UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
PURSUANT TO SECTION 13 OR 15(D)
OF THE SECURITIES EXCHANGE ACT OF 1934

Date of Report (Date of earliest event reported): September 4, 2020

AKEBIA THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-36352**	**20-8756903**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

245 First Street **Cambridge, Massachusetts**	**02142**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (617) 871-2098

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.00001 per share	**AKBA**	**The Nasdaq Global Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§ 240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 1.01. Entry into a Material Definitive Agreement.

As previously disclosed, on December 11, 2017, Keryx Biopharmaceuticals, Inc. ("Keryx"), which became a wholly owned subsidiary of Akebia Therapeutics, Inc. (the "Company") on December 12, 2018, entered into a Product Manufacture and Supply and Facility Construction Agreement with BioVectra Inc. ("BioVectra"), which was amended on April 20, 2018 (the "Original Agreement"). Pursuant to the Original Agreement, BioVectra has constructed a new facility for the manufacture and supply of Auryxia® (ferric citrate) drug substance (the "New Facility"), and Keryx has reimbursed BioVectra for certain New Facility construction costs. On September 4, 2020, consistent with the Company's previously disclosed plans to lower the cost of goods sold for Auryxia, BioVectra and Keryx entered into an Amended and Restated Product Manufacture and Supply and Facility Construction Agreement (the "Amended and Restated Agreement").

Pursuant to the Amended and Restated Agreement, Keryx is obligated to reimburse BioVectra for certain New Facility construction costs and to purchase minimum quantities of Auryxia drug substance that are lower than the minimum quantities under the Original Agreement, for a total cost of approximately $81.4 million through the end of the Term (as defined below), which amount may decrease upon the occurrence of certain conditions. This dollar amount is substantially lower than the dollar amount of the contractual obligation under the Original Agreement.

The term of the Amended and Restated Agreement began September 4, 2020 and ends December 31, 2026 (the "Term"), after which it automatically renews for successive one-year terms unless either party gives notice of its intention to terminate within a specified time prior to the end of the then-current term. Each party has the ability to terminate earlier upon the occurrence of certain conditions.

The Amended and Restated Agreement includes customary indemnification, intellectual property, confidentiality, remedies, and warranty terms, as well as certain quality requirements and other provisions.

The foregoing description of the Amended and Restated Agreement does not purport to be complete and is qualified in its entirety by reference to the Amended and Restated Agreement, a copy of which is filed as Exhibit 10.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 9.01. Financial Statements and Exhibits

(d) Exhibits

Exhibit No.	Description
10.1#	Amended and Restated Product Manufacture and Supply and Facility Construction Agreement between BioVectra, Inc. and Keryx Biopharmaceuticals, Inc., dated September 4, 2020.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

# Indicates portions of the exhibit (indicated by asterisks) have been omitted pursuant to Item 601(b)(10)(iv) of Regulation S-K

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

AKEBIA THERAPEUTICS, INC.

Date: September 11, 2020

By: /s/ John P. Butler
Name: John P. Butler
Title: President and Chief Executive Officer

Exhibit 10.1

EXECUTION VERSION

Certain identified information has been excluded from the exhibit because it is both (i) not material and (ii) would likely cause competitive harm to the Company, if publicly disclosed. Double asterisks denote omissions.

AMENDED AND RESTATED
PRODUCT MANUFACTURE AND SUPPLY AND FACILITY CONSTRUCTION AGREEMENT
Between
BIOVECTRA INC.
And
KERYX BIOPHARMACEUTICALS, INC.

This amended and restated Product Manufacture and Supply and Facility Construction Agreement (this "Amended Agreement") is made and entered into on September 4, 2020 ("Amendment Effective Date") by and between BioVectra Inc., with its registered offices at 11 Aviation Avenue, Charlottetown, PEI, C1E 0A1, Canada ("BioVectra") and Keryx Biopharmaceuticals, Inc., a wholly owned subsidiary of Akebia Therapeutics, Inc., with its offices at 245 First Street, Cambridge, Massachusetts 02142, USA ("Keryx") (each hereafter a "Party," and together, "Parties").

WHEREAS, BioVectra has the capability to Manufacture, and in the past has Manufactured GMP-grade quantities of Keryx's proprietary active pharmaceutical ingredient, ferric citrate, at BioVectra's API Facility, pursuant to the Manufacture and Supply Agreement (as defined herein below);

WHEREAS, Keryx desires to purchase certain quantities of Product (as defined herein below) from BioVectra over a defined period of time and BioVectra is willing to construct a facility for the Manufacture of Product and to supply Product to Keryx on the terms and conditions provided herein;

WHEREAS, effective December 11, 2017 (the "Effective Date"), BioVectra and Keryx entered into a Product Manufacture and Supply and Facility Construction Agreement, as amended by Amendment No. 1 to Product Manufacture and Supply and Facility Construction Agreement, dated April 20, 2018 ("Original Agreement"); and

WHEREAS, the Parties now desire to amend and restate the Original Agreement by entering into this Amended Agreement (the Original Agreement, as amended and restated by this Amended Agreement, the "Agreement").

NOW THEREFORE, in consideration of the mutual covenants hereafter set forth, the Parties hereto mutually agree as follows:

1. **Definitions.** Unless this Agreement expressly provides to the contrary, the following terms, whether used in the singular or plural, have the respective meanings set forth below

a. Affiliate means, with respect to either Party, any other corporation or business entity that directly, or indirectly through one or more intermediaries, controls, is controlled by or is under common control with such Party. For purposes of this definition, the term "control" means direct or indirect ownership of more than fifty percent (50%) of the securities or other ownership interests representing the equity voting stock or general partnership or membership interest of such entity or the power to direct or cause the direction of the management or policies of such entity, whether through the ownership of voting securities, by contract, or otherwise.

b. API Facility means BioVectra's facility for the manufacture of ferric citrate drug substance for Keryx under the Manufacture and Supply Agreement located at [**].

c. Applicable Law means all applicable ordinances, rules, regulations, laws, guidelines, guidances, requirements and court orders of any kind whatsoever, including those issued by any Authority, as amended from time to time, including GMP.

d. Authority means any government authority responsible for granting approvals for the performance of the Parties' obligations under this Agreement or for issuing rules, regulations, laws, guidelines, guidances and requirements pertaining to the Facility and or the Manufacture and/or use of Product in the intended country of use, including the FDA.

e. Batch means approximately [**] of Product that is intended to be of uniform character and quality, within specified limits, and is produced during the same cycle of Manufacture as defined by the applicable Batch Documentation.

f. BioVectra Technology means the Technology of BioVectra (i) existing prior to the Effective Date; or (ii) developed or obtained by or on behalf of BioVectra independent of this Agreement and without reliance upon the Confidential Information of Keryx.

g. Business Day means all days excluding Saturdays and Sundays and any other public holiday in either Canada or the US.

h. Certificate of Analysis means a document signed by an authorized representative of BioVectra, describing Specifications for, and testing methods applied to, Product, and the results of testing.

i. Certificate of Compliance means a document signed by an authorized representative of BioVectra, certifying that a particular Batch was manufactured in accordance with GMP, all other Applicable Law, the Manufacturing Procedure, and the Specifications.

j. CMC shall mean the chemistry, manufacturing, and controls section(s) and data in any Health Registration(s) that covers the chemical composition of a given Product and its components and the control and Manufacturing Procedure for any Products and their components, as may be amended or supplemented from time to time.

k. Comparability Report means a report delivered by Keryx to BioVectra containing information that confirms adherence of multiple Engineering Batches to the Comparability Protocol.

l. Effective Date has the meaning set forth in the recitals.

m. Equipment means all process equipment used in the manufacture of Product as defined in the Final Design.

n. Facility has the meaning set forth in Section 2.a.

o. Facility Approval means the earlier of (i) FDA Approval, and (ii) receipt by BioVectra of a notice from Keryx approving the Manufacture of Product in the Facility.

p. Facility Reimbursement Payment means [**].

q. FDA means the U.S. Food and Drug Administration.

r. FDA Approval means FDA approval of the NDA Manufacturing Supplement for the Facility.

s. GMP means Current Good Manufacturing Practices, which are requirements for the quality system under which Product will be Manufactured. Those practices are laid down in guidelines and regulations, including ICH Q7 Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients and US Code of Federal Regulations 21 CFR parts 210 & 211.

t. Health Registration shall mean the technical, medical and scientific licenses, registrations, authorizations and/or approvals of the Product that are required by any national, supra-national (e.g., the European Commission or the Council of the European Union), federal, regional, state or local Authority or other governmental entity, for the Manufacture, use or sale of the subject Product.

u. Improvements means all Technology and discoveries, inventions, developments, modifications, innovations, updates, enhancements, improvements, writings or rights (whether or not protectable under patent, trademark, copyright or similar laws) that are conceived, discovered, invented, developed, created, made or reduced to practice in the performance under this Agreement.

v. Keryx Supplied Materials means those materials and equipment, if any, supplied by, or on behalf of, Keryx to BioVectra for use in the Manufacture of Product hereunder (including any Starting Materials). Keryx Supplied Materials shall at all

times remain the property of Keryx (and BioVectra shall ensure that no pledges, liens, restrictions, claims, charges, security interests or other encumbrance are placed on such Keryx Supplied Materials).

w. Keryx Technology means (i) Keryx Supplied Materials and any intermediates, components, or derivatives thereof; (ii) Product and any intermediates, components, or derivatives of Product; (iii) the Specifications and Manufacturing Procedure; and (iv) the Technology of Keryx (A) existing prior to the Effective Date, or (B) developed or obtained by or on behalf of Keryx independent of this Agreement and without reliance upon the Confidential Information of BioVectra.

x. Latent Defect means [**] as described in the Quality Agreement.

