EX-10.20 5 a2196756zex-10\_20.htm EXHIBIT 10.20  
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 SERVICES AGREEMENT  
(Specialty Pharmacy and Hub Services)  
 This SERVICES AGREEMENT (“Agreement”), dated as of November 19, 2009 (the “Effective Date”), is entered into by and between DYAX CORP., a Delaware corporation with offices located at 000 Xxxxxxxxxx Xxxxxx, Xxxxxxxxx, Xxxxxxxxxxxxx 00000 (“Dyax”), and US BIOSERVICES CORPORATION, a Delaware corporation, on behalf of itself and its subsidiaries IHS Acquisition XXX, Inc., Pharm Plus Acquisition, Inc., Ambulatory Pharmacy Services, Inc. and Specialty Pharmacy, Inc., all of which do business as US Bioservices, with its primary offices located at 0000 Xxxxxxx Xxxxxxx, Xxxxxx, Xxxxx 00000 (collectively, “US Bio”).  
 WHEREAS, Dyax has developed the Product (as defined below);  
 WHEREAS, in the United States, Dyax intends to secure the regulatory approvals required in order to promote, market and sell the Product in the United States as a treatment for patients suffering acute attacks associated with the disease known as hereditary angioedema (“HAE”);  
 WHEREAS, US Bio is in the business of providing specialty pharmacy and retail distribution services for pharmaceutical products; and  
 WHEREAS, Dyax wishes to engage US Bio to provide Dyax with specialty pharmacy and retail distribution services for the Product throughout the United States, and US Bio wishes to accept such engagement, all upon the terms and subject to the conditions set forth in this Agreement.  
 NOW, THEREFORE, for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties agree as follows:  
 1. Definitions.  
 As used in this Agreement, the following capitalized terms shall have the following meanings:  
 1.1 “Affiliate” shall mean any individual, corporation, partnership, association, or business that directly or indirectly through intermediaries, controls, is controlled by or is under common control with, a party. An ownership, voting or similar interest (including any right or option to obtain such an interest) representing more than 50% of the total interests then outstanding of the pertinent entity shall constitute “control” for the purposes of this definition.  
 1.2 “Applicable Laws” shall mean all applicable laws, rules, regulations in the Territory, including guidelines and guidances promulgated by governmental entities.  
 1.3 “Competing Product” shall mean any pharmaceutical product, other than the Product, that is being developed, manufactured or commercialized for use as a therapeutic or prophylactic treatment for Patients.  
 1.4 “FDA” shall mean the United States Food and Drug Administration or any successor agency thereto.  
 \*Confidential Treatment Requested. Omitted portions filed with the Commission.  
 1.5 “Field” shall mean all uses in the therapeutic treatment of HAE.  
 1.6 “HIPAA” shall mean the Health Insurance Portability and Accountability Act of 1996, as amended, 42 U.S.C. § 1320d, et seq., and the implementing regulations promulgated thereunder.  
 1.7 “Hub Services” shall have the meaning set forth in Section 8.1 below.  
 1.8 “Patient” shall mean any person diagnosed with HAE.  
 1.9 “Product” shall mean Dyax’s proprietary plasma kallikrein inhibitor, known as internally as DX-88 and generically as ecallantide, as more formally described on Exhibit A.  
 1.10 “REMS Program” shall mean the Risk Evaluation and Mitigation Program required to be implemented under Section 505-1 of the Federal Food, Drug and Cosmetic Act in connection with the regulatory approval of the Product by the FDA.  
 1.11 “SOPs” shall have the meaning set forth in Section 8.4.  
 1.12 “Specialty Pharmacy Customers” shall mean health-care providers (generally physicians and physician-operated clinics) who receive Product on behalf of specific Patients pursuant to a physician-issued prescription in accordance with the terms and conditions set forth in this Agreement. For the avoidance of doubt, Specialty Pharmacy Customer shall not include specialty pharmacies, distributors, wholesalers or hospital, institutional or other pharmacies.  
 1.13 “Statement of Work” shall have the meaning set forth in Section 8.1.  
 1.14 “Term” shall have the meaning set forth in Section 15.1.  
 1.15 “Territory” shall mean the 50 states of the United States of America, the District of Columbia and Puerto Rico.  
 2. Engagement of US Bio.  
 2.1 Engagement. Upon the terms and conditions set forth herein, Dyax hereby engages US Bio, on an exclusive basis during the Term (subject to Section 15.4), to (i) dispense and distribute Product to Specialty Pharmacy Customers for the Field in the Territory, and (ii) provide the Hub Services. US Bio hereby accepts such engagement and shall dispense and distribute Product to Specialty Pharmacy Customers in the Territory and provide the Hub Services in a professional and responsible manner and in accordance with the terms of this Agreement and all Applicable Laws.  
 2.2 Authorized Distributor. In connection with US Bio’s engagement under Section 2.1 above, and solely for the limited purpose of compliance with the pedigree requirements of the Prescription Drug Marketing Act and any similar state laws, Dyax hereby designates US Bio as an Authorized Distributor of Record (“ADR”) of the Product during the Term.  
 2  
 2.3 Exclusivity.  
 (a) The parties acknowledge and agree that as a result of the exclusive nature of the US Bio engagement, (i) subject to Section 15.4, during the Term, Dyax shall not engage any party other than US Bio or its Affiliates to dispense and distribute Product to Specialty Pharmacy Customers for the Field in the Territory or perform the Hub Services, (ii) during the Term and for [\*\*\*\*\*] thereafter, US Bio shall not, and shall cause its Affiliates providing specialty pharmacy services not to, provide services substantially similar to the Hub Services for any Competing Product, and (iii) during the Term and for [\*\*\*\*\*] thereafter, US Bio shall not promote any Competing Product. To the extent that a non-specialty pharmacy Affiliate of US Bio provides services for a Competing Product, US Bio acknowledges that it will maintain the confidentiality and security of all Dyax Confidential Information in accordance with Article 11 and that US Bio will not disclose any Confidential Information of Dyax, or any acquired knowledge or learnings that US Bio may obtain in connection with the performance of the Hub Services, to any such Affiliate.  
 (b) The parties acknowledge and agree that the restriction set forth in Section 2.3(a)(iii) shall not preclude US Bio from (i) dispensing a Competing Product, (ii) providing clinically appropriate information to healthcare providers, patients and others in connection with dispensing a Competing Product, or (iii) providing general information on US Bio’s specialty pharmacy services; provided that, in each case US Bio does not violate the terms of this Agreement or otherwise Disadvantage the Product in any way in the Territory. For purpose of the foregoing sentence, “Disadvantage” shall mean any activities that (X) are intended to encourage, or could reasonably be foreseen to encourage, the utilization of a Competing Product, such as advertising the Product in a manner that suggests that a Competitive Product is superior to the Product in terms of acquisition price, reimbursement rates, or efficacy, or (Y) otherwise operate to the disadvantage of the Product.  
 2.4 Reserved Rights.  
 (a) Except as expressly provided in this Agreement, no right, title or interest in or to Product or any patent, trade secret, trademark or any other intellectual property right of Dyax or its Affiliates is granted, whether express or implied, by Dyax to US Bio. In furtherance of the foregoing and not in limitation thereof, nothing herein shall in any way limit Dyax’s ability to (i) dispense or distribute Product to Specialty Pharmacy Customers outside of the Territory, (ii) dispense or distribute Product to Specialty Pharmacy Customers in the Territory for uses outside the Field or (iii) dispense or distribute Product to any person or entity other than a Specialty Pharmacy Customer, including specialty pharmacies, distributors, wholesalers or hospital pharmacies or health-care providers that purchase Product on a wholesale basis (e.g., buy-and-xxxx or consignment).  
 (b) Except as expressly provided in this Agreement, no right, title or interest in or to any patent, trade secret, trademark or any other intellectual property right of US Bio or its Affiliates is granted, whether express or implied, by US Bio to Dyax. By way of clarification, all proprietary systems, databases and web-based applications, and any  
 3  
 standard operating procedures, work rules, programming, software, routines, analytic tools, embedded logic or table structures associated therewith, that have been developed, maintained, utilized and improved by US Bio (or its Affiliates) in connection with this Agreement or the Hub Services are and will remain the property of US Bio (or its Affiliates).  
