastructure to ensure regulatory impact is assessed. If any changes could have a material effect on Bioverativ or its Affiliates’ product filing requirements or requirements for product, Biogen shall provide at least twelve (12) months’ notice of any such proposed changes and shall not proceed without Bioverativ’s prior written consent, such consent not to be unreasonably withheld.  
 11.2 Required Changes in Specifications or Process. If Bioverativ or Biogen is required to change the Facility, any Specifications or the Process (i) in order to comply with any requirement of any Regulatory Authority, (ii) in response to the order or request of any Regulatory Authority, (iii) due to the loss of a validated source of a material, or (iv) in order to avoid infringing any third-party patent (each of the foregoing, a “Required Change”), all of the following provisions shall apply:  
 (a) The Party receiving the order or request from the Regulatory Authority shall promptly advise the other Party in writing of any such Required Change(s) to Specifications or the Process and each Party shall promptly advise the other as to scheduling adjustments that may result from such Required Change(s), if any.  
 (b) Biogen shall exercise commercially reasonable efforts to implement all such Required Changes and to resume production schedules to Specifications and the Process as soon as reasonably possible after implementing such Required Changes notice thereof, but in any event shall do so within the time required by any Regulatory Authority.  
 (c) Bioverativ shall reimburse Biogen for all costs reasonable incurred arising out of Biogen’s efforts to implement any Required Changes relating to Bioverativ products within forty-five (45) days of receipt, upon delivery by Biogen to Bioverativ of an itemized invoice for the same, including but not limited to: (i) all Third Party costs or expenses, to the extent incurred by Biogen or arising as part of Biogen’s efforts to implement any such Required Changes of Bioverativ to Specifications or the Process, (ii) Biogen’s reasonable actual costs of all supplies provided by Biogen, and (iii) time spent by Biogen personnel at the FTE Rate to the extent not already included in the pricing for Drug Substance, Drug Product and Finished Goods.  
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 (d) The JMSC may adjust pricing for product supplied under this Agreement to reflect the change in the incremental cost arising out of any Required Change. Biogen shall provide to Bioverativ such documentation as is reasonably necessary to verify such cost changes, and the price increase or decrease shall be negotiated in good faith between the Parties.  
 (e) Bioverativ shall prepare for submission, and Biogen shall review and provide comments upon, any regulatory filings or portions thereof related to the Process or the product required in relation to implementation of any Required Change.  
 (f) Biogen shall prepare for submission, and Bioverativ shall review and provide comments upon, any regulatory filings or portions thereof related to the Facility or the equipment required in relation to implementation of any Required Change.  
 11.3 Discretionary Changes to Specifications, Process or Suppliers.  
 (a) If either Party desires to change Specifications or the Process in a way that does not involve a Required Change, it shall notify the other Party in writing of the proposed change (a “Proposed Change”), and the Parties shall review and discuss such Proposed Change, including whether the implementation of such Proposed Change is expected to result in material changes to costs compared to what Biogen is then incurring to manufacture product.  
 (b) Biogen shall be entitled to propose, as Proposed Changes, any changes to the Process or Specifications, for batches or lots of product resulting from a particular Campaign, due to events or circumstances which arise following the start of such Campaign and are, for Biogen, reasonably unexpected with respect to such Campaign.  
 (c) Neither Party shall have any obligation to give effect to any Proposed Change that is not a Biogen Broader Change (as defined below) unless the Parties agree in writing to effect the Proposed Change.  
 (d) Biogen shall be entitled to implement, and Bioverativ shall have an obligation to give effect to, changes to or within Biogen manufacturing facilities, including changes to general equipment, any facility-wide standard operating procedures, or any other general change to or within the Facility, (each a “Biogen Broader Change”) that are intended by Biogen to address matters other than the Process or Specifications but which may have an effect on the same on reasonable advance notice to Bioverativ and subject to Biogen providing, at no cost to Bioverativ, all reasonable assistance to Bioverativ to make any regulatory filings required in relation to implementation of any such change within any applicable time periods required by law. Should any such Proposed Change affect filing requirements with governmental agencies, the parties shall discuss and reasonably agree upon a plan to provide Bioverativ with sufficient supply of product  
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 manufactured according to the then current Specifications and allow Biogen to implement such Facility changes within a commercially reasonable time. Notwithstanding the foregoing, Biogen cannot make any changes without Bioverativ’s prior written consent, such consent not to be unreasonably withheld, if any such changes would affect Biogen’s supply of product as set forth herein or affect any requirements, such as filing requirements with governmental agencies, that Bioverativ or its Affiliates may have for the product.  
 (e) Each Party shall reimburse the other Party for the reasonable out-of-pocket expenses incurred by the other Party as a result of any Proposed Change by such Party that is implemented, in each case as approved by the JMSC prior to either party incurring any costs. In addition, either Party may condition its consent to any Proposed Change on the implementation of satisfactory reimbursement arrangements to cover its costs and expenses, including ongoing costs and expenses, which are beyond reasonable out-of-pocket expenses.  
 (f) Notwithstanding the other provisions of this Section 11.3: (i) Biogen shall not propose any Proposed Change if the implementation of such Proposed Change would, itself, infringe any third party intellectual property rights; and (ii) any Proposed Change in respect of the Process of manufacturing for product shall require Bioverativ’s prior written consent, which may be withheld in its sole discretion, and (iii) all costs associated with a Biogen Broader Change shall be the sole responsibility of Biogen.  
 (g) For the avoidance of doubt, Proposed Changes shall include but not be limited to changes in the type or model of equipment used in the Process, but not the substitution of a new piece of equipment of the same make and model in replacement of an older piece of equipment, and shall also include proposed substitution (other than in the context of a Required Change) of any assay, process validation procedure, vendor or contract supplier of materials or other components used in providing manufacturing services of the product.  
 (h) The JMSC may adjust the pricing for product under this Agreement to reflect any change in ongoing cost of manufacturing of product resulting from any Proposed Change.  
 (i) For any Proposed Changes, Bioverativ shall prepare for submission, and Biogen shall review and provide comments upon, any regulatory filings required in relation to implementation of any such Proposed Change.  
 (j) Biogen shall devote commercially reasonable efforts to implement any Proposed Changes in a manner that is orderly and avoids any supply interruption to Bioverativ.  
 11.4 Facility Validation. Except as expressly provided in this Agreement, and excluding process validation and validation of Bioverativ-owned equipment, Biogen shall perform at no additional cost to Bioverativ and on an on-going basis the necessary Facility  
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 validation activities required by cGMPs or Applicable Law in connection with the regular course of manufacturing the product.  