y. Manufacture and Manufacturing means any steps, processes and activities necessary to produce Product including purchasing Starting Materials, subcontracting or performing services, formulating, processing, cleaning, maintenance, packaging, labeling, quality control testing, stability testing, release, storage, shipping or supply of Product.

z. Manufacture and Supply Agreement means the Manufacture and Supply Agreement, between BioVectra and Keryx dated May 26, 2017, as amended from time to time.

aa. Manufacturing Procedure means the process by which the Starting Materials and any intermediate compounds are used to create the Product as communicated by Keryx to BioVectra from time to time, as detailed in the Quality Agreement, and as memorialized in Batch Documentation, including the testing plan.

bb. Manufacturing Requirements means the standards to which BioVectra agrees to Manufacture the Product under this Agreement, which shall be in accordance with GMP, the Manufacturing Procedure, the Specifications, the quality requirements set forth in the Quality Agreement, and all Applicable Law.

cc. Metric Tons or MT means one thousand kilograms.

dd. NDA Manufacturing Supplement means an application filed with the FDA, or any comparable application filed with the regulatory authorities of a country other than the United States, to obtain approval to manufacture Product at the Facility.

ee. Nonconforming, Nonconformity and Nonconformance means that a Batch of Product does not comply with the Manufacturing Requirements.

ff. Party or Parties has the meaning set forth in the preamble.

gg. Physical Delivery means physical receipt of Product by Keryx or its designee.

hh. Product(s) means GMP-grade quantities of Keryx's proprietary active pharmaceutical ingredient, ferric citrate drug substance.

ii. [**].

jj. Process Validation Report means a report delivered by BioVectra to Keryx containing information that confirms adherence to the Process Validation Protocol.

kk. Quality Agreement means the Quality Agreement executed by the Parties, as amended and updated by mutual approval from time to time, describing, in accordance with this Agreement, the quality assurance responsibilities and obligations of the Parties for the Manufacture of the Product.

ll. Quality Module shall mean the chemistry, manufacturing, and controls section(s) and data in any Health Registration(s) that covers the chemical composition of a given Product and its components and the control and Manufacturing Procedure for any Products and their components, as may be amended or supplemented from time to time.

mm. Records are all records (including reports, accounts, notes, raw data, and records of all information and results obtained from performance of BioVectra's activities under this Agreement) of all work done by BioVectra under this Agreement, in form and substance as specified in the applicable purchase order, the Quality Agreement, and this Agreement.

nn. Reprocess and Reprocessing means [**].

oo. Specification(s) shall mean the specifications for the Product and Starting Materials, along with the analytical test methods and acceptance criteria applicable thereto, as set forth in the Quality Agreement, as amended in accordance with the change control procedures in the Quality Agreement. The Specifications as of the Amendment Effective Date are set forth in Appendix 2 hereto.

pp. Starting Materials means the chemical entities and materials required to synthesize the Product, including [**].

qq. Substantial Completion means the Facility has been certified to commence Process Engineering for the Product by the Certified Engineer.

rr. Supply Term means the period commencing [**] and ending at the end of the Term.

ss. Supporting Documentation means authorizations, certificates, methodologies, Starting Material specifications, standard operating procedures ("SOPs"), standard test methods, and other documentation in the possession or under the control of BioVectra relating to the development and/or Manufacture of Product (or any intermediate or component of Product).

tt. Technology means all methods, techniques, trade secrets, copyrights, know-how, data, documentation, regulatory submissions, specifications and other intellectual property of any kind (whether or not protectable under patent, trademark, copyright or similar laws).

uu. Working Capacity means [**].

2. Construction of Facility

a. Facility Construction and Timeline. BioVectra will construct a production facility in [**] with the Working Capacity (the "Facility") for Manufacturing of Product in accordance with GMP and all other Applicable Law. The Facility, which will be [**]. BioVectra's obligations hereunder include, but are not limited to the following:

i. Construction of the Facility to perform the Manufacturing Requirements in the Facility in accordance with the design of the Facility previously approved in writing by the Parties (the "Final Design"), which includes but is not limited to all work related to the procurement, design, project management, installation, assembly, commissioning and validation of the Facility and all Equipment;

ii. Engineering of the Manufacturing Requirements at the Facility (the "Process Engineering"); and

iii. Validation of the Manufacturing Requirements at the Facility ("Process Validation").

The Parties will work [**], to complete the activities set forth in Sections 2.k-n in accordance with the timelines set forth in [**] approved by the Parties, as may be amended from time to time by mutual agreement of the Parties (the "Timeline"), *provided that* [**].

b. Facility Financing. Except as set forth herein, BioVectra will be responsible for financing all costs associated with constructing the Facility.

c. Equipment. With respect to all Equipment, BioVectra shall provide engineering project management and process validation, qualification support, installation and commissioning services. BioVectra shall manage the installation, commissioning and validation activities of such Equipment.

d. Vendors. BioVectra shall disclose to Keryx in writing within [**] after Keryx's written request: (i) all persons and entities proposed by BioVectra to produce, construct, fabricate or supply any component part of the Facility, including all Equipment; (ii) the location(s) where each component of the Facility, including all

Equipment, will be produced, constructed or fabricated or from which such component shall be sourced; and (iii) any other information relating to sourcing and/or construction and assembly of the Facility which is [**] requested by Keryx. BioVectra shall promptly pay to each vendor the amount due for such vendor's work, provided BioVectra shall have the right to withhold payment to any of its vendors who have furnished defective, substandard, and/or incorrect materials, workmanship, or deliverables. Keryx shall have no obligation to pay, or cause the payment of, any money to any vendor or any other party acting through, under or on behalf of BioVectra.

e. Design Documents. BioVectra shall build, construct and assemble the Facility in strict accordance with the Final Design, photographs, plans, designs, drawings, Facility construction specifications, reports, and other documents relating thereto (collectively, the "Design Documents"), as may be updated, amended, or modified and otherwise in accordance this Agreement and all Applicable Law. Any material update, amendment or modification being either approved in writing by the Supply Committee within [**] from receipt, not to exceed [**].

f. Keryx Right of Access. Not in limitation of any other provision of this Agreement, Keryx shall have the right of access to any of BioVectra's and/or its vendor's plants (including the Facility) as may be necessary to allow Keryx to: (i) review BioVectra's progress; (ii) verify that the Facility is being built, constructed and assembled so as to conform to the Design Documents, the Timeline, and this Agreement; and/or (iii) verify that a progress payment contingency has been completed. Payments to BioVectra under this Agreement shall not constitute acceptance or impede Keryx's right to subsequently inspect the Facility or pursue remedies available to it.

g. Facility Costs. The Parties shall use [**] to minimize the costs of procurement, installation and commissioning of the Equipment. BioVectra shall provide Keryx with quotes and copies of all applicable invoices from vendors, for the costs of procurement, transportation, installation, and commissioning of the Equipment.

h. [**] Facility Reimbursement [**]. Keryx will pay the Facility Reimbursement Payment [**].

i. Inspection Right. Keryx will have, upon [**] notice to BioVectra, the right to monitor, review and inspect the Facility and Equipment any time during construction of the Facility and on and after the Substantial Completion of the Facility. BioVectra shall give [**] to any comments provided by Keryx resulting from the monitoring, review and inspection of the construction site, Facility and Equipment.

j. Certification of Substantial Completion. The Parties engaged a mutually-agreed independent certified engineer (the "Certified Engineer") to conduct a review to certify Substantial Completion, which certification was accepted by the Parties on

[**]. Both Parties shall be entitled to obtain copies of all results of the Certified Engineer's review. The findings of the Certified Engineer were binding on the Parties, absent fraud or manifest error. The Parties will [**] of the Certified Engineer's initial review. To the extent [**].

k. Process Engineering.

i. The Parties have agreed on a comparability protocol (the "Comparability Protocol") and an engineering protocol (the "Engineering Protocol") for Process Engineering, which together contain the manufacturing conditions, process controls, testing and expected outcomes for Process Engineering, including drug substance and drug product stability, either of which may be amended from time to time by mutual agreement of the Parties (the Comparability Protocol and the Engineering Protocol together, the "Process Engineering Protocols").

ii. BioVectra and Keryx will be responsible for completing Process Engineering consistent with the steps set forth in the Timeline and the Process Engineering Protocols. [**] following Substantial Completion, BioVectra will commence Process Engineering and produce [**] of Product in accordance with the Process Engineering Protocols during Process Engineering (the "Engineering Batches"). In accordance with the Process Engineering Protocols, BioVectra will supply Keryx with (i) Batch Documentation from the Engineering Batches, and (ii) Product from the Engineering Batches for evaluations, including but not limited to [**] In the event that Process Engineering does not adhere to the Process Engineering Protocols at any point during Process Engineering, the Parties will work [**] to resolve any issues that prevent such adherence, which may include [**]. Process Engineering will be considered complete upon written confirmation from both Parties that the Comparability Report confirms adherence to the Comparability Protocol ("Completion of Process Engineering").

iii. Within [**] following the Amendment Effective Date, [**]. In the event that BioVectra produces [**], *provided that*, if [**] are required to be produced [**].

l. Process Validation.

i. [**] following Completion of Process Engineering, but no later than [**] thereafter, the Parties will agree on a protocol for Process Validation, the first draft of which will be generated by [**], that will contain the manufacturing conditions, controls, testing and expected outcomes for Process Validation (the "Process Validation Protocol"). In the event there is a disagreement between the Parties with respect to one or more technical issues in the Process Validation Protocol that prevent the Parties from

agreeing to the Process Validation Protocol within [**] following Completion of Process Engineering, then the Parties will engage a mutually-agreed, independent CMC expert to make a determination on the disputed technical issues. Consent to the appointment of such CMC expert will not be [**] withheld or delayed by either Party. The determination of such CMC expert on the disputed technical issues will be binding on the Parties.

