KERYX BIOPHARMACEUTICALS INC
Form 8-K
October 17, 2016

**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): October 12, 2016**

**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.

**Item 1.01. Entry into a Material Definitive Agreement.**

On October 12, 2016, Keryx Biopharmaceuticals, Inc. ( Keryx ) and Patheon Manufacturing Services LLC and certain of its affiliates (collectively, Patheon ) entered into a Master Manufacturing Services Agreement (the Master Agreement ) and two related Product Agreements (each a Product Agreement , and collectively with the Master Agreement, the Agreement ) for Patheon s manufacture of commercial supplies of Auryxia® (ferric citrate) tablets at Patheon s Greenville, North Carolina and Bourgoin-Jallieu Cedex, France manufacturing sites. Under the Agreement, Keryx is responsible for supplying the active pharmaceutical ingredient for Auryxia to Patheon. Patheon is responsible for manufacturing the Auryxia tablets, conducting quality control, quality assurance, analytical testing and stability testing, packaging, and providing related services for the Auryxia tablets.

Pursuant to the Agreement, Keryx has agreed to order from Patheon at least a certain percentage of its annual commercial requirements for Auryxia tablets in the United States and European Union each year for the term of the Agreement, which initial percentage is subject to reduction if Patheon fails to supply specified quantities of Auryxia tablets within specified timeframes.

The Agreement has an initial term ending December 31, 2021, 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 Agreement within a specified time prior to the end of the then current term.

Keryx may terminate a 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 a Product Agreement (a) upon written notice if the other party has failed to remedy a material breach under the Master Agreement or a 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 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 a 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 will have the option, at its sole discretion, to provide a 60 day notice to Keryx of Patheon s intention to terminate the Product Agreement if Keryx does not require Patheon s manufacturing services for a specified time period.

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 Master Agreement and each Product Agreement does not purport to be complete and is qualified in its entirety by the full text of each agreement, copies of which Keryx expects to file as exhibits to Keryx s Annual Report on Form 10-K for the year ended December 31, 2016.

**Item 7.01. Regulation FD disclosure.**

On October 14, 2016, Patheon filed a Current Report on Form 8-K in which it announced that it was experiencing temporary work stoppages at three of its facilities, including its Greenville, North Carolina facility, due to power

outages and weather-related events. Patheon disclosed that Hurricane Matthew caused local flooding on roadways near its Greenville facility, but there was no damage to this facility, and that the decision to temporarily close the facility was to ensure the safety of its employees traveling to and from work. Patheon stated that it expects to resume operations at the Greenville facility in the course of this week.

Keryx has been in communication with Patheon, and Keryx does not expect the work stoppage at Patheon s Greenville facility to impact Keryx s previously announced expectation to make Auryxia available to patients when supply of Auryxia is back to adequate levels, which Keryx anticipates will be during the fourth quarter of 2016. The FDA has assigned a Prescription Drug User Fee Act, or PDUFA, action date of November 13, 2016 for its review of our application to approve Patheon to manufacture Auryxia at its Greenville facility.

**Forward-Looking Statements**

Some of the statements included in this report, particularly those regarding the expected timing of when Keryx will have adequate supply of Auryxia to make it available to patients again, may be forward-looking statements that involve a number of risks and uncertainties. For those statements, Keryx claims the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995. Among the factors that could cause Keryx s actual results to differ materially from these forward-looking statements are the following: Keryx s ability to quickly and successfully identify and resolve the production-related issue; Keryx s ability to quickly and successfully identify and engage secondary suppliers of finished drug product; Keryx s ability to receive FDA approval of any secondary suppliers of finished drug product, including approval of Patheon and its Greenville, North Carolina facility by the assigned PDUFA action date; Patheon s ability to resume operations at its Greenville, North Carolina facility within its expected time frame; and other risk factors identified from time to time in Keryx s reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this report speak only as of the date of this report. Keryx does not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof.

**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: October 17, 2016

By: /s/ Brian Adams

Brian Adams
General Counsel and Corporate Secretary