 11.5 Other Manufacturing Process Change. During the First Phase, subject to obtaining any required Regulatory Approval, Biogen has authority to change the manufacturing Process if Biogen provides Bioverativ advance written notice of such change and copies of any regulatory filings prepared by Biogen in connection with such proposed change and Bioverativ consents in writing to such change. In the event that a change of the manufacturing Process results in significant change of the yield or manufacturing cost, the Parties shall negotiate in good faith to change the corresponding batch or unit price to reflect such change.  
 11.6 Capital Expenditures. All capital expenditures, to the extent arising out of any Required Change specific to a Bioverativ product, shall be the sole responsibility of Bioverativ. General facility or process related capital changes required to meet cGMP’s, age of life or any other non-specific Bioverativ product requirement will be the responsibility of Biogen. For expenditures related to Bioverativ area of responsibility, Biogen will invoice such expenditures as incurred by Biogen. To the extent that any such capital expenditures have not been fully reimbursed upon termination or expiration of the Agreement, Bioverativ shall pay any such unreimbursed amounts to Biogen prior to any such termination or expiration.  
 11.7 Drug Product and Finished Goods Failures. If Biogen or Bioverativ determines that an ADP Lot or Diluent Lot or Finished Goods manufactured for Bioverativ is Non-Conforming or is subject to a Compliance Issue that, in each case, is caused by the Third Party Manufacturer, then Biogen shall be responsible to Bioverativ to the same extent that Biogen’s Third Party Manufacturer is responsible to Biogen with respect to the portion of the loss caused by the Third Party Manufacturer. For the avoidance of doubt, Biogen’s liability for damages or loss with respect to any rejected ADP Lot or Diluent Lot or Finished Goods that is caused by the Third Party Manufacturer shall be limited to the extent of the Third Party Manufacturer’s liability for damages or loss to Biogen under Biogen’s agreement with the Third Party Manufacturer, except as provided in this Section 11.7 or in Section 11.10 below, as limited in each case by Article 17. Biogen shall have no liability with respect to any damages or loss with respect to any Compliance Issue, Non-Conformity or failure to comply with Applicable Law that is caused by a Third Party Carrier.  
 11.8 Product Complaints. If, after the release of Finished Goods or Drug Product, either Party becomes aware that any such Finished Goods are, or Drug Product is, Non-Conforming or is subject to a Compliance Issue, or that such Finished Goods are, or Drug Product is, the subject of a complaint, then such Party shall immediately notify the other Party. The Parties shall then confer and coordinate as to the actions required, if any, to comply with Applicable Law, and Bioverativ shall have responsibility for responding and taking the action required by Applicable Law. Nothing herein is intended to preclude either Party from acting as required under Applicable Law.  
 11.9 Recalls, Product Withdrawals and Field Corrections. If any governmental entity issues a request, directive or order to a Party (or its Affiliate) requiring that any of the Finished Goods or Drug Product be recalled, or detains or destroys or prevents the release of any of the Finished Goods or Drug Product, or if either Party becomes aware of any other facts or  
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 circumstances that suggest a recall, withdrawal or field correction may be warranted, such Party shall give the other Party telephonic notice within twenty-four (24) hours (to be confirmed in writing within one (1) Business Day) of the occurrence of such event. In the Second Phase and Third Phase, Bioverativ shall have the sole right to determine whether to implement a recall, product withdrawal or field correction of the Finished Goods or Drug Product, but shall make such decision in accordance with the instructions of the Regulatory Authority of the country where such Finished Goods or Drug Product was distributed and shall reasonably take into consideration Biogen’s comments and concerns in relation to any proposed recall, withdrawal or field correction. If Bioverativ decides that there shall be a recall, withdrawal or field correction, Bioverativ shall have the sole right to control the implementation of such recall, withdrawal or field correction, but shall keep Biogen informed on a regular basis of its progress in planning and implementing the recall, withdrawal or field correction. Biogen shall cooperate with Bioverativ in connection with, and the provisions of Section 11.10 below shall be applicable to, any such action, and Bioverativ shall provide to Biogen all documentation reasonably requested by such other Party.  
 11.10 Cost of Recalls, Product Withdrawals and Field Corrections. If any of the Finished Goods are, or Drug Product is, quarantined, recalled, withdrawn, or subject to a field correction (whether voluntary or by governmental action), any direct costs and expenses incurred and paid by Bioverativ (including government fines or penalties related to such quarantine, recall, withdrawal or field correction) shall be (a) reimbursed by Biogen, if such corrective action is demonstrated to be due to the negligence or willful misconduct of Biogen (or its Third Party Manufacturer) or (b) borne by Bioverativ, for all other corrective actions. Where such corrective action is due to a Latent Defect or Biogen’s (or its Third Party Manufacturer’s) negligence or willful misconduct, Biogen shall use commercially reasonable efforts to schedule manufacturing Campaigns to replace the quantities of Finished Goods or Drug Product affected by the corrective action. Notwithstanding anything to the contrary in this Agreement, in the case of any such actions caused by the negligence of Third Party Manufacturer, Biogen shall not be required to reimburse Bioverativ in an amount that exceeds the reimbursement to which it is entitled from its Third Party Manufacturer or beyond the limitations set forth in Article 17.  
 11.11 Record-Keeping. Each Party (as applicable) shall maintain, in accordance with and for the period required under cGMPs and all other Applicable Laws, complete and accurate records pertaining to its manufacture, processing, testing, packing, labeling, holding, marketing, and distribution activities of the Finished Goods, Drug Substance and Drug Product, as applicable. Each Party shall provide the other Party with reasonable access to and the right to copy, at the requesting Party’s expense, such documentation maintained by the other Party during normal business hours and upon reasonable advance notice.  
 11.12 Person In Plant. Bioverativ shall have the right but not the obligation to establish its employees or up to three (3) outside consultants, in each case under strict confidentiality and non-use provisions at least as stringent as those applicable to Bioverativ employees with respect to Confidential Information of Biogen, as resident in Biogen’s Drug Substance manufacturing facility in order to observe operations relevant to products and to facilitate communications between the Parties regarding same. For avoidance of doubt, any such resident employee or consultant shall not have authority to direct or interfere with the operations at such facility and Biogen shall have the right to exclude any such employee or consultant from  
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 areas of the facility deemed in Biogen’s reasonable judgment to be particularly commercially sensitive or as reasonably required by any agreement with a Third Party having a bona fide interest in confidentiality at the facility. Bioverativ shall in all cases remain responsible for any equipment, salary, benefits and insurance associated with any such employee or consultant, who shall under no circumstances be deemed in the employment of or under contract to Biogen. Biogen’s sole obligation with respect to any such employee or consultant shall be to provide reasonable working space at or near the facility and to grant the agreed access to the facility to such employee or consultant.  
 11.13 Facility Access. Biogen shall use commercially reasonable efforts to accommodate a request from Bioverativ, upon reasonable notice, for facility tours with external patient groups, key opinion leaders and other key scientific and leaders. All such tours shall be conducted by Biogen during normal business hours and follow all site protocols, procedures and confidentiality requirements.  