ii. BioVectra will be responsible for completing Process Validation consistent with the steps set forth in the Timeline and the Process Validation Protocol. [**] following Completion of Process Engineering but no later than [**] after agreement by the Parties on Process Validation Protocol, BioVectra will commence Process Validation. BioVectra must produce [**] Product during Process Validation (the "Validation Batches") in accordance with the Process Validation Protocol. In accordance with the Process Validation Protocol, BioVectra will supply Keryx with (i) Batch Documentation from the Validation Batches, and (ii) Product from the Validation Batches for evaluations, including but not limited to stability testing and drug product formulation. [**] Process Validation will be considered complete upon written confirmation from both Parties that the Process Validation Report confirms adherence to the Process Validation Protocol ("Completion of Process Validation").

iii. [**] for the Validation Batches in accordance with the price [**] set forth in Appendix 1 to this Agreement and in accordance with the procedures set forth in Section 7 hereto, *provided that*, [**]. In the event that Keryx requests that BioVectra produce additional Validation Batches, [**].

m. Mock FDA Audit. As soon as practicable following Completion of Process Validation, but no later than [**] thereafter, Keryx will engage a mutually-agreed independent regulatory expert (the "Regulatory Expert") to perform a mock FDA audit of the Facility (the "Mock FDA Audit"). Consent to the appointment of the Regulatory Expert will not be [**] withheld or delayed by either Party. Both Parties will cooperate with the Regulatory Expert's reasonable requests for assistance in connection with its evaluation hereunder. Both Parties shall be entitled to observe the Mock FDA Audit. Following completion of the Mock FDA Audit, unless otherwise agreed by the Parties, BioVectra will address the findings from the Mock FDA Audit prior to Keryx's submission of the NDA Manufacturing Supplement (the "Key Findings"), and [**] in addressing the Key Findings as appropriate. [**].

n. Submission of NDA Manufacturing Supplement. As soon as practicable after BioVectra has addressed the Key Findings [**], Keryx will file the NDA Manufacturing Supplement with the FDA. Keryx will provide BioVectra with written updates as to the status of the NDA Manufacturing Supplement every [**], until the NDA Manufacturing Supplement has been filed with the FDA. BioVectra shall, upon Keryx's request, provide Keryx with all supporting data and information relating to the Facility, the Equipment, the Manufacturing Process and any other information reasonably necessary to obtain and maintain FDA Approval.

3. Management

a. Following the Effective Date, Keryx and BioVectra established a supply committee to facilitate regular and efficient communication between the Parties regarding their activities and issues relating to the design and construction of the Facility and the Manufacture and supply of Product under this Agreement ("Supply Committee"). Keryx and BioVectra each designated three (3) representatives with appropriate expertise to serve as members of the Supply Committee, which membership may change during the course of the various activities under this Agreement (i.e. during the design and construction phases of the Facility vs. the Product Manufacture and supply activities thereafter). Each Party shall select one (1) person appointed by it to the Supply Committee to serve as co-chair. Either Party may designate substitutes for its Supply Committee representatives to participate if one or more of such Party's designated representatives are unable to be present at a meeting. A Party may replace its representatives serving on the Supply Committee from time to time by written notice to the other Party specifying the prior representative(s) to be replaced and the replacement(s) therefor. The co-chairpersons of the Supply Committee shall be responsible for calling meetings, preparing and circulating an agenda in advance of each meeting. One of BioVectra's Supply Committee representatives shall be responsible for preparing and issuing minutes of each meeting within [**] thereafter. Such minutes shall not be finalized until Keryx reviews and confirms with BioVectra the accuracy of such minutes in writing within [**] after Keryx receives such minutes. If BioVectra does not receive any written comments on such minutes from Keryx within such [**] period, then such minutes shall be deemed to be approved by Keryx.

b. The Supply Committee shall meet at least once [**] until successful completion and validation of the Facility and the Manufacturing Procedure and thereafter once every [**], and more frequently as the Parties deem appropriate, on such dates, and at such places and times as the Parties shall agree. Both Parties may agree in writing to cancel one or more Supply Committee meetings. Meetings of the Supply Committee may be held by audio or video teleconference with the consent of each Party. Meetings of the Supply Committee that are held in person shall occur at such place as the Supply Committee may determine based on the agenda proposed for the meeting and the place of convenience as relating to the agenda items. The members of the Supply Committee also may be polled or consulted from time to time by means of electronic mail or correspondence, as deemed necessary or appropriate. With the consent of each co-chair, other representatives of each Party or of third parties involved in the design and construction of the Facility and Manufacture and supply of Product may attend meetings of the Supply Committee as non-voting participants.

c. The Supply Committee shall operate by consensus. With respect to matters to be discussed by the Supply Committee, the representatives of each Party shall present a unified position on behalf of such Party. In the absence of consensus of Supply Committee members with respect to any matter before the Supply Committee, such matter shall be deemed not to have been approved by the Supply Committee and the matter shall be escalated to each Party's senior management for review and consideration.

d. In addition to its overall responsibility for overseeing the Parties' activities with respect to design and construction of the Facility and Manufacture and supply of Product under this Agreement, the Supply Committee shall in particular:

(a) Review and update during design of Facility;

(b) Review and update during construction of Facility;

(c) Review Process Engineering and Process Validation;

(d) Oversee Manufacture and quality of Product, including labeling, packaging, logistics;

(e) Discuss any changes to Manufacturing Procedure or Specifications;

(f) Oversee and coordinate regulatory activities;

(g) Discuss changes to Forecast and supply schedule;

(h) Oversee and agree Process Development Work and any resulting [**] to the Manufacturing Procedure;

(i) Oversee and address issues that may affect the Timeline;

(j) Oversee any other aspects expressly contemplated by this Agreement or otherwise mutually agreed by the Parties in writing; and

(k) Establish such working groups or sub-committees as it may choose from time to time to accomplish its purposes.

e. The Supply Committee shall have only those powers set forth herein, and, without limiting the generality of the foregoing, shall not have any power to amend, modify or waive compliance with this Agreement.

4. Product Supply & Purchase

a. During the Term of this Agreement, BioVectra will Manufacture Product in accordance with the terms and conditions of this Agreement exclusively for Keryx for the US, Europe and any other market in which Keryx has license to sell ("Territory") in the Facility [**].

b. Starting Materials. [**] all Starting Materials used in the Manufacture of Product. [**]orderly supply of Starting Materials, [**] Starting Materials in sufficient volumes [**].

c. Minimums. Subject to Section 4.d, the minimum order quantity ("Minimum Order Quantity") for [**]:

[**]

d. Subject to BioVectra's termination right in Section 13.c, [**].

e. Forecasting.

i. Keryx will provide to BioVectra a non-binding, rolling forecast of its estimated Product requirements for a [**] period. Keryx will provide such forecast to BioVectra [**] during the Term of this Agreement.

ii. Keryx will provide BioVectra with a rolling [**] non-binding forecast of its Product requirements consistent with the Minimum Order Quantities and the Working Capacity (the "Forecast"). Keryx will commence providing such Forecast within [**] following the Amendment Effective Date, and update such Forecast no later than [**] after the start of [**] thereafter.

f. Purchase Orders. Purchase and shipment of Product will be in response to binding written purchase orders submitted by Keryx according to the process set out herein. At least [**] prior to the commencement of [**] in the Supply Term, Keryx will place a binding purchase order for all its requirements of Product for the subsequent [**]. Purchase orders will be confirmed by BioVectra for acceptance and BioVectra shall not reject any Keryx purchase orders for Product that are in accordance with the Minimum Order Quantities and the terms and conditions of this Agreement. Each purchase order shall be on such form of purchase order or document [**]. BioVectra shall be obligated to manufacture and supply such quantities of Product as are set forth in each purchase order and deliver such quantities in accordance with the mutually agreed-upon delivery schedule. For the purposes of this Agreement, "delivery" of Product means [**]. BioVectra shall, within [**] of receipt of a purchase order, confirm in writing that the purchase order has been accepted, including the confirmation of the mutually agreed upon delivery date(s) for the Product listed in such purchase order. BioVectra shall be required to accept the purchase orders (or portions thereof, as applicable) submitted to BioVectra in accordance with the terms and conditions of this Agreement. In the event that the terms of any purchase order or purchase order acceptance are not consistent with this Agreement, the terms of this Agreement shall prevail. [**].

g. Shortfalls. If BioVectra fails, or anticipates that it will fail, to Manufacture and deliver the quantity of Product set forth in a purchase order for which BioVectra has provided a notice of acceptance in accordance with the delivery schedule set forth in such purchase order [**] then BioVectra will notify Keryx as soon as practicable (each such failure, a "Shortfall"). Within [**] of receipt of notification of a Shortfall, Keryx will provide to BioVectra written notification of its decision to either [**].

h. If there is a [**], then within [**] following written notification by either Party of [**] the Parties will (i) develop a plan, [**] and (ii) [**] implement such plan. [**].

i. If, after the first [**] of Product manufactured in the Facility, BioVectra delivers less than [**] of the volume of Product ordered by Keryx [**], BioVectra shall [**]. If there is a dispute as to the quantity delivered, the Parties will work in good faith towards prompt resolution.

j. If, commencing with [**], BioVectra delivers less than [**] of the volume of Product ordered by Keryx [**], BioVectra shall [**]. If there is a dispute as to the quantity delivered, the Parties will work in good faith towards prompt resolution.

k. Any changes to the Manufacturing Procedure, Manufacturing schedule, the Keryx Release requirements or quality requirements and associated impact(s), including impacts to costs, will be reviewed and assessed prior to implementation, and in all cases subject to the prior mutual agreement of both Parties.

l. Process Development.

i. Whether initiated by Keryx, BioVectra, or a joint effort of the two Parties, BioVectra may, at Keryx's cost, from time to time and with the prior written agreement of Keryx, engage in Process Development Work. "Process Development Work" means the conduct by BioVectra of activities to develop, confirm and/or refine processes for producing the Product and/or activities to develop, optimize and/or scale-up a manufacturing process suitable for GMP Manufacture of the Product. A Party wanting to initiate Process Development Work will bring a proposed plan to the Supply Committee for consideration, approval, and further development. The Supply Committee will receive regular updates regarding the Process Development Work and generally oversee its progress. Any Improvements to the Manufacturing Procedure will be the sole and exclusive property of Keryx.