 2.5 Service Level Commitments. The parties to this Agreement desire to define a mutually beneficial relationship between Dyax and US Bio in order to achieve Dyax’s goals of high patient level product availability, high levels of consumer and pharmacy confidence in the integrity and quality of the Product, and achievement of a collaborative, transparent, and cost-effective distribution system. In order to achieve the stated goals, US Bio agrees to dispense and distribute the Product and perform the Hub Services hereunder in accordance with the key performance indicators described in the Statement of Work attached hereto as Exhibit B and incorporated herein by this reference.  
 3. Purchase and Sale of Product.  
 3.1 Purchase of Product. US Bio shall (i) purchase Product only from Dyax (or its third party logistics provider acting on Dyax’s behalf) and no other supplier, (ii) dispense and distribute Product that it has purchased from Dyax, and (iii) dispense and distribute Product only to Specialty Pharmacy Customers for the Field in the Territory. US Bio shall fill orders for Product only with Product and shall not substitute other products.  
 3.2 Purchase Price; Payment Terms.  
 (a) The price payable by US Bio to Dyax for all Product purchased by US Bio hereunder (the “Purchase Price”) shall be [\*\*\*\*\*].  
 (b) Dyax promptly shall invoice US Bio for the Purchase Price for all Product purchased hereunder. All Dyax invoices for Product shall be due and payable by US Bio within [\*\*\*\*\*] after receipt by US Bio [\*\*\*\*\*]. On all undisputed balances exceeding [\*\*\*\*\*] from invoice receipt, US Bio shall pay interest equal to the lesser of (i) [\*\*\*\*\*] per month and (ii) the maximum allowed by law.  
 4. Delivery of Product to US Bio.  
 4.1 Product Orders. US Bio shall submit all Product orders electronically in the industry standard format in accordance with such procedures as may be mutually agreed upon by the parties. Unless otherwise agreed between the parties, all Product orders shall be submitted in quantities of 20 units (or multiples of 20 units).  
 4.2 Delivery Times. Dyax shall make commercially reasonable efforts to ship all US Bio orders completely and to have Product from such orders shipped to US Bio within a mutually agreeable schedule of up to [\*\*\*\*\*] of order placement. US Bio acknowledges and agrees that Dyax may not be able to fill all orders completely or within a specified time due to shortages or other causes and such inability shall not constitute a breach of this Agreement.  
 4  
 4.3 Product Dating. Dyax shall ship Product to US Bio with at least [\*\*\*\*\*] shelf life remaining, unless otherwise agreed in writing (including via email or other electronic communication) by US Bio. [\*\*\*\*\*]  
 4.4 Product Delivery; Risk of Loss. Dyax shall deliver all Product Free On Board to US Bio’s facility in the Territory designated in the applicable order. For purposes of this Section, the term “Free On Board” means that Dyax shall (i) bear all costs associated with shipping Product to the US Bio designated facility, and (ii) bear all risk of loss for Product until its delivery to the designated US Bio facility. Title to, and risk of loss of, all Product shall pass to US Bio on delivery.  
 4.5 Inspection of Product. US Bio shall examine the Product upon delivery at US Bio’s designated facility and shall notify Dyax in writing (including via email or other electronic communication) within one (1) business day of any problems relating to the quantity of Product delivered or any defect in any of the Product that is reasonably discoverable upon visual inspection of the Product without unpacking of pallets.  
 4.6 No Alteration. US Bio shall not alter the Product in any way, including the packaging thereof, without Dyax’s written consent (except to remove the Product from the shipping containers) and shall not alter the Product labeling, except to add a prescription label to the Product upon dispensing or shipment, as required by Applicable Laws.  
 4.7 Storage Conditions. US Bio will maintain Product stored at, and shipped from, its facilities under (i) the Product storage, shipment and handling requirements set forth in the FDA-approved labeling and (ii) any additional requirements mutually agreed upon between US Bio and Dyax. US Bio shall notify Dyax within one (1) business day of any deviation from such requirements so that Dyax can determine whether any further action must be taken with respect to such Product. Failure of US Bio to notify Dyax promptly of such deviation shall constitute a breach of this Agreement by US Bio.  
 5. Product Inventories.  
 5.1 Inventory Levels. During the Term, unless otherwise agreed to by Dyax in writing (including via email or other electronic communication) and subject to Section 5.2, US Bio shall maintain at all times an inventory of Product in an amount equal to not less than [\*\*\*\*\*] nor more than [\*\*\*\*\*] of [\*\*\*\*\*].  
 5.2 Supply Shortages. US Bio shall have no obligation to maintain the minimum inventory levels described in Section 5.1 if Product is unavailable from Dyax.  
 6. Product Returns.  
 Dyax (or Dyax’s third party logistics provider acting on Dyax’s behalf) shall accept and process returns of Product purchased by US Bio hereunder in accordance with Dyax’s Product Returns Policy, as it may be amended from time to time by Dyax. A copy of the Product Returns Policy in effect as of the Effective Date is attached to this Agreement as Exhibit D.  
 5  
 7. Suspension, Recalls and Government Notices.  
 7.1 Suspension. Upon written notification by Dyax to suspend distribution of Product, US Bio immediately shall suspend its distribution of Product. If the suspension continues for more than [\*\*\*\*\*], Dyax will repurchase Product in saleable condition held in inventory by US Bio at the price paid for such Product by US Bio. All repurchased Product shall be returned to Dyax (or Dyax’s third party logistics provider) at Dyax’s expense.  
 7.2 Recalls.  
 (a) Recalls Procedures. Dyax shall promptly notify US Bio of any recalls or market withdrawals initiated by Dyax or required by the FDA or any other governmental agency. US Bio shall notify Dyax immediately of any event or circumstance that US Bio reasonably believes may necessitate a recall or market withdrawal. Upon receipt of notice of a recall or market withdrawal from Dyax, US Bio shall administer such recall or market withdrawal under the direction of Dyax, including promptly notifying the affected Specialty Pharmacy Customers of US Bio in accordance with Dyax’s instructions. Dyax shall provide US Bio with a form letter to be used in connection with notice of any recall or market withdrawal, and shall, to the extent practicable, provide US Bio the opportunity to review and comment on such letter. Dyax shall be responsible for the mailing, shipping, and reasonable administrative expenses incurred by US Bio in connection with the recall or market withdrawal, plus a reasonable service fee as mutually agreed upon in advance by the parties as well as the cost of replacement Product for US Bio’s Specialty Pharmacy Customers. Notwithstanding the foregoing, to the extent that such recall or market withdrawal arises or results from (i) the negligence or intentional misconduct of US Bio or any of its permitted agents or employees or (ii) the breach by US Bio of this Agreement, US Bio shall bear and be responsible for all such costs as well as the reasonable, documented, out-of-pocket expenses of Dyax incurred in connection with such recall or market withdrawal.  
 (b) Investigations; Cooperation. US Bio shall reasonably cooperate with Dyax in investigating any Product failure that resulted in the need for a recall or market withdrawal and any reasonable, documented, out-of-pocket cost involved with such investigation shall be reimbursed by Dyax, except to the extent that such recall or market withdrawal arises or results from (i) the negligence or intentional misconduct of US Bio or any of its permitted agents or employees or (ii) the breach by US Bio of this Agreement, in which event US Bio shall bear and be responsible for such costs as well as the reasonable, documented, out-of-pocket expenses of Dyax incurred in connection with such investigation.  