 ARTICLE 12  
 REGULATORY MATTERS  
 12.1 Regulatory Support. Bioverativ may request regulatory support that is related to the Manufacture of Drug Substance. Biogen shall use commercially reasonable efforts to provide the following support services and shall be reimbursed by Bioverativ for reasonable costs incurred in connection therewith and in accordance with Schedule 6 attached hereto: (a) providing regulatory information, drafts and filings that Biogen already has in its possession and (b) answering questions reasonably necessary for the preparation of regulatory filings for the products. For purposes of clarity, Biogen shall not be required to hire and/or transfer from other projects any regulatory full-time equivalents in order to meet the regulatory support needs described in this Section 12.1. In any event, Biogen will provide to Bioverativ free of charge copies of any regulatory filings prepared by Biogen relating to changes to Regulatory Approvals that arise from CMC-related changes for the products.  
 12.2 Inspection by Regulatory Authority. The Parties shall cooperate in good faith with respect to the conduct of any inspections by any Regulatory Authority of Biogen’s Drug Substance manufacturing facility and/or the Third Party Manufacturer’s Drug Product and Finished Goods manufacturing facility. Biogen shall give Bioverativ notice of, and Bioverativ shall have the right to be on site during the portion of, any such regulatory inspection conducted by a Regulatory Authority that relates to the Drug Substance or the Drug Product or Finished Goods, except to the extent (a) not permitted by applicable law of the Regulatory Authority conducting the inspection, (b) any such attendance would result in the disclosure of Confidential Information or trade secrets unrelated to the Drug Substance, Drug Product or Finished Goods (where Biogen shall have taken reasonable measures to seek to avoid disclosure of Confidential Information and such trade secrets, provided, however, that in no event shall such reasonable measures be deemed to include any measures under which Biogen would incur unreasonable additional costs), or (c) the Third Party Manufacturer’s contract with Biogen does not permit such attendance. If in Biogen’s reasonable judgment Bioverativ’s presence on site is required, Biogen will notify Bioverativ and may require Bioverativ to attend such inspection (or answer questions of the Regulatory Authority).  
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 ARTICLE 13  
 TERM AND TERMINATION  
 13.1 Term.  
 (a) Term. Unless earlier terminated in accordance with Section 13.2, this Agreement will remain in force for the period commencing on the Effective Date and continuing through the day immediately prior to the fifth (5th) anniversary (the “Initial Term”).  
 (b) Renewals. Bioverativ may, in its sole discretion, renew this Agreement for a five year term and the Parties may further renew this Agreement an additional five (5) year term thereafter (but are not obligated to do so) (each, a “Renewal Term”). If Bioverativ intends to renew the Agreement, it shall give such notice of intent to renew at least two (2) years prior to the expiration of the Initial Term. If either Party intends to further renew this Agreement, such Party shall give notice of intent to renew at least three (3) years prior to the expiration of the first Renewal Term. The Parties shall use good faith efforts, for a period not to exceed ninety (90) days after receipt of the renewal notice for the second Renewal Term, unless a longer negotiation period is agreed to in writing by the Parties, to agree in writing to the terms applicable to the second Renewal Term. If no such notice of intent to renew is issued by Bioverativ, with respect to the first Renewal Term, or by Bioverativ or Biogen, with respect to the second Renewal Term, in each case prior to the applicable deadline for such renewal or if, in the case of the second Renewal Term, such notice is issued but the Parties fail to agree to a new Renewal Term and the terms thereof within the permitted negotiation period, then, if Bioverativ wishes to assume manufacturing of Drug Substance and Drug Product and Finished Goods upon the expiration of this Agreement, the Parties shall use good faith efforts to agree upon and implement a technology transfer plan in accordance with Section 13.4(e) within a reasonable timeframe to enable Bioverativ to assume manufacturing of Drug Substance, Drug Product and Finished Goods as of the date of expiration of this Agreement. To the extent that any Forecast for Drug Substance, Drug Product or Finished Goods extends after the Initial Term or, if applicable, a Renewal Term, no Binding Forecast contained therein shall be made for applicable months following the anticipated expiration of this Agreement unless mutually agreed by the Parties.  
 13.2 Termination.  
 (a) Debarment or Exclusion. Either Party, at its sole option, may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party in the event that the other Party has been debarred under 21 U.S.C. Section 335a or excluded under Section 1128 of the Social Security Act of 1935.  
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 (b) Bankruptcy; Insolvency. To the extent allowable under Applicable Law, either Party at its sole option may immediately terminate this Agreement upon written notice, but without prior advance notice, to the other Party in the event that (i) the other Party is declared insolvent or bankrupt by a court of competent jurisdiction; (ii) a voluntary petition of bankruptcy is filed in any court of competent jurisdiction by such other Party; or (iii) this Agreement (or a Party’s other assets) is (are) assigned by such other Party for the benefit of creditors.  
 13.3 Termination for Material Breach.  
 (a) Notice and Cure. If one Party commits a material breach of this Agreement (the “Breaching Party”), the other Party (the “Notifying Party”) may provide fifty-nine (59) days’ advance written notice to the Breaching Party of its intent to terminate this Agreement, which notice shall identify the material breach and the actions or conduct that it considers to be an acceptable cure of such material breach, which shall be in accordance with the terms of this Agreement. During such fifty-nine (59) day period, the Breaching Party may seek to cure such material breach (the “Initial Cure Period”). If the material breach is not cured within such fifty-nine (59) day period, the Notifying Party may terminate this Agreement upon twenty (20) days written notice; provided, that if the Breaching Party disputes such material breach as provided in subsection (b) below, such termination shall be effective only as provided in such subsection (b).  
 (b) Disputed Breach. If the Notifying Party gives notice of material breach under this Section 13.3 and the Breaching Party disputes whether there is a material breach, then the issue of whether the Notifying Party may properly terminate this Agreement on expiration of such Initial Cure Period shall be resolved in accordance with Article 20 (Dispute Resolution), and the Agreement shall not terminate except as provided in this Section 13.3(b). Such dispute resolution proceeding does not suspend either Party’s obligations hereunder and each Party shall use reasonable efforts to mitigate all damages prior to the conclusion of the dispute resolution proceeding. If, as a result of such dispute resolution proceeding, it is determined that the Breaching Party did not commit a material breach (or that such material breach was cured within the Initial Cure Period) then no termination shall be effective and this Agreement shall remain in effect as it was prior to such notice by the Notifying Party for the remaining duration of the Term. If, as a result of such dispute resolution process, it is determined that the Breaching Party committed a material breach and the Breaching Party does not cure such breach within sixty (60) days after the date of the arbitration award (the “Additional Cure Period”), then such termination shall be effective upon the expiration of the Additional Cure Period.  