ii. Following completion of any Process Development Work, BioVectra shall within the timeline approved by the Supply Committee provide Keryx with a final written report on the development work completed, including, if called for in the written project plan agreed by the Supply Committee for the Process Development Work, the impact of any such Process Development Work on the costs to Manufacture Product.

iii. If called for in the written project plan agreed by the Supply Committee for the Process Development Work, BioVectra shall perform one or more process development runs and Manufacture non-GMP process development

batches of Product in accordance with the project plan. BioVectra will provide the services to perform such process development runs and produce such process development batches in accordance with the project plan. BioVectra shall provide Keryx with all process development batches requested by Keryx that result from any partial or completed process development runs. While there will be no final specifications for acceptance of process development batches, the Parties will mutually agree on certain target quality attributes, to be set forth in the applicable project plan. BioVectra shall provide analytical testing of the batch as agreed by the Parties in each project plan and will report the results to Keryx. Keryx shall have the right to make whatever further use of such process development batches as it shall determine, provided that such use does not violate any Applicable Law.

iv. If, as a result of any Process Development Work, the cost to Manufacture Product is reduced (including a situation in which the yield is increased or cycle time is reduced), [**] subject to Keryx consenting to, and the implementation by BioVectra of, the process development improvements resulting from the Process Development Work. Notwithstanding the foregoing, before any [**] between the Parties, [**].

v. The Parties shall mutually agree on the proposed plan for Keryx's [**]. If the Parties disagree, they shall submit such dispute to an independent pharmaceutical manufacturing expert agreed by the Parties (an "Expert") for evaluation, provided that both Parties shall be entitled to observe and obtain copies of all results of such evaluation. The Expert must be of recognized standing in the industry, and consent to the appointment of such Expert will not be [**] withheld or delayed by either Party. The Expert will determine the resulting cost reduction. Both Parties shall cooperate with the Expert's reasonable requests for assistance in connection with its evaluation hereunder. The findings of the Expert shall be binding on the Parties, absent fraud or manifest error. The Parties shall [**] the Expert.

m. Non-Compete and Non-Use.

i. Other than [**] during the Term and for [**] after expiry of Term (unless terminated by Keryx pursuant to Section 13.b.ii or 13.b.iii and for termination by BioVectra under Section 13.d.) BioVectra and its Affiliates agrees that they will not, directly or with or on behalf of a third party, develop, market, advertise, promote, Manufacture, supply, distribute, offer to sell or sell: [**] without Keryx's prior written consent. In all cases, under no circumstances will BioVectra (or any of its Affiliates) use any Keryx Technology, Improvements or Confidential Information of Keryx to Manufacture, for itself or for any other person or entity other than for Keryx pursuant to this Agreement any product at any time, or for any other purpose other than for the Manufacture of Product for Keryx hereunder, and such

obligation not to use any Keryx Technology, Improvements or Confidential Information of Keryx shall survive the expiration or termination of this Agreement.

ii. Subject to Section 4.m.i, BioVectra [**] with BioVectra's obligations to Keryx under this Agreement.

5. Product Quality, Disposition & Release

a. Product Manufacture. BioVectra will Manufacture Product according to the Manufacturing Requirements. The Quality Agreement contains and governs all quality-related matters and sets forth the responsibilities of the Parties with respect to certain tasks, including change control, deviations, stability, complaints, records, sampling, testing, retaining of samples, release, as well as tasks related to regulatory reporting, investigations, and recalls.

b. BioVectra Disposition. Each Batch of Product will be sampled and tested by BioVectra against the Manufacturing Requirements. The quality assurance department of BioVectra will review the documentation relating to the Manufacture of the Batch and assess if the Manufacture has taken place in compliance with the Manufacturing Requirements. In addition to any requirements set forth in the Quality Agreement, and in accordance with the Manufacturing Requirements, BioVectra shall provide to Keryx a Certificate of Compliance, Certificate of Analysis, certificate of origin (including a BSE / TSE statement), and copies of any Batch deviations (collectively "Batch Documentation") for each Batch of Product that BioVectra has deemed to meet the Manufacturing Requirements (hereinafter, "BioVectra Disposition"). Such Batch Documentation will be delivered to Keryx by electronic mail in the form of a PDF upon BioVectra Disposition. No Keryx Release of any Batch of Product Manufactured under this Agreement may occur until BioVectra Disposition for such Batch has occurred. Upon Keryx's request, BioVectra will also deliver to Keryx all Records and Supporting Documentation in the possession or under the control of BioVectra relating to the Manufacture of each Batch of Product (or any intermediate or component of Product).

c. Keryx Release. Upon BioVectra Disposition of a Batch of Product Manufactured under this Agreement, Keryx shall review such Batch's Batch Documentation in order to determine that the Product complies with the Manufacturing Requirements and is ready for shipment. Keryx's Quality department will review the documentation provided by BioVectra for any Batch of Product, and will provide BioVectra with the documentation of lot disposition or, otherwise, with its justified objections to issuing the certificate of lot disposition in accordance with the Quality Agreement (hereinafter, "Keryx Release").

d. Stability Testing. During each [**]. Any additional Batches designated for stability testing will be considered outside of the scope of this Agreement [**].

e. Facility Status. BioVectra shall [**] ensure that at all times during the Term of this Agreement, the Facility is in a qualified and validated state appropriate for inclusion as a manufacturing site for Product as required by the applicable Authorities, Applicable Law, the Manufacturing Requirements, and any Health Registrations and shall ensure that at all times there is sufficient capacity to Manufacture Product ordered hereunder.

f. Location of Manufacturing Activities. Notwithstanding anything to the contrary contained herein, except as set forth in Section 4.a of this Agreement, all Manufacturing activities shall occur at the Facility and BioVectra may not change the location of such Manufacture to a different facility (for all or any portion of the Manufacture of Product hereunder) unless consented to by Keryx in writing in Keryx's sole discretion; *provided*, that in all cases no change of Facility shall relieve BioVectra of any of its obligations under this Agreement. BioVectra shall provide to Keryx supporting data in order to permit Keryx to amend its (and its Affiliate's and designee's, as applicable) regulatory filings to reflect any such change and shall otherwise cooperate in good faith with Keryx to comply with all regulatory obligations arising out of such changes (and BioVectra shall reimburse Keryx for all costs incurred in connection therewith).

g. Person in Plant. At all times during the Term of this Agreement, Keryx shall be allowed to have two representatives on site at the Facility (including adequate temporary desk space and other reasonable resources available to these representatives during the periods they are at the Facility) and access to all applicable portions of the Facility (including the Manufacturing train), and all Records, for the purpose of observing, reporting on, and consulting as to the activities hereunder (hereinafter, "Keryx On-Site Representatives"). The Keryx On-Site Representatives shall be appropriately trained by Keryx (e.g., GMP training), shall observe at all times BioVectra's policies and procedures as they pertain to the Facility, and comply with all reasonable directions of BioVectra in relation to the same. BioVectra may refuse or limit in its sole discretion at any time admission to the Facility by any Keryx On-Site Representative who fails to observe policies or comply with reasonable directions.

h. Quality Agreement. In the event of any discrepancy or inconsistency between the tasks listed in such Quality Agreement and the terms of this Agreement, the terms of the Quality Agreement will govern with respect to quality matters and other similar matters, and the terms of this Agreement shall govern with respect to all other matters; *provided*, that the Quality Agreement may not be interpreted or construed by either Party as amending or modifying in any way any terms of this Agreement except those terms specifically governed by the Quality Agreement. The Quality Agreement may be modified or amended by the Parties, in writing; *provided*, that such modification or amendment shall not be deemed to modify or amend the terms of this Agreement.

i. Batch Failure. BioVectra agrees to notify Keryx within [**] of discovery after any Batch failure which could result in BioVectra's inability to meet the agreed upon delivery dates, or of learning of any failure of any Batch of Product to meet Specifications or the Manufacturing Requirements, or if BioVectra has any other safety or efficacy concerns with respect to a Batch of Product. BioVectra agrees not to Reprocess any Batch of Product, or any intermediate in the Manufacture of Product, without the prior written approval of Keryx in writing (in Keryx's sole discretion). Should Keryx provide such approval, BioVectra will Reprocess the affected Batch(es) or intermediate(s) in the Manufacture of Product at its own cost. BioVectra will schedule any Reprocess as soon as practicable.