 7.3 Government Notices. Each party shall provide the other with a copy of any correspondence or notices it receives from the FDA, or other governmental entity specifically relating to activities conducted under this Agreement, no later than one (1) business day following such receipt. In addition, US Bio shall provide Dyax with any notice it receives from the FDA or other governmental entity relating to Product no later than one (1) business day following such receipt. Each party shall also provide the other with concurrent copies of any responses to any such correspondence or notices (e.g., a response to an FDA 483 notice, warning letter, or untitled regulatory letter);  
 6  
 provided that Dyax shall review and approve all such responses by US Bio to the extent related to the Product and to the extent reasonably feasible. Where reasonably possible, US Bio shall give prior notice to Dyax of any scheduled FDA or other governmental inspection of US Bio’s facilities specifically relating to the Product, and, if reasonably possible, will afford Dyax the opportunity to be present at such inspection.  
 8. Hub Services and Related US Bio Obligations.  
 8.1 Hub Services; Statement of Work. US Bio shall provide certain support services relating to (i) the sale and use of the Product in the Field in the Territory and (ii) the REMS Program (collectively, the “Hub Services”). The specific nature of such Hub Services, and any additional terms and conditions applicable to such Hub Services, shall be set forth in writing (each such writing, a “Statement of Work”). The initial Statement of Work that has been agreed upon by the parties is attached hereto as Exhibit B. Any changes to the initial Statement of Work or any new Statement of Work must be in writing and approved by both parties, and thereafter shall be considered an addendum to this Agreement. All Services performed under any Statement of Work shall be subject to all the terms and conditions set forth herein.  
 8.2 REMS Program. US Bio shall distribute Product, perform the Hub Services, and otherwise conduct all activities under this Agreement in accordance with the REMS Program and any additional policies Dyax implements and provides in writing to US Bio. Without limiting the scope of the foregoing, US Bio agrees that any promotional, educational or other materials delivered to Specialty Pharmacy Customers and/or Patients in connection with this Agreement shall be preceded or accompanied by the medication guide, the healthcare provider letter and/or any other materials required by the REMS Program, as applicable, and in accordance with the provisions of the REMS Program.  
 8.3 Adverse Event Reporting. In the event that an adverse experience, as that term is defined at 21 C.F.R. § 600.80 (as such provision may be amended from time to time), with regard to the Product is reported to US Bio, US Bio shall ensure that all applicable safety and other relevant information relating to the Product that is obtained during the course of any interaction with patients, healthcare providers, or other individual, is communicated and maintained in accordance with Applicable Laws. US Bio shall notify Dyax of any adverse drug experiences with regard to the Product within three (3) business days after its first receipt; provided however, that any information relating to a serious adverse experience (SAE), as that term is defined at 21 C.F.R. § 600.80 (as such provision may be amended from time to time), shall be provided to Dyax within one (1) business day after its first receipt. US Bio shall also make all reasonable efforts to assist Dyax with any follow-up investigation necessary to comply with Applicable Laws with respect the reporting of adverse drug experiences relating to the Product; provided, that US Bio will not be responsible for reporting of any adverse events to the FDA. Dyax and US Bio will ensure that appropriate SOPs (as defined in Section 8.4) regarding adverse experiences are established, maintained and regularly reviewed to ensure compliance in accordance with the terms of this Agreement and Applicable Laws. Dyax and US Bio will ensure that all staff involved in these activities are appropriately trained and records of such training are maintained.  
 7  
 8.4 Standard Operating Procedures; Other Work Instructions. US Bio shall conduct all Hub Services under this Agreement in accordance with Standard Operating Procedures (“SOPs”) and other Dyax-specific work instructions (“Dyax Instructions”) applicable to such activities, as established and approved in writing by the parties from time to time. The preliminary SOPs and Dyax Instructions that have been approved by the parties are attached hereto as Exhibit C. [\*\*\*\*\*] The parties acknowledge and agree that the Hub Services SOPs and Dyax Instructions are the property of Dyax and to the extent that such Hub Services SOPs and Dyax Instructions are maintained by US Bio, then, upon termination or expiration of this Agreement or otherwise upon Dyax’s request, US Bio will deliver such SOPs and Dyax Instructions to Dyax. Notwithstanding anything to the contrary contained in this Agreement or elsewhere, during the Term of this Agreement, the SOPs shall not include any of US Bio’s internal standard operating procedures or work instructions that are non-specific to Dyax and the Product, which are the confidential and proprietary property of US Bio and shall not be disclosed by Dyax to any third party without the consent of US Bio. Dyax shall be permitted, upon its reasonable request, to review any of US Bio’s internal standard operating procedures or work instructions at US Bio’s facility. Upon termination of this Agreement, any of US Bio’s internal standard operating procedures or work instructions in Dyax’s possession will be returned to US Bio or (at US Bio’s election) destroyed by Dyax, with Dyax providing US Bio with a written certification of destruction.  
 8.5 No Subcontracting or Subdistribution. All obligations and services to be performed by US Bio under this Agreement shall be solely performed by US Bio and US Bio shall not outsource or subcontract any of its obligations hereunder without Dyax’s prior written consent.  
 8.6 Applicable Laws and Regulations. US Bio shall conduct all activities under this Agreement in compliance with all Applicable Laws, including federal and state pharmacy or pedigree laws, laws relating to the promotion of prescription medicines including the prohibition of off-label promotion, federal and state laws protecting the privacy of patient or prescriber identifiable information (including HIPAA), federal and state anti-kickback laws and regulations, laws relating to the disposal of pharmaceutical products and hazardous wastes, and all applicable professional and industry standards and good business practices. If Dyax reasonably determines that US Bio has conducted activities under this Agreement in a manner that could potentially compromise public health or safety, then Dyax may terminate this Agreement immediately, and whether or not Dyax terminates this Agreement, may pursue all other legal remedies available to it.  
 8.7 Product Promotion. US Bio will not provide any information regarding the safety, effectiveness, or use of Product to Specialty Pharmacy Customers or other persons or entities except as approved in advance in writing by Dyax or required by Applicable Laws. US Bio may provide information on its own specialty pharmacy and distribution services to its Specialty Pharmacy Customers in accordance with US Bio standard business practices, including informing its Specialty Pharmacy Customers of pricing available for the Product and other products distributed by US Bio. US Bio warrants that any information it provides to its Specialty Pharmacy Customers regarding Product or its services will be truthful and non-misleading and will comply with all Applicable Laws.  
 8.8 Discounts. To the extent required by Applicable Laws, including 42 U.S.C. §§ 1320a-7b(b) and in conformance with the standards set forth in 42 C.F.R. § 1001.952(h) for safe harbor protection, US Bio shall advise and inform each of its Specialty Pharmacy Customers to fully report, as required by  
 8  
 law or contract, any discounts, rebates, or reductions in prices on Product and provide the discount information supplied by US Bio to the Department of Health and Human Services or a state agency upon request, consistent with the requirements of 42 U.S.C. § 1320a-7b(b) and 42 C.F.R. § 1001.952(h).  
 8.9 Diversion. US Bio shall notify Dyax in writing (including via email or other electronic communication) promptly within one (1) business day of learning of information to suggest that any person or entity is diverting or attempting to divert Product. For the purposes of this Section 8.9, “diverting” means the unauthorized sale, distribution, purchase, receipt, or handling of Product. Dyax may immediately terminate this Agreement upon written notice if it is determined by Dyax that US Bio has purchased Product from sources other than Dyax or its designated third party logistics provider.  
 9. Compensation for Hub Services.  
 Dyax will compensate US Bio for the Hub Services in accordance with the Statement of Work. For clarity, the fees on Statement of Work shall be and remain in effect for the duration of the Term, provided that if Dyax terminates its agreement with either of US Bio’s Affiliates, Integrated Commercialization Solutions, Inc. or ASD Specialty Healthcare, Inc., such fees may be subject to adjustment. Within [\*\*\*\*\*] following the end of each calendar month during the term of this Agreement, US Bio shall provide a detailed invoice that specifically identifies the Hub Services conducted by US Bio during that calendar month. Dyax shall notify US Bio of any disputed charges in writing within [\*\*\*\*\*] following receipt of the invoice covering such charges. In the absence of any such notice of dispute, all invoices shall be deemed to be correct and due in full within [\*\*\*\*\*] following receipt of the invoice. On all undisputed invoice balances exceeding [\*\*\*\*\*], Dyax shall pay interest equal to the lesser of (i) [\*\*\*\*\*] per month and (ii) the maximum allowed by law.  
