KERYX BIOPHARMACEUTICALS INC
Form 8-K
November 09, 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): November 9, 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-2(b) under the Exchange Act.

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

Item 8.01. Other Events.

On August 1, 2016, Keryx Biopharmaceuticals, Inc. (Keryx) announced that an interruption in the supply of Auryxia® (ferric citrate) tablets was imminent due to a production-related issue in converting active pharmaceutical ingredient to finished drug product at its contract manufacturer. Keryx is working with this manufacturer to resolve the production-related issue. In addition, since approval of Auryxia in 2014, Keryx had been working to bring a secondary manufacturer online to supply finished drug product. Keryx recently filed for approval of an additional manufacturer, Patheon Manufacturing Services LLC (Patheon), with the U.S. Food and Drug Administration (the FDA) and entered into a long-term arrangement with Patheon in October 2016 to supply finished Auryxia drug product.

On November 9, 2016, the FDA approved Keryx s application to approve Patheon and Patheon is now an approved drug product manufacturer of Auryxia. With FDA approval of this manufacturer, Keryx has rebuilt supply and will promptly make Auryxia available to wholesalers.

Forward-Looking Statements

Some of the statements included in this report, particularly those regarding the supply, commercialization and ongoing clinical development of Auryxia as well as the expected impact of the supply interruption of Auryxia, 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 resupply the market with Auryxia following the approval of Patheon and Keryx s ability to sustain that supply; whether Keryx can increase adoption of Auryxia in patients with chronic kidney disease (CKD) on dialysis; whether Keryx can maintain its operating expenses to projected levels while continuing its current clinical, regulatory and commercial activities; the risk that the FDA may not concur with Keryx s interpretation of its Phase 3 study results in non-dialysis dependent (NDD) CKD, supportive data, conduct of the studies, or any other part of Keryx s regulatory submission and could ultimately deny approval of ferric citrate for the treatment of iron deficiency anemia in adults with stage 3-5 NDD-CKD; the risk that if approved for use in NDD-CKD that Keryx may not be able to successfully market Auryxia for use in this indication; 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: November 9, 2016

By: /s/ Brian Adams

Brian Adams
General Counsel and Corporate Secretary