 13.4 Effect of Termination or Expiration.  
 (a) Upon expiration of this Agreement, Biogen will, upon Bioverativ’s request, perform a technology transfer in accordance with Section 13.4(e).  
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 (b) Upon termination of this Agreement by Biogen under Sections 13.2(a) (Debarment or Exclusion), 13.2(b) (Bankruptcy; Insolvency) or 13.3 (Termination for Material Breach): Bioverativ shall be obligated to purchase and pay Biogen for the Finished Goods, Drug Substance and Drug Product (and all starting materials and components necessary to produce the Finished Goods, Drug Substance and Drug Product) pursuant to the quantities contained in its Binding Forecast. For avoidance of doubt, Biogen shall have no obligation to conduct technology transfer activities under this Section 13.4(b).  
 (c) Upon termination of this Agreement by Bioverativ under Sections 13.2(a) (Debarment or Exclusion), 13.2(b) (Bankruptcy; Insolvency) or 13.3 (Termination for Material Breach): (i) the Parties will conduct the technology transfer activities in accordance with Section 13.4(e); and (ii) Biogen shall, unless otherwise notified by Bioverativ to halt such production, continue to produce Drug Substance and Drug Product and Finished Goods in accordance with the Binding Forecast in effect as of the date of notice of termination and Bioverativ shall purchase and pay Biogen for such Drug Substance and Drug Product and Finished Goods in accordance with Article 7.  
 (d) Upon any expiration or termination of this Agreement, remedies for breach, rights to accrued payments and Articles and Sections 1 (Definitions), 7.1 (Pricing), 7.2 (Invoicing and Payment), 7.3 (Payment Denominations), 7.4 (Taxes), 9.1(c) (Bioverativ Rejection) (solely with regard to Latent Defects and the entire sub-section with regard to any Drug Substance supplied after the date of termination), 9.2(c) (Bioverativ Rejection) (solely with regard to Latent Defects and the entire sub-section with regard to any Drug Product and Finished Goods supplied after the date of termination), 11.7 (Drug Product and Finished Goods Failures) (solely with regard to any Drug Product and Finished Goods supplied after the date of termination), 11.8 (Product Complaints), 11.9 (Recalls, Product Withdrawals and Field Corrections), 11.10 (Cost of Recalls, Product Withdrawals and Field Corrections), 11.11 (Record-Keeping), 13.4 (Effect of Termination or Expiration), 13.5 (Quality Agreement), Article 14 (Intellectual Property), Article 15 (Confidentiality), 16.1(c), 16.2 (Warranty Limitations and Disclaimer), 17 (Liability Limitation), 18 (Indemnity), 19 (Insurance Coverage), Article 20 (Dispute Resolution), Article 21 (Miscellaneous) and Schedule 7 attached hereto shall survive.  
 (e) In the event that a provision of this Article 13 specifies that the Parties will conduct technology transfer activities, Biogen will assist Bioverativ and be reimbursed in accordance with Schedule 8, and at Bioverativ’s cost (provided that upon termination by Bioverativ according to Section 13.3 or upon certain sale or transfers with respect to Biogen as specified in Section 21.3, there shall be no such reimbursement), with technology transfer and validation activities in connection with transferring Drug Substance manufacturing and Drug Product and Finished Goods manufacturing (as applicable) to another manufacturer, except that it shall be solely Bioverativ’s responsibility and obligation to secure and make arrangements with any such replacement manufacturer as well as any  
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 other vendors Bioverativ deems necessary, subject to a technology transfer plan or agreement to be negotiated in good faith by the Parties and the relevant manufacturers and/or other vendors within six (6) months of the event triggering the technology transfer obligation, and in all events prior to commencing such technology transfer, and provided that each such manufacturer and vendor is reasonably acceptable to Biogen and has executed a confidentiality and limited use agreement with Biogen to protect Biogen’s rights in its intellectual and proprietary or Confidential Information.  
 13.5 Quality Agreement. For the avoidance of doubt, a breach of the Quality Agreement shall not constitute a breach of this Agreement.  
 ARTICLE 14  
 INTELLECTUAL PROPERTY  
 14.1 Background IP. As between Bioverativ and Biogen, Biogen shall exclusively own all right, title and interest in and to any Intellectual Property owned by Biogen as of immediately following the Distribution Effective Time (collectively, the “Biogen Background IP”). As between the Parties, Bioverativ shall exclusively own all right, title and interest in and to any Intellectual Property owned by Bioverativ as of immediately following the Distribution Effective Time (collectively, the “Bioverativ Background IP”). Except for the license rights expressly provided for herein, nothing herein shall be construed as granting any rights (ownership, licensed or otherwise) to Bioverativ in any such Biogen Background IP or to Biogen in any such Bioverativ Background IP.  
 14.2 Foreground IP.  
 (a) As between the Parties, Biogen shall own and retain the entire right, title and interest in and to all Intellectual Property made solely by the employee(s) or agent(s) of Biogen or any of its Affiliates, including all Patents and Copyrights arising from such Intellectual Property subject only to the rights expressly granted to Bioverativ under this Agreement.  
 (b) As between the Parties, Bioverativ shall own and retain the entire right, title and interest in and to all Intellectual Property made solely by the employee(s) or agent(s) of Bioverativ or any of its Affiliates, including all Patents arising from such Intellectual Property subject only to the rights expressly granted to Biogen under this Agreement.  
 14.3 Joint IP. Each Party shall own and retain an undivided equal ownership interest in all Intellectual Property made jointly by the employee(s) or agent(s) of one Party or any of its Affiliates and the employee(s) or agent(s) of the other Party or any of its Affiliates, including all Patents arising from such Intellectual Property (the “Joint IP”), subject only to the rights expressly granted by the Parties under this Agreement. For purposes of control of the prosecution, maintenance, defense and assertion of Joint IP arising under this Agreement, the  
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 applicable provisions of the IP License Agreement as related to the Biogen Shared Intellectual Property (as defined in the IP License Agreement) shall apply. Except as expressly permitted under this Agreement or the IP License Agreement, neither Party shall have the right to license or sublicense any Joint IP to any Third Party without the prior written consent of the other Party.  
 14.4 Ownership of Intellectual Property and Patents arising from the activities under this Agreement will be determined in accordance with U.S. laws of inventorship. Each Party agrees to take all actions that are reasonably necessary to give effect to the ownership interests set forth in this Article 14.  
 14.5 This Agreement shall be understood to be a joint research agreement in accordance with 35 U.S.C. §103(c) or 35 U.S.C. §102(c), as applicable, provided that neither Party shall (i) unilaterally invoke the protections of or (ii) be required by this reference to have any Patent take advantage of or become subject to, such §103(c)(3) or 35 U.S.C. §102(c), as applicable, except with the prior written consent of the other Party.  
