

KERYX BIOPHARMACEUTICALS INC
Form 8-K
December 21, 2017

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): December 20, 2017

Keryx Biopharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware
(State or Other Jurisdiction

of Incorporation)

000-30929
(Commission

File Number)
One Marina Park Drive, 12th Floor

13-4087132
(IRS Employer

Identification No.)

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Boston, Massachusetts 02210

(Address of Principal Executive Offices)

(617) 466-3500

(Registrant's telephone number, including area code)

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.

Soliciting material pursuant to Rule 14a-12 under the Exchange Act.

Pre-commencement communications pursuant to Rule 14d-2b under the Exchange Act.

Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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.

On December 20, 2017, Keryx Biopharmaceuticals, Inc. (Keryx) and Siegfried Evionnaz SA, together with its affiliates and subsidiaries (collectively, Siegfried), entered into a Master Manufacturing Services and Supply Agreement (the Agreement) for Siegfried to perform, directly or through its local affiliate, certain manufacturing expansion services at its manufacturing facilities in Saint Vulbas, France and Pennsville, New Jersey (the Manufacturing Facilities) as well as to manufacture and supply GMP-grade quantities of the proprietary active pharmaceutical ingredient (the Product) for Keryx s drug product, Auryxia.

Siegfried is responsible for procuring, commissioning and validating certain equipment at the Manufacturing Facilities in order to expand its operational capacity (the Expansion Services), and Keryx will make a fixed lump sum payment (the Service Payment) to support such Expansion Services. Any amounts required to finance the Expansion Services above the Service Payment will be paid by Siegfried.

Pursuant to the Agreement, Keryx has agreed to order a minimum quantity of Product annually. Siegfried has committed to achieve timely delivery of Product and to accept all orders of Product from Keryx up to its operational capacity. After a specified time, Siegfried will issue a credit to Keryx if it has failed to deliver a minimum percentage of the quantity of Product scheduled to be delivered monthly.

The Agreement has an initial term ending on December 31, 2021 and will automatically renew after the initial term for successive terms of one year each, unless either party gives notice of its intention to terminate the Agreement within a specified time prior to the end of the then current term.

Keryx may terminate the Agreement upon sixty (60) days prior written notice due to certain regulatory authority action that prevents Keryx from developing, importing, exporting, purchasing, selling or otherwise commercializing Auryxia in the United States.

Either Party may terminate the Agreement in the event of: (i) the cessation of all or substantially all of the other party s business operations immediately upon written notice, or (ii) a material breach or default, provided that such party has provided written notice and an opportunity to cure and the other party has not cured such material breach or default within sixty (60) days of receipt of the notice. After a specified period, late delivery of Product for a certain number of times within any 12-month period, which has not been cured within a specified time frame, constitutes a material breach by Siegfried. Additionally, either party may terminate the Agreement upon thirty (30) days prior written notice if the other party (the Bankrupt Party) has become bankrupt or made an assignment for the benefit of creditors, or there has been appointed a trustee for all or substantially all of the Bankrupt Party s property, or any case or proceeding has commenced or other action taken by or against the Bankrupt Party in bankruptcy or seeking reorganization, liquidation, dissolution, winding-up, arrangement, composition or readjustment of its debts or any other relief under any bankruptcy, insolvency or reorganization or other similar act of law.

The Agreement contains certain representations, warranties, limitations of liabilities, confidentiality and indemnity obligations, and other provisions customary for agreements of this type.

The foregoing description of the Agreement does not purport to be complete and is qualified in its entirety by the full text of the Agreement, a copy of which Keryx expects to file as an exhibit to Keryx s Annual Report on Form 10-K for the year ended December 31, 2017.

SIGNATURE

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.

Keryx Biopharmaceuticals, Inc.

(Registrant)

Date: December 21, 2017

By: /s/ Brian Adams
Brian Adams
General Counsel and Corporate Secretary