 10. Reports and Records.  
 10.1 Product Reports. US Bio shall generate and furnish to Dyax (or its designee) the Product reports specified in the Statement of Work attached as Exhibit B (collectively, the “Product Reports”).  
 10.2 Activity Reports. In addition to any specific reports that US Bio may be required to deliver to Dyax under this Agreement, US Bio shall provide to Dyax (or its designee) all information and reports related to its activities with respect to the Product that are reasonably requested by Dyax and can be prepared by US Bio without undue burden; provided, that US Bio shall be compensated and fully reimbursed by Dyax for any additional time and expense incurred in connection with the preparation and delivery of such information and/or reports.  
 10.3 Compliance. The parties intend that all reports provided to Dyax under Sections 10.1, 10.2 and 13.3 shall comply with Applicable Laws, including HIPAA and any laws relating to the identity of the Patient or prescriber. Accordingly, the parties agree that US Bio shall only provide Dyax with patient information that is de-identified in accordance with HIPAA’s de-identification provision, 45 C.F.R. § 164.514(b), unless: (i) Dyax or US Bio has on file a valid, HIPAA-compliant written authorization for each patient whose protected health information (“PHI”) is sought to be disclosed; or (ii) written authorization is not required under Applicable Laws in order to disclose the PHI sought. To the extent they may be required by HIPAA, US Bio shall obtain any Business  
 9  
 Associate Agreements (as described in 45 C.F.R. § 164.504) that are necessary to fulfill its obligations under this Agreement. In the event of any inconsistency between the data file layouts described for the Product Reports in the Statement of Work attached as Exhibit B and this Section 10.3, the terms of this Section 10.3 shall control. In the event of any amendment to any Applicable Laws, US Bio shall be entitled to unilaterally modify the data reports, without consent from Dyax, as required to comply with such amendments; provided that US Bio shall provide Dyax with notice of such modification and a description of the amendment requiring such modification prior to submitting a modified data report. In addition to the foregoing, the parties acknowledge that existing contractual relationships with third party payors may restrict US Bio’s ability to collect, use, and/or disclose certain Patient-, payor-, or physician-specific data.  
 10.4 Ownership and Use of Data. Subject to Applicable Laws, Dyax shall have the following rights with respect to information and data relating to Product, the sale of Product to Specialty Pharmacy Customers and the use by Product of Patients obtained, maintained, generated or furnished by US Bio to Dyax in connection with performing US Bio’s obligations hereunder, including such data and information contained in the reports delivered pursuant to Sections 10.1 and 10.2:  
 (a) With respect to the activity and other data generated in connection with the Hub Services (which shall be captured in the Hub Services database and may be reported to Dyax pursuant to this Agreement), Dyax shall own and have the exclusive right to use all such information and data (provided, that US Bio may use any and all information and data to the extent required in its performance of the Hub Services or as otherwise necessary in connection with its dispensing of Product and related services to Patients) and all such information shall be deemed to be Dyax Confidential Information; and  
 (b) The parties acknowledge and agree that US Bio shall own product dispensing data and any other clinical data related to such dispensing activities. With respect to all information and data not covered by Section 10.4(a) but which is provided by US Bio to Dyax in accordance with this Agreement, Dyax shall have a right to use any and all information and data, for any purpose as permitted by law or, to the extent such data contain PHI, as permitted by the applicable patient’s written authorization or as otherwise allowed under the law.  
 10.5 Records. US Bio shall keep complete and accurate books and records pertaining to US Bio’s activities under this Agreement. Such books and records shall be retained for at least [\*\*\*\*\*] after the expiration or termination of this Agreement or for such longer period as may be required by Applicable Laws.  
 10.6 Audits. Dyax, at its expense, from time to time may perform, or have an independent third party auditor (subject to execution of a mutually agreeable nondisclosure agreement) perform, audits of the records maintained pursuant to Section 10.5 and may observe, or have an independent third party auditor observe, the performance by US Bio of its activities hereunder to verify the status of Product and ensure compliance with the terms of this Agreement. Dyax shall provide US Bio with at least ten (10) business days advance written notice of such audits or observations, and shall conduct any audit or observation during normal business hours in a manner that does not interfere with US Bio’s normal business operations. US Bio shall make available relevant records that do not  
 10  
 contain information pertaining to US Bio’s other clients or products and permit such observations. Dyax and US Bio shall discuss the results of any such audits or observations and US Bio shall implement all corrective measures reasonably requested by Dyax. All audits shall be reasonable in time and scope.  
 11. Confidentiality.  
 11.1 Confidential Information. All confidential, non-public documents and other information disclosed to a party by or on behalf of the other party pursuant to this Agreement, which includes but is not limited to information concerns prices and quantities purchased by any customer, Product information, pricing, fees and proposals, operating and sales data, information about processes, systems, strategic plans, business plans, financial information, processes (including SOPs), customer information, information concerning patients or physicians, methods, databases, technology (including software and all source code), and any analysis, compilation, or study, and any other information or materials prepared or derived from such information (collectively, “Confidential Information”), shall, subject to Sections 11.2 and 11.3, be held by the receiving party in strict confidence and not disclosed either directly or indirectly to any third party (other than Affiliates, advisors and consultants who have a need to know such information and who are subject to obligations of confidentiality at least as onerous as those set forth herein) and shall only be used for purposes of fulfilling the receiving party’s obligations, or exercising its rights, under this Agreement. Notwithstanding the foregoing, all data and information owned by Dyax pursuant to Section 10.4 shall be the Confidential Information of Dyax and not US Bio, and regardless of the party that discloses such Confidential Information hereunder, Dyax shall be deemed the disclosing party, and US Bio shall be deemed the receiving party, with respect to such Confidential Information. The terms and conditions of this Agreement and any amendments or addenda thereto shall be deemed the Confidential Information of each party.  
 11.2 Exclusions from Confidentiality. Notwithstanding anything to the contrary in this Agreement, the receiving party shall have no liability to the disclosing party for the use or disclosure of any Confidential Information that the receiving party can establish by written documentation to:  
 (a) have been publicly known prior to disclosure by the disclosing party of such information to the receiving party;  
 (b) have become publicly known without fault on the part of the receiving party, subsequent to disclosure to the receiving party;  
 (c) have been received by the receiving party at any time from a source, other than the disclosing party, lawfully having possession of and the right to disclose such information;  
 (d) have been otherwise known by the receiving party prior to disclosure by the disclosing party to the receiving party of such information; or  
 (e) have been independently developed by the receiving party without use of information disclosed by the Disclosing Party.  
 11  
 11.3 Required Disclosure. A party receiving Confidential Information may disclose such Confidential Information if required to do so by a court (or other governmental agency or stock exchange of competent jurisdiction), any governmental body or as required under any Applicable Laws; provided that (i) the party required to disclose such Confidential Information provides prompt notice of such pending disclosure to the disclosing party so that the disclosing party can seek a protective order or to prevent such disclosure, and (ii) the party required to disclose such Confidential Information shall exercise reasonable efforts to ensure that the information is accorded confidential treatment by the court or other governmental agency or stock exchange.  
 11.4 Survival of Confidentiality Obligations. The provisions of this Section 11 shall survive for a period of [\*\*\*\*\*] following the expiration or termination of this Agreement.  
 11.5 Injunctive Relief. Each party acknowledges that the failure by the Receiving Party to comply with any of the provisions of this Section 11 will result in irreparable injury and continuing damage to the disclosing party for which there will be no adequate remedy at law and that, in the event of a failure of the receiving party so to comply, the disclosing party shall be entitled to seek such preliminary and permanent injunctive relief as may be necessary to ensure compliance with all the provisions of this Section without having to prove actual damages or to post a bond.  