 ARTICLE 15  
 CONFIDENTIALITY  
 15.1 Confidential Information. The provisions of Article VII (PRESERVATION OF RECORDS; ACCESS TO INFORMATION; CONFIDENTIALITY; PRIVILEGE) of the Separation Agreement shall apply to disclosures of information made pursuant to this Agreement mutatis mutandis. In addition, Biogen shall have the right to provide to each Third Party Manufacturer and other third party contractors retained by Biogen such Confidential Information of Bioverativ as is reasonably necessary for such Third Party Manufacturer to perform its services with respect to the manufacture of Drug Substance, Drug Product or Finished Goods, subject to a confidentiality and limited use agreement containing appropriate restrictions and Bioverativ shall have the right to provide to Third Party contractors retained by Bioverativ such Confidential Information of Biogen as is reasonably necessary for such Third Party to perform its services with respect to manufacture of finished product from the Drug Product or of Drug Product, distribution of Finished Goods, or for enabling Bioverativ’s marketing, sale and distribution of the Drug Product or Finished Goods, in each case in accordance with the terms of this Agreement, subject to a confidentiality and limited use agreement containing appropriate restrictions.  
 ARTICLE 16  
 REPRESENTATIONS AND WARRANTIES; COVENANTS  
 16.1 Representations and Warranties.  
 (a) Each Party (the “Representing Party”) represents and warrants to the other Party that, as of the Effective Date: (i) the Representing Party is a corporation duly organized and in good standing under the laws of the jurisdiction of its incorporation, and it has full power and authority and the legal right to own and operate its property and assets and to carry on its business as it is now being  
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 conducted and as it is contemplated to be conducted by this Agreement; (ii) the Representing Party has the full right, power and authority to enter into this Agreement and to perform as required under this Agreement; (iii) there are no existing or, to the Representing Party’s knowledge, threatened actions, suits or claims pending with respect to the subject matter of this Agreement or the Representing Party’s right to enter into and perform its obligations under this Agreement; (iv) the Representing Party has taken all necessary action on its part to authorize the execution and delivery of this Agreement and the performance of its obligations under this Agreement; (v) this Agreement has been duly executed and delivered on behalf of the Representing Party, and constitutes a legal, valid, binding obligation, enforceable against it in accordance with the terms hereof, subject to the general principles of equity and to bankruptcy, insolvency, moratorium and other similar laws affecting the enforcement of creditors’ rights generally; (vi) all necessary consents, approvals and authorizations of all regulatory and governmental authorities and other persons required to be obtained by the Representing Party in connection with the execution and delivery of this Agreement have been obtained; (vii) the execution and delivery of this Agreement by the Representing Party and the performance of the Representing Party’s obligations hereunder do not conflict with, or constitute a default under, any of its contractual obligations; and (viii) the Representing Party has not been debarred under 21 U.S.C. Section 335a, excluded under Section 1128 of the Social Security Act of 1935, convicted of any crime or engaged in any conduct for which such Representing Party could be so debarred or excluded, is not under investigation for any debarment or exclusion action, has not been disqualified as an investigator pursuant to 21 C.F.R. §312.70, does not have a disqualification hearing pending and is not currently employing any person or entity that has been so debarred, excluded or disqualified to perform any of the Representing Party’s obligations under this Agreement.  
 (b) The Representing Party shall promptly notify the other Party if it is debarred, excluded or disqualified as described in Section 16.1(a)(viii) and shall terminate any so debarred, excluded or disqualified individual’s or entity’s participation in the performance of any of the Representing Party’s obligations under this Agreement promptly upon the Representing Party’s awareness of such debarment, exclusion or disqualification.  
 (c) Biogen represents and warrants to Bioverativ that the Finished Goods supplied to Bioverativ under this Agreement shall be Manufactured in accordance with the Finished Goods Specifications and cGMPs, the Drug Substance released under this Agreement shall be in accordance with the Drug Substance Specifications and cGMPs, and the Drug Product (either directly or through the Third Party Manufacturer) supplied to Bioverativ under this Agreement shall be Manufactured in accordance with the Drug Product Specifications and cGMPs. The Parties agree that a breach of the foregoing warranty (i) shall, without prejudice to Bioverativ’s rights pursuant to Sections 11.8, 11.10 and 18.2, be subject to the sole remedy, as applicable, set forth in Sections 9.1(c)(i) with respect to Non-Conforming Drug Substance, 9.1(c)(ii) with respect to Drug  
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 Substance Compliance Issues, 9.2(c)(i) with respect to Non-Conforming Drug Product or Non-Conforming Finished Goods, or 9.2(c)(ii) with respect to Drug Product Compliance Issues or Finished Goods Compliance Issues, (ii) shall not be deemed a breach of this Agreement giving rise to a right of termination by Bioverativ under Section 13.3, unless such breach is based on the third consecutive Campaign of Drug Substance or Drug Product or Finished Goods, as the case may be, containing a Batch that fails the foregoing warranty; provided, for avoidance of doubt, that any failure to replace any Batch of such non-compliant Drug Substance or Drug Product or Finished Goods in accordance with Sections 9.1(c)(i), 9.1(c)(ii), 9.2(c)(i) or 9.2(c)(ii), as applicable, may give rise to a right of termination, subject to Section 13.3.  
 16.2 Warranty Limitations and Disclaimer. EXCEPT AS EXPRESSLY SET FORTH IN THE REPRESENTATIONS AND WARRANTIES INCORPORATED UNDER SECTION 16.1 HEREOF, NEITHER PARTY MAKES ANY REPRESENTATIONS OR EXTENDS ANY WARRANTIES OF ANY KIND UNDER THIS AGREEMENT (INCLUDING WITH RESPECT TO ANY FINISHED GOODS, DRUG SUBSTANCE OR DRUG PRODUCT PROVIDED UNDER THIS AGREEMENT), EITHER EXPRESS OR IMPLIED, INCLUDING WARRANTIES OF MERCHANTABILITY, QUALITY, FITNESS FOR A PARTICULAR PURPOSE, NON-INFRINGEMENT, OR VALIDITY OF PATENT CLAIMS, WHETHER ISSUED OR PENDING.  
 16.3 Covenants.  
 (a) Each Party has (or will timely obtain) and will maintain and comply with at all relevant times throughout the term of this Agreement in all respects, all material applicable supra-national, federal, regional, state, provincial, and local permits, licenses, registrations and other governmental authorizations and approvals as may be required by Applicable Law in order for it to perform its obligations under this Agreement.  
 (b) Bioverativ shall make its Forecasts in good faith based on information reasonably available to it at such time.  