6. Regulatory Requirements

a. Sarbanes-Oxley Compliance. Without limiting the foregoing, if and to the extent reasonably necessary to ensure Keryx's continuing compliance with the requirements of the Sarbanes-Oxley Act of 2002 (as determined by Keryx in its sole discretion), BioVectra shall, at Keryx's request, provide the appropriate report(s) as established by the Statement on Standards for Attestation Engagements No. 16 (SSAE 16) (or its successor standard), and other report(s) as requested by Keryx covering the manufacturing services provided by BioVectra to Keryx. The audit will be performed at BioVectra's expense and audit findings shall be provided to Keryx on an annual basis consistent with SSAE 16 (or its successor standard) and with the requirements of the Keryx. The report should be prepared by a public accounting firm that is reasonably acceptable to Keryx (preferably one of the Big Four – Deloitte, Ernst & Young, KPMG or PricewaterhouseCoopers). Any material weaknesses in BioVectra's internal controls revealed by the audit will be promptly remedied by BioVectra.

b. Filing and Maintenance of the Health Registrations. As between the Parties, Keryx shall have the sole right to prepare and file for the Health Registrations with the applicable Authorities and, for clarity, BioVectra shall have no right to do so and shall not communicate with any Authorities in connection with any Health Registration. If determined by Keryx in its sole discretion, Keryx shall have the right to include a designation of BioVectra and the Facility as a manufacturer and manufacturing site of Product in the applicable Health Registrations. Notwithstanding the foregoing, if, in connection with Keryx's state licensing requirements for pharmaceutical manufacturers in the United States, BioVectra is required to register with a state as a manufacturer in order for Keryx to obtain its license with such state, BioVectra shall do so promptly at Keryx's request.

c. CMC Information. Keryx, in its discretion, may provide BioVectra with CMC information applicable to BioVectra for BioVectra to Manufacture Product in accordance with this Agreement and the Health Registrations (hereinafter, "CMC Information"), and BioVectra shall comply with all such CMC Information in performing its activities hereunder. Any changes to a Quality Module section of a Health Registration after the Amendment Effective Date will need to be reviewed

for scope changes to the manufacturing schedule, release requirements or quality requirements and associated impact(s), including impacts to costs prior to implementation. For clarity, all CMC Information shall be considered Confidential Information of Keryx hereunder.

d. Regulatory Support for Maintaining Filings. For regulatory filings that occur after FDA Approval of the Facility, BioVectra shall perform, [**], the activities (including tests and also including at Keryx's request, preparing documents to support Quality Modules for filing or filing related support for the Health Registrations) in connection with the receipt and maintenance of the Health Registrations as requested in writing by Keryx from time to time, which activities shall be performed by BioVectra in compliance with all Applicable Law. In all cases, BioVectra shall be prepared for any and all inspections, including pre-approval inspections, by Authorities. Without limitation of the foregoing, BioVectra shall provide Keryx with such information and assistance as Keryx may [**] for purposes of applying for and maintaining all relevant Health Registrations for Product including providing Keryx with all reports, authorizations, certificates, methodologies, specifications and other documentation in the possession or under the control of BioVectra (or any of its Affiliates) relating to the pharmaceutical/technical development and/or Manufacture of Product or any component thereof. BioVectra hereby grants Keryx an irrevocable, perpetual, worldwide, fully paid-up license, with the right to grant sublicenses (through multiple tiers) to use such information, data and other BioVectra Technology reflected in such documentation for the purpose of obtaining and maintaining the Health Registrations for Product as well as a right of reference to any regulatory approvals of BioVectra for use in connection with Product.

e. Communications by Keryx. For purposes of clarity, nothing in this Agreement, including the provisions of this Section 6, shall restrict the right of Keryx (or its Affiliates or other designees) from taking any action that it deems to be appropriate or required by Applicable Law with respect to Product, including making a timely report to a given Authority or other governmental entity with respect to Product.

7. Invoicing, Payment & Shipping

a. BioVectra will invoice Keryx for Product in accordance with the pricing [**] set forth in Appendix 1 upon [**]. Keryx will pay for invoices less any holdback for disputed amounts, within [**] of invoice receipt. [**] Akebia Therapeutics, Inc., [**], 245 First Street, Cambridge, MA 02142 USA.

b. Keryx will be responsible for [**]. Keryx will also be responsible, [**]. After Product delivery, Keryx will review the Batch Documentation and, within [**]. Once BioVectra has received a written authorization to ship from Keryx, BioVectra shall promptly comply with Keryx's shipping instructions. For the avoidance of doubt, BioVectra shall not ship Product from the Facility until [**]. Notwithstanding the

foregoing, if so requested by Keryx, BioVectra shall store Product on site at the Facility for up to [**]. Whether or not Product has shipped from the Facility, Keryx does not waive its right to reject the Product under Section 8 by not providing such rejection within the aforementioned [**] period.

c. Any services requested that are beyond the activities related to design and construction of the Facility, Manufacture of Product, [**]. BioVectra will charge Keryx according to BioVectra's FTE hourly rate[**], for any such ad hoc services.

8. Nonconforming Product & Recalls

a. Acceptance of Product. Keryx or its designees shall have [**]to inspect Product for Nonconformance. Keryx or its designees may inspect the Product, review the Batch Documentation for each Batch of Product, test samples of the Batch of Product against the Specifications, and perform any or all of the quality control procedures outlined in the Quality Agreement to determine if there is a Nonconformance. During this review period, the Parties agree to respond promptly, but in any event within [**], to any reasonable inquiry or request for a correction or change by the other Party with respect to such Batch Documentation. Keryx has no obligation to accept a Batch if such Batch does not comply with the Manufacturing Requirements. Notwithstanding the foregoing, in the event there is a Nonconformance that is a [**], then Keryx shall promptly, and in no event more than [**] after discovery of such Nonconformance, notify BioVectra of [**]. If Keryx rejects a Batch of Product or a portion thereof pursuant to this section for Nonconformance, Keryx will inform BioVectra of the reason in writing. If BioVectra confirms that the Product(s) shall be rejected for Nonconformance or if, pursuant to Section 8.b the independent testing lab or GMP consultant determines there has been a Nonconformance, then [**] Moreover, the Parties will meet to discuss, evaluate and analyze the reasons for and implications of the Nonconformance.

b. Quality Disputes. If BioVectra does not agree with Keryx's rejection of the Product pursuant to Section 8.a, the difference of opinion shall be first negotiated in good faith by the Parties through their quality assurance representatives, who will attempt in good faith to resolve any such disagreement and Keryx and BioVectra will follow their respective SOPs to determine the conformity of the Product to the Manufacturing Requirements. If such dispute is not resolved within [**] after BioVectra's receipt of Keryx's written notice of its disagreement, the Parties shall submit such dispute to a mutually acceptable independent third party laboratory for such laboratory's determination as to whether Product meets or fails to meet Specifications and/or mutually acceptable independent GMP consultant in the case of an alleged failure to comply with GMP or any of the other Manufacturing Requirements, as appropriate. The laboratory and consultant, as applicable, must be of recognized standing in the industry, and consent to the appointment of such laboratory and consultant will not be [**] withheld or delayed by either Party. Such laboratory will use the test methods contained in the applicable Specifications and the Quality Agreement. [**]. The ultimate disposition of Nonconforming Product will be the responsibility of Keryx's quality assurance department.

c. Customer Returns. Keryx will have the responsibility for handling customer returns of the Products. BioVectra will give Keryx any assistance that Keryx may reasonably require to handle the returns.

d. Recalls. If a recall or return results from, or arises out of, a failure by BioVectra to provide Product that conforms to the Specifications or other Manufacturing Requirements, in addition to the amounts payable under this Agreement, BioVectra will also be responsible for the documented out-of-pocket expenses of the recall or return. [**] If Product is recalled because the Product Manufactured and released by BioVectra deviates from the Specifications or otherwise does not meet the Manufacturing Requirements, Keryx shall have the right to avail itself of the remedies set forth in Section 8.a above.

9. Warranties & Indemnifications

a. BioVectra warrants and represents that:

i. BioVectra is a corporation duly organized, validly existing and in good standing under the laws of the Prince Edward Island, Canada;

ii. BioVectra has full right, power and authority to enter into this Agreement, and that the execution and performance of this Agreement shall not constitute a violation of any material covenant of restriction, or breach of any obligation under any other agreement, contract, commitment, rule, or regulation to which BioVectra is a party or by which BioVectra is bound;

iii. the Product supplied to Keryx shall meet all the Manufacturing Requirements;

iv. when delivered, Keryx will have good and marketable title, free and clear of any liability, pledge, lien, restriction, claim, charge, security interest and/or other encumbrance, to all Product;

v. the work hereunder will be performed with requisite care, skill and diligence, by individuals who are appropriately trained and qualified and in facilities suited for such work;

vi. the conduct and the provision of the work hereunder, including use of any BioVectra Technology, will not violate any patent, trade secret or other proprietary or intellectual property rights of any third party and BioVectra will promptly notify Keryx in writing should BioVectra become aware of any claims asserting such violation; and

vii. BioVectra and its officers and directors and any person or entity engaged by BioVectra in connection with the Manufacture of Product or performance of any other obligations under this Agreement: (i) have not been debarred and are not subject to a pending debarment pursuant to section 306 of the United States Food, Drug and Cosmetic Act, 21 U.S.C. § 335a; (ii) are not ineligible to participate in any federal and/or state

healthcare programs or federal procurement or non-procurement programs (as that term is defined in 42 U.S.C. § 1320a-7b(f)); (iii) are not disqualified by any government or regulatory authorities from performing specific services, and are not subject to a pending disqualification proceeding; and (iv) have not been convicted of a criminal offense related to the provision of healthcare items or services and are not subject to any such pending action. BioVectra will notify Keryx immediately if BioVectra and its officers and directors and any person or entity engaged by BioVectra in connection with the Manufacture of Product or performance of any other obligations under this Agreement is subject to the foregoing, or if any action, suit, claim, investigation, or proceeding relating to the foregoing is pending, or to the best of BioVectra's knowledge, is threatened

b. Keryx warrants and represents that:

i. Keryx is duly organized validly existing and in good standing under the laws of the State of Delaware, USA;

ii. Keryx has full right, power and authority to enter into this Agreement, and that the execution and performance of this Agreement shall not constitute a violation of any material covenant or restriction, or breach of any obligation under any other agreement, contract, commitment, rule, or regulation to which Keryx is a party or by which Keryx is bound;

iii. To the knowledge of Keryx, the provision of and use of any Keryx Technology will not violate any patent, trade secret or other proprietary or intellectual property rights of any third party and Keryx will promptly notify BioVectra in writing should Keryx become aware of any claims asserting such violation; and

iv. Keryx has or will maintain all the necessary qualified personnel, equipment, materials, quality systems recall procedures, facilities and support to maintain performance hereunder.