 12. Use of Marks.  
 For the purposes of this Agreement, Dyax hereby grants to US Bio a non-exclusive, non-transferable, revocable license to use Dyax’s trademarks, trade names and service marks used and/or owned by Dyax with respect to the Product (collectively, the “Marks”). The Marks shall be used by US Bio solely in connection with its sale, distribution and/or delivery of Product, and other activities conducted under this Agreement, in each case solely in accordance with the terms hereof. The ownership of and goodwill in all Marks shall remain the sole and exclusive property of Dyax and inure exclusively to Dyax’s sole benefit, both during the Term and thereafter. US Bio agrees that nothing in this Agreement shall give US Bio any right, title or interest in or to the Marks other than the right to use the same in the manner contemplated by this Agreement and only for so long as this Agreement is in force.  
 13. Additional Representations, Warranties and Covenants.  
 13.1 Authorization. Each party represents and warrants to the other party that it has the legal right and power to enter into this Agreement, to extend the rights and licenses granted to the other in this Agreement, and to fully perform its obligations hereunder, and that the performance of such obligations will not conflict with its charter documents or any agreements, contracts, or other arrangements to which it is a party. Furthermore, no approvals, consents, orders or authorizations of or designation, registration, declaration or filing with any governmental authority (within the Field in the Territory) is required for either party’s performance of its obligations under this Agreement, other than any approvals that have been obtained already or will be obtained in the ordinary course of the performance of such obligations.  
 13.2 No Other Agreements. Each party represents and warrants to the other that this Agreement is not dependent on, and does not operate in conjunction with (either explicitly or implicitly), any other arrangement between Dyax and US Bio.  
 12  
 13.3 Product Pricing. US Bio represents, warrants and covenants that:  
 (a) it will refrain from doing anything that would impede Dyax from meeting any reporting obligations with respect to Product pricing that Dyax may have under Applicable Laws;  
 (b) it will report the Product sales price offered to Specialty Pharmacy Customers on the invoices or statements submitted by US Bio to Dyax; and  
 (c) no discount provided or other payment made pursuant to this Agreement is intended in any way as a discount related to a drug formulary and has not been negotiated or discussed between the parties in connection with any drug formulary.  
 To the extent required under Applicable Laws, US Bio will report the discounts to appropriate Federal health care programs, and in any event, will promptly disclose such discounts if requested by a government agency.  
 13.4 Hub Services; Service Fees. The parties mutually represent and warrant to each other that:  
 (a) the service fees paid to US Bio in connection with the Hub Services (i) are not intended in any way as remuneration for US Bio to use, purchase, or recommend any Dyax product or service, except as provided for in this Agreement, (ii) represent the fair market value for the Hub Services based upon arms length negotiations, (iii) are bona fide service fees that do not constitute a discount or other form of compensation that must be included in Dyax’s reporting of pricing information for Product to the Centers for Medicare and Medicaid Services;  
 (b) the service fees paid to US Bio in connection with the Hub Services are not intended in any way as payment related to a drug formulary or drug formulary activities and have not been negotiated or discussed between the parties in connection with any such drug formulary or formulary activities; and  
 (c) the Hub Services do not involve the counseling or promotion of a business arrangement or other activity that violates any state or federal law.  
 13.5 Federal Programs. US Bio represents, warrants and covenants to Dyax that (a) neither US Bio nor any of its Affiliates that perform activities under this Agreement has been debarred or is subject to debarment pursuant to Section 306 of the Act or listed on either Excluded List (as defined herein), and (b) neither US Bio nor any of its Affiliates that perform activities under this Agreement will knowingly (after reasonable investigation) use in any capacity, in connection with the services to be performed under this Agreement, any person who has been debarred pursuant to Section 306 of the Act, or who is the subject of a conviction described in such section, or listed on either Excluded List. US Bio shall inform Dyax in writing immediately if it or any person who is performing services hereunder is debarred or is the subject of a conviction described in Section 306 of the Act or listed on either Excluded List, or if any action, suit, claim, investigation or legal or administrative proceeding is pending or, to the best of US Bio’s knowledge, is threatened, relating  
 13  
 to the debarment or conviction Section 306 of the Act, or listing on either Excluded List, of US Bio or any person performing services hereunder. “Excluded Lists” means the Department of Health and Human Service’s List of Excluded Individuals/Entities and the General Services Administration’s Lists of Parties Excluded from Federal Procurement and Non-Procurement Programs.  
 13.6 Licensure. US Bio represents and warrants that it now has and shall maintain in full force during the Term all applicable federal and state pharmacy and other licenses or approvals required under Applicable Laws and regulations to fulfill its obligations under this Agreement in each state in the Territory, the District of Columbia and Puerto Rico. US Bio promptly shall notify Dyax of any denials, revocations or suspension of license or registrations by any state or federal agency or any other regulatory authority in the Territory, or any written notice from a governmental body proposing such a denial, revocation or suspension of a license or registration. US Bio shall promptly provide Dyax with notice of any material communications with pharmacy licensing boards which relate to potential problems with facilities, operations, contractors or procedures used by US Bio in distribution of the Product, including notices of inquiries, investigations or inspections and resulting findings, except that in no event shall US Bio be required to disclose information concerning its other clients or the products of such clients.  
 13.7 Dyax Representations and Warranties. Dyax hereby represents and warrants to US Bio that, at the time of delivery of Product by Dyax to US Bio hereunder: (a) such Product shall not in any material respect be adulterated, misbranded or otherwise prohibited within the meaning of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. §§ 301 et. seq., as amended and in effect at the time of delivery (the “Act”), or within the meaning of any applicable state or local law; (b) such Product will be merchandise that may be introduced and delivered into interstate commerce under the provisions of Section 301 of the Act or Section 351 of the Public Health Service Act; (c) Dyax (or as applicable its designated third-party logistics provider) has and will maintain, in full force and effect, all licenses and permits required under Applicable Laws for Dyax to sell and distribute such Product under this Agreement; (d) such Product will be the subject of a duly approved Biologics License Application and may be legally transported or sold under Applicable Laws; (e) such Product will have been approved by each applicable governmental authority for commercial sale and shipment of such Product within the Territory; and (f) Dyax either (i) owns or holds the duly approved Biologics License Application, as such term is used in the Public Health Service Act, Xxxxx 00, Xxxxxx Xxxxxx Code, as amended for such Product, or (ii) is otherwise considered the “manufacturer” of such Product within the meaning of any applicable federal, state or local law relating to pedigrees.  
 13.8 No Other Warranties. Except as expressly provided herein, neither party hereto makes any representations or warranties to the other party, express or implied, either in fact or by operation of law, by statute or otherwise, and each party specifically disclaims any express or implied representations and warranties of merchantability or fitness for a particular purpose.  
 14  
 14. Liability, Indemnification and Insurance.  
 14.1 Remedies.  
 (a) Generally. Rights and remedies under this Agreement are cumulative and in addition to any other available rights or remedies under any other agreement, at law or in equity.  
 (b) Equitable Relief. If either party violates or threatens to violate any provision of this Agreement, the other party may suffer irreparable harm and its remedies at law may be inadequate. Accordingly, the other party may seek equitable relief.  
 14.2 Indemnification.  
 (a) Indemnification by US Bio. US Bio shall indemnify, defend, and hold harmless Dyax and its Affiliates and its and their respective directors, officers, employees, representatives and agents and their respective successors, heirs and assigns (the “Dyax Indemnitees”) against any liability, damage, loss, penalty, fine or expense (including reasonable attorneys fees and expenses of litigation) (collectively, “Losses”) incurred by or imposed upon the Dyax Indemnitees or any of them in connection with any claims, suits, demands, investigations, enforcement actions, or judgments, in each case initiated by a third party (including any governmental or regulatory agency) (collectively, “Third Party Claims”) which arise out of: (a) the gross negligence or willful misconduct of US Bio in connection with this Agreement; or (b) the breach of this Agreement by US Bio, in each case except for those Losses for which Dyax has an obligation to indemnify US Bio pursuant to Section 14.2(b), as to which Losses each party shall indemnify the other to the extent of its respective liability for such Losses.  