 (c) Biogen shall take all reasonable and necessary steps to:  
 (i) Ensure the manufacture of the initial order of rFIIIFc-VWF-XTEN batches in a timely manner and as otherwise set forth in the initial Forecast under the Agreement (as set forth on Schedule 10 attached hereto); and  
 (ii) Expand the visual inspection capacity for Drug Product intended for distribution and use in Japan in cooperation with Bioverativ.  
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 ARTICLE 17  
 LIABILITY LIMITATION  
 17.1 EXCEPT WITH RESPECT TO A BREACH OF THE CONFIDENTIALITY PROVISIONS INCORPORATED IN ARTICLE 15 (CONFIDENTIALITY) OR A PARTY’S LIABILITY UNDER ARTICLE 18 (INDEMNITY), IN NO EVENT SHALL EITHER PARTY BE LIABLE TO THE OTHER PARTY OR ANY OTHER PERSON FOR INCIDENTAL, CONSEQUENTIAL, EXEMPLARY, PUNITIVE, MULTIPLE OR OTHER INDIRECT DAMAGES, OR FOR LOSS OF PROFITS, LOSS OF DATA OR LOSS OF USE DAMAGES ARISING OUT OF THIS AGREEMENT, WHETHER BASED UPON WARRANTY, CONTRACT, TORT, STATUTE, STRICT LIABILITY OR OTHERWISE, EVEN IF SUCH PARTY HAS BEEN ADVISED OF THE POSSIBILITY OF SUCH DAMAGES OR LOSSES.  
 17.2 NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS AGREEMENT, EXCEPT WITH RESPECT TO A BREACH OF THE CONFIDENTIALITY PROVISIONS INCORPORATED IN ARTICLE 15 (CONFIDENTIALITY) OR TO THE EXTENT THE SAME ARE AWARDED TO A THIRD PARTY IN ANY JUDGMENT OR SETTLEMENT IN A CLAIM AGAINST WHICH A PARTY IS OBLIGATED TO INDEMNIFY ANY OF THE INDEMNIFIED PARTIES PURSUANT TO ARTICLE 18 (INDEMNITY), (A) BIOGEN’S LIABILITY FOR ANY LOSS OR DAMAGES SUFFERED BY BIOVERATIV IN CONNECTION WITH THIS AGREEMENT SHALL NOT EXCEED (I) $150 MILLION IF INCURRED ON OR PRIOR TO THE THIRD ANNIVERSARY OF THE DATE OF THIS AGREEMENT OR (II) $10 MILLION IF INCURRED AFTER THE THIRD ANNIVERSARY OF THE DATE OF THIS AGREEMENT, PROVIDED THAT IF SUCH LOSS IS DUE TO THE ACTS OR OMISSIONS OF A THIRD PARTY MANUFACTURER, BIOGEN’S LIABILITY SHALL NOT EXCEED THE AMOUNT THAT BIOGEN IS ENTITLED TO RECEIVE FROM ITS THIRD PARTY MANUFACTURER AS DAMAGES OR IN SETTLEMENT OF SUCH CLAIM, AND (B) BIOVERATIV’S LIABILITY FOR ANY LOSS OR DAMAGES SUFFERED BY BIOGEN IN CONNECTION WITH THIS AGREEMENT SHALL NOT EXCEED THE GREATER OF $10 MILLION OR THE TOTAL AMOUNT OF UNPAID INVOICES DUE FROM BIOVERATIV TO BIOGEN UNDER THIS AGREEMENT. NOTWITHSTANDING ANYTHING IN THIS AGREEMENT TO THE CONTRARY, THE LIMITATIONS IN CLAUSE (A) OF THIS SECTION 17.2 SHALL NOT APPLY WITH RESPECT TO ANY LOSS OR DAMAGES SUFFERED BY BIOVERATIV ARISING OUT OF OR IN CONNECTION WITH A WILLFUL BREACH OF THIS AGREEMENT BY BIOGEN.  
 17.3 For avoidance of doubt, either Party’s liability with respect to its activities under this Agreement, including the supply to Bioverativ of Finished Goods and the commercial manufacture and supply of Drug Substance and Drug Product, shall be limited to claims under this Agreement, and neither Party shall have any liability under any other Transaction Agreement with respect to the activities under this Agreement, including the supply of Finished Goods or the commercial manufacture or supply of Drug Substance or Drug Product.  
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 ARTICLE 18  
 INDEMNITY  
 18.1 Bioverativ Indemnification. Bioverativ shall indemnify, defend, and hold harmless the Biogen Indemnified Parties from and against all liability, claims, damages, loss, or expense (including reasonable attorneys’ fees) resulting from any Third Party claims made or legal proceedings instituted against the Biogen Indemnified Parties to the extent such claims arise out of or result from: (a) death or bodily injury based on the Manufacture by or for Bioverativ (other than by Biogen or its Affiliates) or its sublicensees of Drug Substance or Drug Product or Finished Goods, but, for clarity, excluding any claim that is subject to Section 18.2(a); (b) infringement, or alleged infringement, of any patents due to the Manufacture of Drug Substance or Drug Product or Finished Goods by or for Bioverativ or its sublicensees; (c) Bioverativ’s breach of its representations and warranties in Sections 16.1(a) or 16.1(b); or (d) Bioverativ’s gross negligence or intentional misconduct in connection with this Agreement, except, in each case, to the extent Biogen is obligated to indemnify and hold harmless the Bioverativ Indemnified Parties therefrom pursuant to Section 18.2 below.  
 18.2 Biogen Indemnification. Biogen shall indemnify, defend, and hold harmless the Bioverativ Indemnified Parties from and against all liability, claims, damages, loss, or expense (including reasonable attorneys’ fees) resulting from any Third Party claims made or legal proceedings instituted against the Bioverativ Indemnified Parties to the extent such claims arise out of or result from: (a) death or bodily injury arising out any Non-Conformity or Compliance Issue of any Finished Goods, Drug Substance or Drug Product provided by Biogen under this Agreement; (b) Biogen’s breach of its representations and warranties in Sections 16.1(a) or 16.1(b); or (c) Biogen’s gross negligence or intentional misconduct in connection with this Agreement, except to the extent Bioverativ is obligated to indemnify and hold harmless the Biogen Indemnified Parties therefrom pursuant to Section 18.1 above. Notwithstanding anything to the contrary in this Agreement, Biogen’s obligation to indemnify with respect to any Non-Conformity or Compliance Issue to the extent that such claim is caused by the Third Party Manufacturer shall not exceed the amounts Biogen is entitled to receive from its Third Party Manufacturer (where claims by Bioverativ under this Section 18.2 shall be deemed claims of a third party under Biogen’s agreement with the Third Party Manufacturer), and Biogen shall have no obligation to indemnify with respect to any Non-Conformity or Compliance Issue caused by any Third Party Carrier, which shall be a matter solely between Bioverativ and such Third Party Carrier.  
