KERYX BIOPHARMACEUTICALS INC
Form 8-K
September 01, 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): August 29, 2017

Keryx Biopharmaceuticals, Inc.

(Exact Name of Registrant as Specified in Charter)

Delaware	**000-30929**	**13-4087132**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

One Marina Park Drive, 12th Floor

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 August 29, 2017, Keryx Biopharmaceuticals, Inc. (Keryx) and Patheon Inc. (Patheon Whitby), an affiliate of Patheon Manufacturing Services LLC (Patheon Greenville, and collectively with its affiliates, Patheon), entered into a product agreement (the Product Agreement) under the existing Master Manufacturing Services Agreement among Keryx and Patheon Greenville (the Master Agreement, and together with the Product Agreement, the Agreement), for Patheon Whitby s manufacture of commercial supplies of Auryxia® (ferric citrate) tablets at its Whitby, Ontario, Canada manufacturing site from active pharmaceutical ingredients supplied by Keryx. This Product Agreement is in addition to the two previous product agreements entered into by Keryx and Patheon Greenville and Keryx and Patheon UK Limited under the Master Agreement for Patheon s manufacture of Auryxia tablets at Patheon s Greenville, North Carolina and Bourgoin-Jallieu, France manufacturing sites, respectively.

Pursuant to the Agreement, Keryx orders from Patheon at least a certain percentage of its annual commercial requirements for Auryxia tablets each year for the term of the Agreement, which percentage is subject to reduction if Patheon fails to supply specified quantities of Auryxia tablets within specified timeframes.

The Product Agreement has an initial term ending December 31, 2024, and will automatically renew after the initial term for successive terms of two years each, unless either party gives notice of its intention to terminate the Product Agreement within a specified time prior to the end of the then current term.

Keryx may terminate the Product Agreement upon 30 days prior written notice if any governmental agency takes any action that prevents Keryx from researching, developing, importing, exporting, purchasing, selling or otherwise commercializing Auryxia. Further, Keryx will give at least six months advance notice (or such shorter period if required pursuant to action taken by a governmental agency) if Keryx intends to no longer order manufacturing services for Auryxia due to discontinuance of Auryxia in the market.

Either party may terminate the Master Agreement or the Product Agreement (a) upon written notice if the other party has failed to remedy a material breach under the Master Agreement or the Product Agreement and in the case of curable breaches within 60 days following receipt of written notice of such breach, (b) immediately upon written notice to the other party in the event that the other party is declared insolvent or bankrupt, a voluntary petition of bankruptcy is filed in any court by such other party or the Master Agreement or the Product Agreement is assigned by such other party for the benefit of creditors, and (c) upon six months written notice if the other party assigns the Master Agreement or the Product Agreement to an assignee that, in the opinion of the non-assigning party acting reasonably, is: (i) not a credit worthy substitute for the other party; or (ii) a competitor of the non-assigning party.

Patheon Whitby will have the option, at its sole discretion, to provide a 60-day notice to Keryx of Patheon Whitby s intention to terminate the Product Agreement if Keryx does not require Patheon Whitby s manufacturing services for a specified time period.

The foregoing description of the Product Agreement does not purport to be complete and is qualified in its entirety by the full text of such agreement, a copy of which Keryx expects to file as an exhibit to Keryx s Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, and by the full text of the Master Agreement, a copy of which is filed as Exhibit 10.12 to Keryx s Annual Report on Form 10-K for the year ended December 31, 2016.

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: September 1, 2017

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