 (b) Indemnification by Dyax. Dyax shall indemnify, defend, and hold harmless US Bio and its Affiliates and its and their respective directors, officers, employees, representatives and agents and their respective successors, heirs and assigns (the “US Bio Indemnitees”) against any Losses incurred by or imposed upon US Bio Indemnitees or any of them in connection with any Third Party Claims which arise out of: (a) the negligence or willful misconduct of Dyax in connection with this Agreement; (b) the breach of this Agreement by Dyax, in each case except for those Losses for which US Bio has an obligation to indemnify Dyax pursuant to Section 14.2(a); (c) any claims of patent, trademark, copyright or other infringement related to Products; or (d) the storage, handling, use, non-use, demonstration, consumption, ingestion, digestion, manufacture, production and assembly of Products and their transportation to US Bio (except to the extent that such activities are conducted on Dyax’s behalf by an Affiliate of US Bio), as to which Losses each party shall indemnify the other to the extent of its respective liability for such Losses.  
 (c) Indemnification Procedure. A party that intends to claim indemnification under this Section 14.2 (the “Indemnitee”) shall: (i) promptly notify the indemnifying party (the “Indemnitor”) in writing of any Third Party Claim in respect of which the Indemnitee or any of its Affiliates or any of their respective directors, officers, employees, representatives, agents or their respective successors, heirs or assigns intend to claim such indemnification hereunder; (ii) provide the Indemnitor sole control of the defense and/or settlement thereof with counsel reasonably satisfactory to the Indemnitee; provided, however, that the Indemnitee reserves the right to retain its own counsel to defend itself in, but not control the defense of, such suit, at its own expense, unless (a)   
 15  
 the interests of the Indemnitee and the Indemnitor in the suit conflict in such a manner and to such extent as to require, consistent with applicable standards of professional responsibility, the retention of separate counsel for the Indemnitee, in which case, the Indemnitor shall pay for one separate counsel chosen by the Indemnitee or (b) the Indemnitor shall not have employed attorneys reasonably satisfactory to the Indemnitee to defend any action within a reasonable time after notice of commencement of such action and (iii) provide the Indemnitor, at the Indemnitor’s request and expense, with reasonable assistance and full information with respect thereto. Neither the Indemnitor nor the Indemnitee shall be responsible to or bound by any settlement made by the other without its prior written consent, which shall not be unreasonably withheld or delayed. Without limiting the foregoing provisions of this Section 14.2(c), the Indemnitor shall keep the Indemnitee reasonably informed of the progress of any claim, suit or action under this Section 14.2 and the Indemnitee shall have the right to participate in any such claim, suit or proceeding with counsel of its choosing at its own expense, but the Indemnitor shall have the sole right to control the defense or settlement thereof in accordance with the terms of this Section 14.2(c).  
 14.3 Limitation of Liability.  
 (a) Neither party shall be liable to the other for special, exemplary, consequential, incidental (including lost or anticipated revenues or profits), indirect or punitive damages arising from the performance or nonperformance of such party under this Agreement whether such claim is based on contract, tort (including negligence) or otherwise, even if an authorized representative of such party is advised of the possibility or likelihood of same.  
 (b) Notwithstanding the exclusions and limitations of liability set forth in Section 14.3(a) above, such exclusions and limitations shall not apply to: (i) either party’s indemnification obligations pursuant to Section 14.2; or (ii) either party’s breach of the party’s confidentiality obligations pursuant to Article 11.  
 14.4 US Bio Insurance Obligations. During the Term, US Bio shall maintain the following minimum levels of insurance:  
 (a) Employer’s liability insurance with a limit of [\*\*\*\*\*] for bodily injury by accident per person, [\*\*\*\*\*] for bodily injury by accident, all persons and [\*\*\*\*\*] bodily injury by disease policy limit;  
 (b) Commercial general liability insurance, including personal injury blanket contractual liability and broad form property damage, with a [\*\*\*\*\*] combined single limit;  
 (c) Umbrella liability insurance in the amount of [\*\*\*\*\*] per occurrence and aggregate; and  
 (d) Property insurance covering the business property of US Bio and others while at any unnamed location in the amount of [\*\*\*\*\*].  
 16  
 The insurance required by this Section 14.4 may be made up through a combination of self-insured retention and traditional insurance. Throughout the Term, US Bio shall (a) provide prompt written notice to Dyax in the event US Bio becomes aware or is notified that the insurance described in this Section 14.4 will be materially adversely modified or cancelled in such a manner that US Bio is no longer in compliance with the requirements of this Section 14.4 and (b) provide Dyax with proof of such insurance on or before the date such insurance is renewed for each year.  
 14.5 Dyax Insurance Obligations. During the Term, Dyax will maintain products liability and commercial general liability insurance having a limit of not less than [\*\*\*\*\*] per occurrence, Combined Single Limit (Bodily Injury and Property Damage), pursuant to one or more insurance policies with reputable insurance carriers having a Best’s Rating of A VII or otherwise as reasonably approved by US Bio. Dyax will designate US Bio as an “additional insured” under such insurance policy and will obtain a broad form vendor’s endorsement for products liability for US Bio. Within thirty (30) days after the Effective Date, Dyax will provide to US Bio a certificate of insurance indicating that such obligations have been satisfied. As a condition precedent to the effectiveness of this Agreement, Dyax will execute the form of Continuing Guaranty and Indemnification Agreement (the “Continuing Guaranty”) with AmerisourceBergen Corporation attached hereto as Exhibit E.  
 15. Term and Termination.  
 15.1 Term. Unless earlier terminated in accordance with the terms hereof, the term of this Agreement (the “Term”) shall (i) commence as of the Effective Date and will continue in effect for an initial period of three (3) years (the “Initial Term”), and (ii) automatically renew for subsequent periods of [\*\*\*\*\*] (each, a “Renewal Term”), unless either party provides written notice to the other at least [\*\*\*\*\*] prior to the end of the Initial Term or then-current Renewal Term that it does not wish to renew. The parties will work together in good faith to discuss and agree upon any appropriate fee adjustments at least [\*\*\*\*\*] prior to expiration of the Initial Term (or any subsequent Renewal Terms).  
 15.2 Termination. In addition to any other provision of this Agreement providing for termination hereof, this Agreement may be terminated as follows:  
 (a) Termination by Dyax For Convenience. Dyax may terminate this Agreement for convenience, without cause, upon [\*\*\*\*\*] prior written notice of termination to US Bio; provided, that, upon any such termination that occurs prior to the second anniversary of the Effective Date, Dyax shall pay US Bio the following amount within [\*\*\*\*\*] following the effective date of termination: (i) [\*\*\*\*\*] if prior to the first anniversary of the Effective Date; (ii) [\*\*\*\*\*] if after the first anniversary of the Effective Date but prior to the second anniversary of the Effective Date; and (iii) [\*\*\*\*\*] if after the second anniversary of the Effective Date but prior to the third anniversary of the Effective Date.  
 (b) Termination For Cause.  
 (i) This Agreement may be terminated by either party on written termination notice to the other party in the event of any material breach of this Agreement by the other party (other than a breach by US Bio of Section 8.2, which is governed by  
 17  
 clause (ii) below), which breach is not cured within [\*\*\*\*\*] days after delivery of written notice by the non-breaching party specifying such breach and requiring cure. Notwithstanding the right to cure provided by the foregoing sentence, US Bio shall have the right to cure only two (2) material breaches of any particular obligation hereunder, and this Agreement may be terminated by Dyax immediately on written notice to US Bio in the event of any additional material breach of such obligation by US Bio.  
 (ii) This Agreement may be terminated by Dyax immediately on written notice to US Bio in the event of any material breach by US Bio of Section 8.2.  
 (c) Insolvency. This Agreement may be terminated by either party immediately upon written notice to the other party in the event of any of the following events:  
 (i) the institution by the other party of insolvency, receivership or bankruptcy proceedings or any other material proceedings for the settlement of the other party’s debts, or the institution against the other party of any such proceedings that remain undismissed for [\*\*\*\*\*];  
 (ii) the other party’s making an assignment for the benefit of its creditors; or  
 (iii) the other party’s dissolution.  