 ARTICLE 19  
 INSURANCE  
 19.1 Insurance Coverage. Without limiting either Party’s undertaking to defend, indemnify, and hold the other Party harmless as set forth in Article 18, each Party shall obtain and maintain during the Term either a commercially reasonable self-insurance program or a Commercial General Liability policy including coverage for Commercial General Liability claims and coverage for products liability claims, in an amount and coverage reasonably  
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 determined by each Party on a country-by-country basis. The foregoing coverage shall continue with respect to product liability claims, for a period of five (5) years after the Term.  
 ARTICLE 20  
 DISPUTE RESOLUTION  
 20.1 Initial Disputes Procedure. Within ten (10) days after delivery of a notice of dispute from one Party to the other Party, the JMSC shall attempt in good faith to resolve the dispute. If the JMSC does not resolve the dispute, either Party may present a notice of dispute to the Senior Executives.  
 20.2 Senior Executives Resolution. Within seven (7) days after delivery of the notice of dispute pursuant to Section 20.1 (Initial Disputes Procedure), the Senior Executives shall meet or converse by telephone at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to resolve the dispute. Each Party shall honor all reasonable requests for information made by the other Party, and the Parties shall treat all negotiations pursuant to this clause as confidential and as compromise and settlement negotiations for purposes of applicable rules of evidence. If the Senior Executives do not resolve the dispute within twenty-five (25) days after the delivery of the notice to the Senior Executives under Section 20.1 (or such shorter or longer period as the Parties may agree), then either Party may institute a formal arbitration of such matter pursuant to Section 20.3; provided, however, that to the extent such dispute relates to day-to-day operational decisions regarding the implementation and the conduct of process development and manufacturing activities, including managing (i) sources of raw materials, (ii) the inventory of raw materials, (iii) the staffing of manufacturing facilit(ies), (iv) manufacturing run rates, (v) choice of manufacturing facility(ies), (vi) choice of sub-contractors and Third Party Manufacturers and (vii) choice of which manufacturing processes should be utilized in manufacturing, Biogen shall have the final authority to resolve such dispute in its reasonable discretion, subject to Article 10, and the Parties shall have no recourse to arbitration with respect thereto.  
 20.3 Arbitration.  
 (a) Any dispute, controversy or claim arising out of or relating to this Agreement, or the breach, termination or invalidity thereof, which has not been resolved pursuant to Sections 20.1 or 20.2 shall be finally settled by binding arbitration conducted in the English language in Boston, Massachusetts under the commercial arbitration rules of the American Arbitration Association. Each Party shall appoint an arbitrator and the two (2) arbitrators so appointed shall jointly appoint a third arbitrator; provided, however, that if they cannot agree (or if one Party refuses to appoint an arbitrator) within thirty (30) days after the initiation of the arbitration, then such unappointed arbitrator(s) shall be appointed by the American Arbitration Association. Disputes about arbitration procedure shall be resolved by the arbitrators or failing agreement, by the American Arbitration Association. The arbitrators may proceed to an award notwithstanding the failure of the other Party to participate in the proceedings. Discovery shall be limited to  
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 mutual exchange of documents relevant to the dispute, controversy or claim; depositions shall not be permitted unless agreed to by both Parties.  
 (b) The arbitrators shall be authorized to grant interim relief, including to prevent the destruction of goods or documents involved in the dispute, protect trade secrets and provide for security for a prospective monetary award. The limitations on liability set out in Article 17 shall apply to any award of the arbitrators. Specifically, but without limitation, under no circumstances shall the arbitrators be authorized to award punitive or multiple damages. Any purported award of punitive or multiple damages or of other damages not permitted under Article 17 shall be beyond the arbitrators’ authority, void, and unenforceable.  
 (c) If the dispute subject to such arbitration proceeding arises under Section 13.3(b), the arbitral tribunal shall be directed to first determine whether the applicable Party is entitled to terminate under Section 13.3(b). The arbitral tribunal’s decision on such issue shall be the arbitration award referred to in Section 13.3(b) for the purpose of commencing the Breaching Party’s final right to cure during the Additional Cure Period. The same tribunal shall then continue such proceeding for the purpose of determining all damages and other remedies, including a monetary amount to compensate the Notifying Party for all damages and other losses incurred or suffered as a result of a material breach and any failure to cure such breach while dispute resolution proceeding is pending and the Additional Cure Period (subject to the limitations of Article 17).  
 20.4 Award. The prevailing Party shall be entitled to an award of reasonable attorney fees incurred in connection with the arbitration in such amount as may be determined by the arbitrators. The award of the arbitrators shall be the sole and exclusive remedy of the Parties and shall be enforceable in any court of competent jurisdiction, subject only to revocation on grounds of fraud or clear bias on the part of the arbitrators. Notwithstanding anything contained in this Article 20 to the contrary, each Party shall have the right to institute judicial proceedings against the other Party or anyone acting by, through or under such other Party, in order to enforce the instituting Party’s rights hereunder through reformation of contract, specific performance, injunction or similar equitable relief.  
 ARTICLE 21  
 MISCELLANEOUS  
 21.1 Notice.  
 (a) All notices, requests, consents and other communications required or permitted under this Agreement shall be in writing and shall be sent by hand, delivered by messenger or courier service, or mailed by registered or certified mail (postage prepaid), return receipt requested, or delivered by reputable international air courier delivery service, addressed to:  
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 If to Bioverativ:  
 Bioverativ Inc.  
 000 Xxxxxx Xxxxxx  
 Xxxxxxx, XX 00000  
 Attn: [·]  
 Facsimile: [·]  
 with a copy to:  
 Bioverativ Inc.  
 000 Xxxxxx Xxxxxx  
 Xxxxxxx, XX 00000  
 Attn: Chief Legal Officer  
 Facsimile: [·]  
 If to Biogen:  
 SVP, Global Operations Biogen  
 000 Xxxxxx Xxxxxx  
 Xxxxxxxxx, XX 00000  
 XXX  
 with a copy to:  
 Executive VP and Chief Legal Officer  
 Biogen Inc.  
 000 Xxxxxx Xxxxxx  
 Xxxxxxxxx, XX 00000  
 XXX  
 E-mail: xxxxxxxxxxxxxxx@xxxxxx.xxx  
 (b) Each such notice shall be deemed delivered (i) on the date delivered if by personal or overnight delivery, (ii) on the date upon which the return receipt is signed or delivery is refused or the notice is designated by the postal authorities as not deliverable, as the case may be, if mailed, or (iii) four (4) calendar days after delivery to the applicable air courier.  
 (c) Either Party may from time to time to change its address upon written notice to the other Party in accordance with this Section 21.1.  