c. Indemnifications. BioVectra will defend, indemnify, and hold Keryx and its directors, officers, employees, agents and Affiliates (all the foregoing "Keryx Indemnitees"), harmless from any and all losses, liabilities, judgments, fines, penalties, damages and reasonable out-of-pocket expenses, including [**] (all the foregoing "Losses"), arising from or related to any and all third-party related claims, actions, suits or proceedings (all the foregoing "Third-Party Claims") arising as a result of [**].

d. Keryx will defend, indemnify, and hold BioVectra and its directors, officers, employees, agents and Affiliates (all the foregoing "BioVectra Indemnitees"), harmless from any and all Losses arising from or related to any and all Third-Party Claims arising as a result of [**].

e. In the event a Party seeks indemnification under this Section 9 (each an "Indemnitee"), it shall: (i) inform the other Party (the "Indemnifying Party") of a Third-Party Claim as soon as reasonably practicable (and in any event within [**]) after it receives notice of the Third-Party Claim; (ii) shall permit the Indemnifying Party to assume direction and control of the defense of the Third-Party Claim (including the right to settle the claim solely for monetary consideration with no admission of fault and using legal counsel of its choice) at the Indemnifying Party's expense; and (iii) shall cooperate as reasonably requested (at the expense of the Indemnifying Party) in the defense of the claim; provided, however, no Indemnitee, as applicable, shall be required to admit fault or responsibility in connection with any settlement. An Indemnitee's failure to perform any obligations under this Section 9 shall not relieve the Indemnifying Party of its obligations under this Section 9 except to the extent that the Indemnifying Party can demonstrate that it has been materially prejudiced as a result of such failure. An Indemnitee shall have the right participate in and observe the proceedings through its own separate legal counsel at its own expense.

f. Disclaimer. Except as otherwise set forth in this Agreement, neither Party makes any warranties, express or implied, with respect to the Product. No representation or statement not expressly contained in this Agreement shall be binding upon a Party as a warranty or otherwise. The stated warranties are exclusive and in lieu of all other warranties provided by law.

10. Insurance.

a. BioVectra and Keryx will maintain comprehensive general liability insurance (which may be in the form of primary insurance and umbrella coverage) with an aggregate limit of [**] and product liability insurance against claims regarding the Product under this Agreement at an aggregate limit of [**]. Each Party shall maintain such insurance during the Term of this Agreement and, thereafter, for so long as it customarily maintains insurance for itself for similar products and activities, but in no event less than [**]. Each Party shall cause the other Party to be named as an additional insured under such insurance and shall provide the other Party proof of such insurance upon request. If requested each Party will give the other a certificate of insurance evidencing the above and showing the name of the issuing company, the policy number, the effective date, the expiration date, and the limits of liability. The insurance certificate will further provide for a minimum of [**] written notice to the insured of a cancellation of the insurance.

11. Confidential Information

a. Confidential Information. Each of the Parties shall protect all information supplied or revealed to it by the other Party pursuant to this Agreement ("Confidential Information"), and shall not directly or indirectly disclose to any third party the other Party's Confidential Information without the prior written consent of the other Party. Neither Party will use the other Party's Confidential Information for any purpose except as may be necessary for such Party to perform its obligations pursuant to this Agreement or to exercise its rights under this Agreement.

Confidential Information shall include any and all non-public scientific, technical, financial, regulatory, business information, or data or trade secrets in whatever form (written, oral or visual) that may be furnished or made available by the disclosing Party to the other Party, whether marked in writing or communicated in visual or oral form. Confidential Information of Keryx includes (i) the Manufacturing Procedure, Keryx Supplied Materials, Keryx Technology, the Manufacturing Requirements, and Improvements; (ii) development and marketing plans, regulatory and business strategies, financial information, and Forecasts of Keryx; (iii) information regarding the Facility design and construction; and (iv) all information of third parties that Keryx has an obligation to keep confidential. Confidential Information of BioVectra includes (i) BioVectra Technology; (ii) capabilities, regulatory and business strategies, financial information; and (iii) all information of third parties that BioVectra has an obligation to keep confidential.

b. Treatment of Confidential Information. Each Party shall take such steps as are reasonably required (including, without limitation, such steps as such Party takes to protect its own proprietary information) to protect the other Party's Confidential Information from unauthorized disclosure or use. Product, Records and other reports and information provided by, or on behalf of, BioVectra to Keryx shall be deemed Confidential Information of Keryx, as to which Keryx shall be deemed the disclosing Party for purposes of this Agreement. The Parties acknowledge and agree that BioVectra and its employees shall have access to Confidential Information of Keryx (which may include information from its Affiliates, its licensors and third party business partners). Except as otherwise stated in this Section 11, for purposes of this Agreement, the terms of this Agreement shall be deemed to be Confidential Information of both Parties. Confidential Information also includes third-party confidential information supplied by receiving Party to disclosing Party hereunder.

c. Permitted Disclosures. Nothing in this Section 11 shall be construed to impose a confidentiality obligation on a Party in connection with any Confidential Information to the extent such information can be shown by clear and convincing evidence: (i) is at the time of disclosure already known to the receiving Party (as clearly established by such Party's prior written records); (ii) is at the time of disclosure or subsequently becomes part of the public domain through no fault, act or omission of the receiving Party; (iii) is subsequently disclosed to the receiving Party by a third party whose receipt and disclosure of such Confidential Information does not, constitute a violation of any confidentiality obligation; or (iv) is independently developed by the receiving Party by employees having no access to or knowledge of Confidential Information received. Further, a receiving Party shall be entitled to disclose the disclosing Party's Confidential Information that is required by a court or government agency to be disclosed; provided that the receiving Party shall promptly provide the disclosing Party notice in writing of any proposed disclosure under this subsection and an opportunity to object to the disclosure or seek confidential treatment thereof. If so requested, the receiving Party shall provide reasonable assistance in opposing such disclosure or seeking a

protective order or other limitations on disclosure. If, after providing such notice and assistance as required herein, the receiving Party remains legally required to disclose any Confidential Information, the receiving Party shall disclose no more than that portion of the Confidential Information which, on the advice of the receiving Party's legal counsel, is require to be disclosed and, upon the disclosing Party's request, shall [**] to obtain assurances from the applicable court or agency that such Confidential Information will be afforded confidential treatment. A receiving Party may disclose a Party's Confidential Information to its Affiliates, and to its and their directors, employees, consultants, contractors and agents; *provided, however*, that (i) any such Affiliates, directors, employees, consultants, contractors and agents are bound by written obligations of confidentiality with respect to the disclosing Party's Confidential Information that are at least as restrictive as those set forth in this Agreement; (ii) the receiving Party remains liable for the compliance of such Affiliates, employees, consultants, contractors and agents with such obligations; and (iii) in the case of BioVectra as the receiving Party, such disclosure is only to the extent necessary for BioVectra to carry out its obligations under this Agreement. Furthermore, during the Term, Keryx may disclose Confidential Information of BioVectra relating to the development and/or Manufacture of Product to entities with whom Keryx has (or may have) a marketing and/or development collaboration or to *bona fide* actual or prospective underwriters, investors, lenders or other financing sources, or to potential acquirers of the business to which this Agreement relates, and who in each case have a specific need to know such Confidential Information and who are bound by a like obligation of confidentiality and restrictions on use.

d. Public Announcements. Neither Party shall issue any public announcement, press release, or other public disclosure of this Agreement, regarding this Agreement, or its subject matter, without the other Party's prior written consent, except for any such disclosure that is, in the opinion of the discloser's counsel, required by Applicable Law or the rules or common practices of a stock exchange on which the securities of the discloser are listed.

e. No Rights/Remedies. All Keryx Confidential Information which BioVectra or its personnel shall obtain or be given access pursuant to or in connection with this Agreement shall be and remain the sole property of Keryx, and BioVectra shall have no rights or interests (except as expressly provided herein) to or in such Confidential Information. The Parties recognize and agree that an action for damages may be inadequate to enforce the restrictions and rights set forth in this Section 11. BioVectra's breach or imminent breach of this Section 11 may cause immediate and irreparable harm and unascertainable damages to Keryx. The Parties agree that in the event of any breach or imminent breach of this Section 11, Keryx shall be entitled, in addition to any other right or remedy it may have at law or in equity, to seek and obtain injunctive relief, without the need to post bond or other security or show monetary damages.

12. Intellectual Property

a. Keryx Technology. All rights to and interests in Keryx Technology (including all intellectual property rights therein) will remain solely with Keryx and no right or interest therein is transferred or granted to BioVectra under this Agreement. BioVectra acknowledges and agrees that it does not acquire a license or any other right to Keryx Technology except for the limited purpose of carrying out its duties and obligations under this Agreement, and that such limited, non-exclusive, license will expire upon the completion of such duties and obligations or the termination or expiration of this Agreement, whichever is the first to occur.

b. BioVectra Technology. All rights to and interests in BioVectra Technology will remain solely in BioVectra and, except as otherwise set forth in this Agreement, no right or interest therein is transferred or granted to Keryx under this Agreement. During the Term of this Agreement, BioVectra hereby grants to Keryx a non-exclusive, perpetual, irrevocable, royalty-free, fully-paid-up, worldwide, transferable and sublicensable right and license to Keryx and its Affiliates to use and modify BioVectra Technology to research, develop, Manufacture, have Manufactured, distribute, offer for sale, sell, market, and otherwise dispose of Product.

c. Improvements. BioVectra agrees (i) to promptly disclose to Keryx all Improvements related to Keryx Technology; (ii) that all Improvements related to Keryx Technology (and all intellectual property rights related thereto) will be the sole and exclusive property of Keryx; and (iii) that BioVectra will assign and does assign all Improvements related to Keryx Technology (and all intellectual property rights related thereto) to Keryx (or its designee) without additional compensation to BioVectra. BioVectra will take such steps as Keryx may reasonably request (at Keryx's expense) to vest in Keryx (or its designee) ownership of the Improvements related to Keryx Technology, and all intellectual property rights related thereto. In furtherance of the foregoing, BioVectra shall, upon request by Keryx, promptly undertake and perform (and/or cause its Affiliates and its and their respective employees and/or contractors to promptly undertake and perform, as applicable) such further actions as are reasonably necessary for Keryx to perfect its right, title and interest in and to any such Improvements, and all intellectual property rights associated therewith, including by causing the execution of any assignments or other legal documentation, and/or providing Keryx or its patent counsel with reasonable access to any employees or contractors who may be inventors of such Improvements, and any intellectual property rights associated therewith.