 (d) Other Agreements. In the event that any of (a) the Distribution Services Agreement of even date herewith between Dyax and ASD Specialty Healthcare, Inc. or (b) the Distribution Services Agreement of even date herewith between Dyax and Integrated Commercialization Solutions, Inc. is terminated for any reason, then (i) this Agreement may be terminated by Dyax immediately upon ninety (90) days written notice to US Bio; and (ii) if not terminated by Dyax, US Bio will notify Dyax of any applicable adjustment to the fees based on such termination.  
 (e) Supervening Illegality.  
 (i) This Agreement shall terminate if both: (A) as a result of the enactment of any new applicable federal or state law or regulation, or any change in any existing applicable federal or state law or regulation or any new interpretation of any applicable federal or state law or regulation by any legislative body, court or regulatory agency, the performance by a party of any material obligation under the Agreement would be rendered illegal or any material provision of the Agreement would be rendered invalid or unenforceable, and (B) the parties are unable to negotiate a mutually acceptable amendment to the Agreement pursuant to Section 15.2(e)(iii) below. If any immaterial provision of this Agreement is held to be illegal, invalid or unenforceable for any reason, the Agreement shall be deemed amended to delete such provision, such amendment to apply only with respect to the operation of the Agreement in the particular jurisdiction in which such provision is held to be illegal, invalid or unenforceable,  
 18  
 and the remainder of the Agreement shall remain in full force and effect and enforceable in accordance with its terms.  
 (ii) The parties agree that the party affected by the new law or regulation or the change in law or regulation or the interpretation of a law or regulation shall use reasonable efforts to give the other party at least [\*\*\*\*\*] prior written notice of the effective date of such new law, change, or interpretation.  
 (iii) The parties agree that, notwithstanding the foregoing provisions of this Section, either party may, within ten (10) business days of giving or receiving notice of the new law, change or interpretation, notify the other party of its wish to renegotiate the applicable terms of the Agreement (“Renegotiation Notice”), in which event the parties shall negotiate in good faith, for a period of sixty (60) days from delivery of the Renegotiation Notice, an amendment to the Agreement that addresses the portion of the Agreement rendered illegal, invalid or unenforceable by the new law, change or interpretation while preserving to the greatest extent possible the original intent of the Agreement. If the parties successfully conclude such negotiations prior to the effective date of the new law, change or interpretation, the Agreement shall not terminate and shall be amended to reflect the negotiated terms. If the parties are unable to successfully conclude such negotiations prior to the effective date of the new law, change or interpretation and such effective date is within the sixty (60) day negotiation period, the Agreement shall be deemed amended to delete such portion rendered illegal, invalid, or unenforceable, such amendment to apply only with respect to the operation of the Agreement in the particular jurisdiction in which such portion is held to be illegal, invalid or unenforceable, and the remainder shall remain in full force and effect and enforceable in accordance with its terms. In the event the parties are unable to successfully conclude such negotiations within the sixty (60) day negotiation period, the Agreement shall terminate at the end of the sixty (60) day negotiation period.  
 15.3 Effect of Termination. Upon the expiration or earlier termination of this Agreement:  
 (a) all Confidential Information received hereunder shall be returned to the disclosing party, or destroyed, at the disclosing party’s election (provided that the receiving party may retain one copy to the extent necessary to comply with any contractual or other legal obligations applicable thereto);  
 (b) all rights granted to US Bio with respect to the Product shall terminate and US Bio shall cease in a timely and orderly manner all activities with respect to the selling and distribution of Product; and  
 (c) unless terminated by US Bio pursuant to Section 15.2(b), for a period of [\*\*\*\*\*] following such expiration or early termination, US Bio and its Affiliates shall provide commercially reasonable assistance in connection with Dyax’s transition of Product distribution and Hub Services to Dyax, its Affiliates or any third party selected by Dyax.   
 19  
 Dyax shall reimburse US Bio for its reasonable, documented out-of-pocket costs and expenses incurred with in connection with providing such transition services; provided that, in the event of a termination due to US Bio’s breach, neither the existence of this provision nor the fact of Dyax’s agreement to pay for such transition services shall in any way effect or limit Dyax’s rights or remedies with respect to such breach.  
 Termination of this Agreement shall not relieve either party of obligations incurred prior to termination. The provisions of Sections 2.3(a)(ii), 2.3(a)(iii), 10.4, 10.5, 10.6, 15.3, 17.10 and 17.11 and Articles 11, 14 and 16, together with and any other provisions which by their express terms extend beyond the expiration or termination of this Agreement, shall survive any termination of this Agreement.  
 15.4 Termination of Exclusivity. In the event that Dyax has the right to terminate this Agreement for any reason (except pursuant to Section 15.2(a) (Termination for Convenience), Dyax, on immediate written notice to US Bio, may terminate Section 2.3(a)(i), which shall have no further force or effect from and after the delivery of such notice by Dyax. In the event that Dyax terminates this Agreement for convenience pursuant to Section 15.2(a), then US Bio’s obligations under Sections 2.3(a)(ii) and 2.3(a)(iii) shall expire one (1) year after the effective date of termination and thereafter have no further force or effect.  
 16. Dispute Resolution.  
 16.1 Resolution by Executives. Any dispute, controversy or claim initiated by either party arising out of, or resulting from the breach or alleged breach by either party of its obligations under this Agreement (other than bona fide third party actions or proceedings filed or instituted in an action or proceeding by a third party against a party to this Agreement), whether before or after termination of this Agreement, shall be in the first instance referred to the respective chief executive officers of the parties unless such dispute or claim must be filed to preserve a legal interest or injunctive relief is required.  
 16.2 Arbitration. If chief executive officers (or their representatives, it being agreed that the chief executive officer of either party may designate a representative, provided such representative is empowered with decision making in the dispute) of the parties fail to resolve any dispute as provided in Section 16.1 within [\*\*\*\*\*], then such dispute shall be finally resolved by binding arbitration as follows:  
 (a) Any dispute that might arise between the parties relating to or arising from this Agreement shall be settled by binding arbitration in accordance with the then-prevailing Commercial Arbitration Rules of the American Arbitration Association (“AAA”), except where those rules conflict with this provision, in which case this provision controls. Arbitration shall be conducted before a single arbitrator selected from the AAA’s National Roster of Arbitrators, each of whom shall be a lawyer with at least 15 years experience with a law firm or corporate law department of over 25 lawyers or who was a judge of a court of general jurisdiction. Each party shall have the right to meet and interview the potential arbitrator for no more than one hour each prior to the selection of an arbitrator. The arbitration shall be held, and Dyax and US Bio irrevocably consent to arbitrate, in a  
 20  
 mutually agreeable location. The arbitration shall be conducted in English. In rendering the award the arbitrator must apply the substantive law of the State of Delaware (except where that law conflicts with this clause); however, the interpretation and enforcement of this arbitration provision shall be governed by the Federal Arbitration Act. The arbitrator shall render a written opinion setting forth findings of fact and conclusions of law with the reasons therefor stated. Under no circumstances shall the arbitrator award damages in excess of or inconsistent with any limitations of liability contained in this Agreement. Any court with jurisdiction shall enforce this clause and enter judgment on any award. US Bio and Dyax will agree upon, within [\*\*\*\*\*] after the arbitrator is selected or, if they fail to agree, the AAA will design, procedures that they will follow to assure that the arbitration will be concluded and the award rendered within no more than eight months from selection of the arbitrator.  
 (b) The arbitration proceedings shall be confidential, and neither party shall publicize the nature of any dispute or the outcome of any arbitration proceedings except to the extent required by law, provided in such case the party required to make any disclosure informs the other party of such requirement to allow the other party to seek a protective order. The arbitrator shall issue appropriate protective orders to safeguard each party’s Confidential Information.  
 (c) Each party has the right before or during the arbitration to seek and obtain from the appropriate court provisional remedies such as attachment, an injunction, replevin, etc., to avoid irreparable harm, maintain the status quo or preserve the subject matter of the arbitration.  