 21.2 Force Majeure. No failure or omission by a Party in the performance of any obligation of this Agreement shall be deemed a breach of this Agreement or create any liability if the same shall arise from any cause or causes beyond the reasonable control of such Party (a “Force Majeure Event”), which may include, but are not limited to, the following: acts of God; acts or omissions of any government; any rules, regulations or orders issued by any governmental authority or by any officer, department, agency or instrumentality thereof; fire; flood; storm; earthquake; accident; war; rebellion; insurrection; riot; and invasion; and provided  
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 that such failure or omission resulting from one of the foregoing causes is cured as soon as is practicable after its occurrence.  
 21.3 Assignment; Binding Effect.  
 (a) Neither this Agreement nor any of the rights or obligations hereunder may be assigned by either Party without the prior written consent of the other Party, except to a single Third Party that acquires, by merger, sale of assets or otherwise, all or substantially all of the business of the assigning Party to which the subject matter of this Agreement relates. Notwithstanding anything to the contrary in this Agreement, (i) Biogen may not assign this Agreement nor any of the rights or obligations hereunder to and for the benefit of creditors without Bioverativ’s prior written consent and (ii) each Party shall have the right to assign this Agreement, in whole or in part, to an Affiliate of such Party, or to procure the performance by an Affiliate of some or all of such Party’s obligations hereunder, without the prior written consent of the other Party, provided that such Party guarantees the performance of such Affiliate of its obligations hereunder. Any assignment not in accordance with the foregoing shall be void.  
 (b) Each Party agrees that, notwithstanding any provisions of this Agreement to the contrary, in the event that this Agreement is assigned by either Party in connection with the sale or transfer (by merger, sale of assets or otherwise) of all or substantially all of the business and assets of such Party to which the subject matter of this Agreement pertains, (i) such assignment shall not provide the non-assigning Party with rights or access to intellectual property or technology of the acquirer of such Party, and (ii) in the case of an sale or transfer to a competitor of the other Party, the transferring Party shall ensure that (A) the Confidential Information of such other Party is maintained in a manner that makes it unavailable to the competitor company, and (B) any employees or agents of the transferring Party who have had or gain access to the other Party’s Confidential Information through the transferring Party do not become involved in any capacity for the competitor business (other than the business of the transferring Party as it was practiced immediately prior to the transfer) that could reasonably be expected to benefit from knowledge of such Confidential Information.  
 (c) In addition, in the case of a sale or transfer (by merger, sale of assets or otherwise) of all or substantially all of the business and assets of Biogen to which the subject matter of this Agreement pertains, Biogen will, upon Bioverativ’s request, perform a technology transfer in accordance with Section 13.4(e).  
 21.4 Modifications; Waivers. No change, modification, extension, termination or waiver of any obligation, term or provision contained herein shall be valid or enforceable unless same is reduced to writing and signed by a duly authorized representative of each of the Parties  
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 to be bound thereby. No waiver of any right in any one instance shall constitute a waiver of that right or of any other right in other instances under this Agreement.  
 21.5 Transferred Agreement Support. To the extent Bioverativ is required to satisfy obligations under the Transferred Agreement for matters not specifically addressed herein, Biogen shall ensure that Bioverativ is able to meet such obligations under the Transferred Agreement.  
 21.6 Entire Agreement. This Agreement and the Schedules attached hereto, together with the Transaction Agreements (including the Quality Agreement), contain every obligation and understanding between the Parties relating to the subject matter hereof and supersedes all prior discussions, negotiations and agreements, if any, between them relating to the subject matter hereof, and neither of the Parties shall be bound by any conditions, definitions, understandings, warranties or representations other than as expressly provided or referred to herein.  
 21.7 Severability. If, under Applicable Law or regulation, any provision of this Agreement is invalid or unenforceable, or otherwise directly or indirectly affects the validity of any other material provision(s) of this Agreement (“Severed Clause”), it is mutually agreed that this Agreement shall endure except for the Severed Clause. The Parties shall consult and use their best efforts to agree upon a valid and enforceable provision which shall be a reasonable substitute for such Severed Clause in light of the intent of this Agreement.  
 21.8 Section Headings. The section headings in this Agreement are for convenience of reference only and shall not be deemed to affect the interpretation of any provision of this Agreement.  
 21.9 Relationship of Parties. This Agreement shall not constitute or be construed as creating a partnership, employer-employee or joint venture relationship between the Parties, and neither Party shall be liable for any debts or obligations of the other Party. Neither Party shall have any power to enter into any contracts or commitments in the name of, or on behalf of, the other Party, or to bind the other Party in any respect whatsoever.  
 21.10 Construction. Each Party acknowledges that it has been advised by counsel during the course of negotiation of this Agreement and, therefore, that this Agreement shall be interpreted without regard to any presumption or rule requiring construction against the Party causing this Agreement to be drafted. Except where the context otherwise requires, wherever used, the use of any gender will be applicable to all genders and the word “or” is used in the inclusive sense (and/or). The captions of this Agreement are for convenience of reference only and in no way define, describe, extend or limit the scope or intent of this Agreement or the intent of any provision contained in this Agreement. The terms “include” and “including,” in all their forms, as used herein mean including, without limiting the generality of any description preceding such term. Unless the context requires otherwise, (a) any definition of or reference to any agreement, instrument or other document refers to such agreement, instrument or other document as from time to time amended, supplemented or otherwise modified (subject to any restrictions on such amendments, supplements or modifications set forth herein or therein), (b) any reference to any laws refer to such laws as from time to time enacted, repealed or amended,  
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 (c) the words “herein”, “hereof” and “hereunder”, and words of similar import, refer to this Agreement in its entirety and not to any particular provision hereof, and (d) all references herein to Articles, Sections and Schedules, unless otherwise specifically provided, refer to the Articles, Sections and Schedules of this Agreement.  
 21.11 Governing Law. The rights and obligations of the Parties to this Agreement shall not be governed by the provisions of the U.N. Convention on Contracts for the International Sale of Goods, 1980; rather this Agreement has been entered into and shall be construed and enforced in accordance with the laws of the State of Delaware, without reference to the choice of law principles thereof.  
 21.12 Conflicting Terms. To the extent the terms of an Order conflict with terms of this Agreement, the terms of this Agreement shall govern, unless otherwise agreed in writing by the Parties.  
 21.13 Injunctive Relief. Unless otherwise expressly stated under this Agreement, the Parties agree that each will have, in addition to any other rights or remedies available to it at law, the right to seek injunctive relief, including specific performance, in the event of any threatened or actual violation of any or all of the provisions of this Agreement.  
 21.14 Counterparts. This Agreement may be executed in any number of counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument.  
 [Signature Page Follows]  
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 IN WITNESS WHEREOF, the Parties have caused this Agreement to be duly executed as of the day and year first above written.  
 BIOGEN INC.  
 By:  
 Name:  
 Title:  
 BIOVERATIV INC.  
 By:  
 Name:  
 Title:  
 [Signature Page to Manufacturing and Supply Agreement]  
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