d. Non-Exclusive License. During the Term of this Agreement, BioVectra agrees to grant to Keryx a non-exclusive, perpetual, irrevocable, fully paid-up, worldwide license, to use Improvements made solely by BioVectra personnel and that relate solely to BioVectra Technology or the Confidential Information of BioVectra to research, develop, Manufacture, have Manufactured, distribute, offer for sale, sell, market, and otherwise dispose of Product.

e. Patent Filings. Keryx will have the exclusive right and option, but not the obligation, to prepare, file, prosecute, maintain and defend, at its sole expense, any patents that claim or cover the Improvements, and any intellectual property rights associated therewith.

f. Technology Transfer. If, during the Term, Keryx elects to Manufacture Product itself, or to have Product Manufactured by a third party (including but limited to in the event of termination of this Agreement), then BioVectra will provide to Keryx or its designee, all manufacturing information, including documentation, technical assistance, materials and cooperation, as Keryx or its designee may reasonably require in order to Manufacture Product. Except for termination by Keryx under Sections 13.d or 14.g, Keryx will [**].

g. Trademarks and Trade Names. Keryx and BioVectra hereby acknowledge that neither Party has, nor shall either Party acquire by reason of this Agreement, any interest or rights of use in any of the other Party's, or such Party's Affiliates', trademarks, trade names, designs or logos unless otherwise expressly agreed in writing by the Parties. Notwithstanding the foregoing, Keryx shall have the right to use BioVectra's trademarks, trade names, designs or logos, as may be required by Applicable Law (or as may otherwise be reasonably necessary) in connection with obtaining and maintaining Health Registrations for the Products or in connection with marketing and sale of Product (*e.g.*, listing BioVectra as the manufacturer of product on the packaging, if applicable).

13. Term and Termination

a. The Agreement will commence on the Amendment Effective Date and end on December 31, 2026, unless terminated earlier as provided herein ("Initial Term"). This Agreement will automatically renew after the Initial Term for successive terms of one (1) year unless either Party gives written notice to the other Party of its intention to terminate this agreement at least twenty-four (24) months prior to the end of the then current term (collectively, the Initial Term and any extensions thereof, the "Term").

b. Keryx may terminate the Agreement for the reasons set out below in this Section 13.b:

i. Due to loss of, or inability of Keryx to obtain, Health Registrations to market the Product in the United States by giving BioVectra sixty (60) days' prior written notice (or such shorter period if required pursuant to the related Authority action). For the avoidance of doubt, failure to obtain FDA Approval does not constitute an event giving rise to a termination right under this Section 13.b.i;

ii. At any time by giving BioVectra sixty (60) days' prior written notice (or such shorter period if required pursuant to the following Authority action) in the event of a permanent withdrawal from the market of the final drug product incorporating the Product in the United States or any Authority takes any action or raises any objection, that prevents Keryx from developing, importing, exporting, purchasing, selling or otherwise commercializing final drug product incorporating the Product in the United States. For the avoidance of doubt, failure to obtain FDA Approval does not constitute an event giving rise to a termination right under this Section 13.b.ii; or

iii. Within [**] of its awareness, Keryx will notify BioVectra if a party has filed an abbreviated new drug application ("ANDA") with a Paragraph IV certification, certifying against current or future Orange Book-listed patents related to Keryx's final drug product incorporating the Product. Keryx will provide BioVectra immediate notice, after Keryx's awareness, if the FDA has approved a drug product, [**] pursuant to an ANDA for a version of Auryxia, in any dosage form, that is identified in FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* as therapeutically equivalent (i.e., that is identified with an "A" therapeutic equivalence rating) ("Generic Entry"). If Generic Entry occurs on or before [**] and the market share of Auryxia [**] erodes [**] Keryx may terminate the Agreement [**] eroded [**].

c. BioVectra may terminate this Agreement on [**] prior written notice from the date on which BioVectra provides notice of acceptance of a Purchase Order for [**] in which Keryx requests [**] in accordance with Section 4.d.

d. Either Party may terminate this Agreement for breach by the other Party of any of its material obligations under this Agreement: (A) upon [**] prior written notice to the other, if such default occurs prior to Substantial Completion and during such [**] notice period the default is not corrected to the reasonable satisfaction of the non-defaulting Party; or (B) upon [**] prior written notice to the other, if such default occurs on or after Substantial Completion and during such [**] notice period the default is not corrected to the reasonable satisfaction of the non-defaulting Party;

e. Upon expiration or termination of this Agreement, the following shall apply:

i. Except for termination by Keryx under Sections 13.b.i., 13.b.ii., 13.d or 14.g, Keryx will, as promptly as practicable, pay to BioVectra the unpaid portion, if any, of the Facility Reimbursement Payment. For termination by Keryx under Sections 13.b.i., 13.b.ii., 13.d or 14.g, Keryx will, as promptly as practicable, pay to BioVectra the Facility Reimbursement Payment invoiced (but not yet paid for by Keryx) up to the effective termination date.

ii. Except for termination by Keryx under Sections 13.d or 14.g, Keryx will pay amounts for Product Manufactured pursuant to existing purchase orders, amounts for work in progress, materials and supplies inventory (to the extent the costs can't be recovered through returns/resale), reasonable wind-down expenses [**], and non-cancellable obligations to third parties that were previously authorized by Keryx in writing. If the foregoing wind-down expenses and non-cancellable obligations are covered by Keryx's payment of the Facility Reimbursement Payment under Section 13.e.i., no additional payments therefor will be due by Keryx. BioVectra will [**] mitigate the foregoing expenses. BioVectra shall invoice Keryx for all such expenses incurred under this Section, along with supporting documentation for such expenses, within [**] of the termination date. Prior to any amounts being due and payable to BioVectra under this Section, BioVectra shall provide to Keryx a detailed summary of such, payable as to undisputed amount by Keryx to BioVectra within [**] of Keryx's receipt of such detailed summary. Keryx shall pay such amounts within [**] of receipt of a proper invoice and conforming documentation.

iii. Except termination by Keryx pursuant to Section 13.b.iii. and for termination by BioVectra under Section 13.d., Keryx shall have the option (in its discretion) to either: (A) cancel all outstanding purchase orders; or (B) require BioVectra to continue to supply Product in accordance with purchase orders submitted prior to the termination or expiration of this Agreement (which supply shall be in accordance with the terms and conditions of this Agreement).

iv. Except for termination by Keryx pursuant to Section 13.b.ii and 13.b.iii and for termination by BioVectra under Section 13.d., at the election of Keryx, BioVectra shall continue to supply Product to Keryx on the terms and conditions set forth herein until the earlier of: (i) such time as Keryx notifies BioVectra that Keryx has achieved alternative Manufacturing arrangements which are presently capable of Manufacturing the applicable Products, or (ii) [**].

v. Except for termination by Keryx pursuant to Section 13.b.ii and 13.b.iii and for termination by BioVectra under Section 13.d and upon written request from Keryx to BioVectra, pursuant to Section 12.f. above BioVectra shall transfer to Keryx and/or its designee any and all Keryx Technology and Improvements in BioVectra's possession and shall provide to Keryx and/or its designee BioVectra Technology so as to permit Keryx and/or its designee(s) to produce/Manufacture Products with such technical assistance being provided in accordance with a plan provided to BioVectra by Keryx at BioVectra's FTE hourly rate [**]. To the extent transferable, BioVectra shall also transfer any license(s) obtained specifically for the production/Manufacture of Products under this Agreement. BioVectra hereby grants to Keryx a non-exclusive, royalty-free, paid-up, perpetual, non-terminable, worldwide license, with the right to grant sublicenses, and otherwise transfer such license to practice (including the right to make

derivative works and copies of) any and all BioVectra Technology to make, have made, use, offer for sale, sell, and import Products, which license shall survive termination of this Agreement.

vi. BioVectra shall thereafter not use in any manner whatsoever any trademarks, service marks, names, logos, designs or trade dress of Keryx or any of its Affiliates, or any other Keryx Technology or any Confidential Information of Keryx.

vii. Except in order to fulfill its obligations to Manufacture and supply Products to Keryx following expiration or termination of this Agreement as expressly set forth in this Section, BioVectra shall immediately cease the Manufacture of any Product(s) as of the date of the notice of termination.

viii. Upon the written request of Keryx, BioVectra shall return to Keryx (or its designee), or destroy, all remaining Keryx Supplied Materials, as requested by Keryx. BioVectra shall perform any such destruction (if destruction was requested by Keryx) in compliance with all Applicable Law.

f. Return of Keryx Supplied Materials and other Information. Upon termination or expiration of this Agreement, or at any time during the Term, in each case upon Keryx's written request, BioVectra shall promptly deliver to Keryx, at Keryx's expense: (a) all unused Keryx Supplied Materials in BioVectra's (or any of its Affiliate's) possession or control; (b) all documentation and all copies thereof in whatever form or medium in BioVectra's (or any of its Affiliate's) possession or control relating to the Product, Quality Modules, Specifications, or Keryx Technology or Improvements other than any documentation which BioVectra must retain for such period of time as required by Applicable Law (as to which copies shall be provided to Keryx); and (c) all other Confidential Information of Keryx and any and all other Records, documents and materials (and all copies thereof) in BioVectra's (or any of its Affiliate's) possession or control relating to Product and/or containing any Confidential Information of Keryx other than any Confidential Information which BioVectra must retain for such period of time as required by Applicable Law (as to which copies shall be provided to Keryx); *provided, however*, that the provisions of this Agreement relating to such Confidential Information shall apply to such Confidential Information for so long as it is so retained notwithstanding the expiration or termination of this Agreement.

g. Inventories. Upon expiration or termination of this Agreement, Keryx at its discretion (i) may obtain from BioVectra any existing inventories of Product ordered under this Agreement at the price for such Product set forth in the Agreement; and (ii) may either (A) purchase any such Product in process held by BioVectra as of the date of the termination, at a price to be mutually agreed (it being understood that such price will reflect, on a pro rata basis, work performed and non-cancelable out-of-pocket expenses actually incurred by BioVectra with respect to the Manufacture of such in-process Product); or (B) direct BioVectra to dispose of such material at Keryx's cost.