 17. Miscellaneous.  
 17.1 Relationship of Parties. US Bio’s relationship with Dyax hereunder shall be that of independent contractor, and neither party shall be considered the agent of, partner of, employee or other member of the workforce of, or participant in a joint venture with, the other party. Neither party shall have authority to bind the other party unless otherwise agreed to in writing by such parties.  
 17.2 Notices. All notices, requests, demands and other communications required or permitted to be given pursuant to this Agreement shall be in writing and shall be deemed to have been duly given upon the date of receipt if delivered by hand, recognized international overnight courier, confirmed facsimile transmission, or registered or certified mail, return receipt requested, postage prepaid to the following addresses or facsimile numbers:  
 If to Dyax:  
 Dyax Corp.  
 000 Xxxxxxxxxx Xxxxxx  
 Xxxxxxxxx, XX 00000  
 [\*\*\*\*\*]  
 If to US Bio:  
 US Bioservices Corporation  
 0000 Xxxxxxx Xxxxxxx  
 Xxxxxx, XX 00000  
 21  
 [\*\*\*\*\*]  
 with a copy to:  
 AmerisourceBergen Specialty Group  
 0000 Xxxxxxx Xxxxxxx  
 Xxxxxx, XX 00000  
 [\*\*\*\*\*]  
 Either party may change its designated address, contact person and facsimile number by notice to the other party in the manner provided in this Section.  
 17.3 Assignment. Neither party may assign its rights or delegate its obligations under this Agreement without the prior written consent of the other party, except that either party may assign this Agreement to any of its Affiliates or to a successor in connection with the merger, consolidation, or sale of all or substantially all of its assets or that portion of its business pertaining to the subject matter of this Agreement, with prompt written notice to the other party of any such assignment; provided that: (i) if such assignee is an Affiliate, the assignor shall responsible for and liable with respect to all assigned obligations and (ii) if such assignee is not an Affiliate, (A) the assignee assumes the assignor’s obligations under the Continuing Guaranty and Indemnification Agreement, and (B) the assignee has net assets as of the end of its most recently completed fiscal year equal to or in excess of the net assets of the assignor as of the end of its most recently completed fiscal year, in each case as set forth in the audited balance sheet of the assignor and assignee, and (iii) in the case of an assignment by Dyax, the assignee is not a Competitor to US Bio. For the purposes of this Section 17.3, a “Competitor” means any organization, entity or person that competes with US Bio including but not limited to the following companies and their affiliated entities: [\*\*\*\*\*] Notwithstanding the foregoing, US Bio acknowledges and agrees that Dyax may perform its obligations and exercise its rights hereunder through a third party logistics provider.  
 17.4 Force Majeure. Each party’s obligation under this Agreement will be excused to the extent any delay or nonperformance is caused by strikes or other labor disturbance, acts of God, war, or other conditions beyond the reasonable control of that party, but only during the duration of such condition.  
 17.5 Amendment and Waiver. This Agreement may be amended, supplemented, or otherwise modified only by means of a written instrument signed by both parties. Any waiver of any rights or failure to act in a specific instance shall relate only to such instance and shall not be construed as an agreement to waive any rights or fail to act in any other instance, whether or not similar. To be valid, any waiver must be in writing.  
 17.6 Severability. In the event any provision of this Agreement should be held invalid, illegal or unenforceable, the remaining provisions shall not be affected or impaired and the parties shall use all reasonable efforts to replace the applicable provision with a valid, legal and enforceable provision which insofar as practical implements the original intent of such invalid, illegal or unenforceable provision, provided, however, that if the parties fail to reach such agreement within  
 22  
 sixty (60) days, a party whose rights or obligations are materially adversely affected as a result of a provision being held invalid, illegal or unenforceable may terminate this Agreement.  
 17.7 Headings. All headings used in this Agreement are inserted for convenience only and are not intended to affect the meaning or interpretation of this Agreement or any Article or Section hereof.  
 17.8 Successors and Assigns. This Agreement shall be binding on and shall benefit any and all successors, trustees, permitted assigns and other successors in interest of the parties.  
 17.9 Applicable Law; Disclaimer of Puerto Rico Law 75.  
 (a) This Agreement shall be construed and enforced in accordance with the laws of the State of Delaware (excluding the choice of law provisions thereof).  
 (b) The parties expressly disclaim, to the fullest extent allowed by Applicable Laws, any application of the Puerto Rico Dealers Act, Law No. 75 of June 1964 (the “Dealers Act”) as amended, and the parties acknowledge that the Dealers Act shall not apply in the interpretation or enforcement of any of the rights and obligations of the parties hereto.  
 17.10 Contract Interpretation. The parties have jointly negotiated this Agreement and, thus, neither this Agreement nor any provision will be interpreted for or against any party on the basis that it or its attorney drafted the Agreement or the provision at issue. When this Agreement requires approval of one or more parties, such approval may not be unreasonably withheld or delayed. Words, regardless of the number and gender specifically used, will be construed to include any other number, singular or plural, and any gender, masculine, feminine, or neuter, as the context requires. “And” includes “or.” “Or” is disjunctive but not necessarily exclusive. “Including” means “including but not limited to.” Unless other specifically stated, the term “days” means calendar days.  
 17.11 Entire Agreement; No Reliance. Each of the parties agrees and acknowledges that this Agreement, including the Continuing Guaranty and the attachments referred to herein, (i) constitutes the entire agreement and supersedes all prior and contemporaneous agreements, understandings, negotiations and discussions, whether oral or written, between the parties with respect to the subject matter of this Agreement, and (ii) is not intended to confer any rights or remedies, or impose any obligations, on any person other than the parties hereto. Each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement.  
 17.12 Counterparts. This Agreement may be executed in multiple counterparts, each of which shall be deemed an original but all of which together shall constitute one and the same instrument. Facsimile execution and delivery of this Agreement are legal, valid and binding execution and delivery for all purposes.  
 [signature page to follow]  
 23  
 IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed by their duly authorized respective officers as of the Effective Date.  
 US Bioservices Corporation  
Dyax Corp.  
 By:  
/s/ Xxxx X. Xxxxxxx  
 By:  
/s/ Xxxxx Xxxxxxxxxx-Xxxxxxxx  
 Name:  
Xxxx X. Xxxxxxx  
Name:  
Xxxxx Xxxxxxxxxx-Xxxxxxxx  
 Title:  
President  
Title:  
Executive Vice President Corporate Development and General Counsel  
 AmerisourceBergen Specialty Group, Inc., a Delaware corporation, agrees that it shall be financially responsible for any unsatisfied liabilities of US Bioservices Corporation under this Agreement; provided that any defense or privilege that may be asserted by US Bioservices Corporation may also be asserted by AmerisourceBergen Specialty Group, Inc.  
 AmerisourceBergen Specialty Group, Inc.  
 By:  
/s/ Xxxx Xxxxxx  
 Name:  
Xxxx Xxxxxx  
 Title:  
President  
 24  
 LIST OF EXHIBITS  
 EXHIBIT A — Product Description  
EXHIBIT B — Initial Statement of Work for Hub Services  
EXHIBIT C — Standard Operating Procedures for Hub Services  
EXHIBIT D — Product Returns Policy  
EXHIBIT E — Continuing Guaranty  
 25  
 EXHIBIT A  
Product Description  
 Product Trade Name:  
 Kalbitor®  
Generic Name:  
 ecallantide  
NDC Number:  
 00000-000-00  
 Kalbitor is a recombinant protein with high affinity and high specificity for human plasma kallikrein and is used in the treatment of Hereditary Angioedema (HAE).  
 Kalbitor is temperature sensitive and must be stored and shipped at 2-8°C (36-42°F).  
 Kalbitor is packaged in a single carton containing three 1 mL vials and is administered through three subcutaneous injections.  
 26  
 EXHIBIT B  
Initial Statement of Work for Hub Services  
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 27  
 EXHIBIT C  
Standard Operating Procedures for Hub Services  
 [\*\*\*\*\*]  
 28  
 EXHIBIT D  
Product Returns Policy  
 [\*\*\*\*\*]  
 29  
 EXHIBIT E  
Continuing Guaranty  
 [attached hereto]  
 30