14. General Provisions

a. Governing Law; Exclusive Jurisdiction/Venue. The rights and obligations of the Parties under this Agreement, and any disputes arising out of or relating to this Agreement, shall be governed by and interpreted in accordance with the laws of the State of Delaware, United Sates of America, without regard to application of any conflicts of laws provisions that would otherwise apply the substantive law of any other jurisdiction. The Parties expressly reject any application to this Agreement of (a) the United Nations Convention on Contracts for the International Sale of Goods; and (b) the 1974 Convention on the Limitation Period in the International Sale of Goods, as amended by that certain Protocol, done at Vienna on April 11, 1980. Any legal action or proceeding concerning the validity, interpretation and enforcement of this Agreement, matters arising out of or related to this Agreement or its making, performance or breach, or related matters will be brought exclusively in the state and federal courts located in the State of Delaware, USA. The Parties consent to the exclusive jurisdiction of those courts and waive any objection to the propriety or convenience of such venues.

b. Relationship of Parties. The relationship of BioVectra to Keryx under this Agreement is intended to be that of independent contractors. Nothing contained in this Agreement is intended or is to be construed so as to constitute BioVectra and Keryx as employer/employee or principal/agent, or the employees or the agents of any Party hereto as employees or agents of the other Party hereto. Neither Party hereto has any express or implied right or authority under this Agreement to assume or create any obligations on behalf of or in the name of the other Party or to bind the other Party to any contract, agreement, or undertaking with any third party, other than the successors and permitted assigns of the respective Parties hereto.

c. Assignment. This Agreement may not be assigned or otherwise transferred by either Party without the prior written consent of the other Party; *provided, however*, that either Party may, without such consent, but with notice to the other Party, assign this Agreement, in whole or in part, [**]. Any purported assignment in violation of the preceding sentence will be void. Any permitted assignee will assume the rights and obligations of its assignor under this Agreement. This Agreement shall be binding upon and inure to the benefit of the Parties hereto and their respective permitted successors and assigns. No transfer or assignment will relieve the transferor or assignor of any liability or obligations hereunder. BioVectra may not subcontract with any third party, including any Affiliate of BioVectra, to perform any of its obligations under this Agreement or the Quality Agreement without the prior written consent of Keryx. BioVectra will be solely responsible for the performance of any permitted subcontractor, and for costs, expenses, damages, or losses of any nature arising out of such performance as if such performance had been provided by BioVectra itself under this Agreement. BioVectra will cause any such permitted subcontractor to be bound by, and to comply with, the terms of this Agreement, as applicable, including all confidentiality, quality assurance, regulatory and other obligations and requirements of BioVectra set forth in this Agreement.

d. Severability. In the event any provision of this Agreement shall be invalid, void, illegal, or unenforceable, the remaining provisions hereof nevertheless will continue in full force and effect without being impaired or invalidated in any way. Each provision in this Agreement is independent and severable from the others, and no provision will be rendered unenforceable because any other provision is found by a proper authority to be invalid or unenforceable in whole or in part. If any provision of this Agreement is found by such an authority to be invalid or unenforceable in whole or in part, such provision will be changed and interpreted so as to best accomplish the objectives of such unenforceable or invalid provision and the intent of the Parties, within the limits of Applicable Law.

e. Survival. Expiration or termination of this Agreement for any reason will not relieve either Party of any obligation accruing prior to such expiration or termination. Unless expressly specified to the contrary in this Agreement, no remedy referred to in this Agreement is intended to be exclusive, but each shall be cumulative and in addition to any other remedy referred to in this Agreement or otherwise available under law or at equity. The rights and obligations of the Parties set forth herein which, either explicitly state they survive or by their nature should survive termination or expiration of this Agreement, will survive any such termination or expiration, including without limitation those respecting confidentiality, intellectual property, indemnification, warranties, governing law and jurisdiction and notices.

f. Notices. All notices under this Agreement shall be in writing and, other than purchase orders and invoices, which may be sent by email, shall be deemed given if sent by certified or registered first class mail, postage prepaid, or commercial express courier (return receipt or confirmation of delivery requested), or by personal delivery to the Party to receive such notices or other communications called for by this Agreement at the following addresses for a Party as shall be specified by such Party by like notice:

If to BioVectra:
BioVectra Inc.
11 Aviation Avenue
Charlottetown, PE C1E 0A1
Canada
Email: [**]
Attention: Legal Department

If to Keryx:
Keryx Biopharmaceuticals, Inc.
c/o Akebia Therapeutics, Inc.
Attention: [**]

Address: 245 First Street
Cambridge, MA 02142 USA
Email: [**]
With a cc. at the above address to attention [**]

g. Force majeure. If either Party shall be delayed, interrupted in, or prevented from the performance of any obligation hereunder by reason of any cause beyond its reasonable control, including an act of God, fire, flood, earthquake, war (declared or undeclared), public disaster, act of terrorism, strike or labor differences, such Party shall not be liable to the other therefor; and the time for performance of such obligation shall be extended for a period equal to the duration of the force majeure which occasioned the delay, interruption or prevention. BioVectra's financial inability to perform, changes in cost or availability of materials, components, or services, market conditions or supplier actions, or contract disputes will not excuse performance by BioVectra under this Section 14.g. The Party invoking such force majeure rights of this Section 14.g must notify the other Party by courier or overnight dispatch (*e.g.*, Federal Express) within a period of [**] of both the first and last day of the force majeure unless the force majeure renders such notification impossible in which case notification will be made as soon as possible. A Party invoking force majeure will use [**] to end the failure or delay and ensure the effects of the force majeure are minimized. The Party invoking force majeure shall resume the performance of its obligations as soon as practicable after the removal of the cause. If the delay resulting from the force majeure exceeds [**] and the Party invoking force majeure has not used diligent efforts to avoid, remove or remedy the force majeure cause during such time, the Party not invoking the force majeure shall [**] The rights granted to BioVectra with respect to excused delays under this Section 14.g are intended to limit BioVectra's rights under theories of force majeure, commercial impracticability, impracticability, or impossibility of performance, or failure of presupposed conditions or otherwise, including any rights arising under Section 2-615 or 2-616 of the State of Delaware UCC.

h. Limited Liability. Except in the case of a Party's indemnification obligations hereunder, [**] of the confidentiality or intellectual property provisions of this Agreement, or [**] (all the foregoing, the "Exceptions"), in no event shall either Party be liable to the other Party for lost profits, loss of goodwill, or any special, indirect, consequential or incidental damages, however caused and on any theory of liability, arising in any way out of the Agreement. This limitation shall apply even if a Party has been advised of the possibility of such damages, and notwithstanding any failure of essential purpose of any limited remedy. Except for cases of Exceptions, a Party's total liability under this Agreement shall not exceed the greater of [**]. The limitations set forth herein shall not apply to claims for (i) death or personal injury caused by a Party's negligence; or (ii) a Party's fraud or fraudulent misrepresentation.

i. Third Party Beneficiaries. Other than Indemnitees with regard to indemnification under Section 9, nothing in this Agreement, express or implied, is intended to confer upon any third party any rights, remedies, obligations or liabilities.

j. Further Actions. BioVectra agrees to execute, acknowledge and deliver such further instruments, and to do all such other acts, requested by Keryx as may be necessary or appropriate in order to carry out the purposes and intent of this Agreement.

k. Entire Agreement, Modification, Waivers. This Agreement, which includes the Appendices and Exhibits attached hereto (including the Quality Agreement) that are incorporated herein by reference, and any purchase orders issued by Keryx and accepted by BioVectra constitute the full and entire understanding and agreement of the Parties hereto with regard to the subject matter hereof, and supersede all prior agreements and understandings, written or oral, between the Parties with respect to the such subject matter. For the avoidance of doubt, nothing herein shall be deemed to modify or revise the Manufacture and Supply Agreement, which remains in full force and effect in accordance with its terms. This Agreement may not be amended except by a written instrument signed by the Parties hereto. Any delay in enforcing a Party's rights under this Agreement, or any waiver as to a particular default or other matter, will not constitute a waiver of such Party's rights to the future enforcement of its rights under this Agreement, except with respect to an express written waiver relating to a particular matter for a particular period of time signed by an authorized representative of the waiving Party, as applicable. The section headings are included solely for convenience of reference and will not control or affect the meaning or interpretation of any of the provisions of this Agreement.

l. Counterparts; Facsimile/PDF Signatures. This Agreement may be executed in counterparts, each of which shall be an original and all of which shall constitute one and the same instrument. Executed signatures pages to this Agreement may be delivered by facsimile or a portable document format (PDF) copy sent by e-mail and such facsimiles or PDFs shall be deemed as if actual signature pages had been delivered.

IN WITNESS WHEREOF, the Parties hereto have caused this Agreement to be executed by their duly authorized representatives as of the date first above written.

BioVectra Inc.

/s/ Oliver Technow
Name: Oliver Technow
Title: CEO

Keryx Biopharmaceuticals, Inc.

/s/ John. P. Butler
Name: John P. Butler
Title: Sole Director

Appendix 1 – Product and Price Schedule

Appendix 2 – Specifications

Appendix 3 – Quality Agreement