KERYX BIOPHARMACEUTICALS INC
Form 8-K
August 01, 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): August 1, 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 2.02. Results of Operations and Financial Condition.

On August 1, 2016, Keryx Biopharmaceuticals, Inc. (Keryx) issued a press release announcing its results of operations for the second quarter ended June 30, 2016 and providing a company update. Keryx also announced that on August 1, 2016 at 8:30 a.m. EDT, it will host an investor conference call to discuss Keryx s second quarter financial results and provide a company update. A copy of such press release is being furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

The information set forth in this Item 2.02, including Exhibit 99.1, shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liability of that section, and shall not be incorporated by reference into any registration statement or other document filed under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 8.01. Other Events.

On August 1, 2016, Keryx announced that an interruption in the supply of Auryxia® (ferric citrate) tablets is imminent due to a production-related issue. Keryx expects 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.

Keryx has determined that a supply interruption is going to occur due to a production-related issue in converting active pharmaceutical ingredient (API) to finished drug product at its contract manufacturer. This issue has resulted in variable production yields of finished drug product and, as a result, Keryx has exhausted its reserve of finished drug product. At this time, current inventories of Auryxia are not sufficient to ensure uninterrupted patient access to this medicine. The supply interruption does not affect the safety profile of currently available Auryxia. Keryx is working with its existing manufacturer to resolve the production-related issue and rebuild adequate supply. In addition, since approval of Auryxia in 2014, Keryx has been working to bring a secondary manufacturer online to supply finished drug product. Keryx recently filed for approval of this manufacturer with the U.S. Food and Drug Administration (FDA) and the FDA has assigned a Prescription Drug User Fee Act (PDUFA) action date of November 13, 2016.

This supply interruption does not affect the supply of ferric citrate (marketed as Riona®) manufactured and sold by Keryx s Japanese partner.

Forward-Looking Statements

Some of the statements included in this report, particularly those regarding the commercialization of Auryxia as well as the expected impact of the supply interruption of Auryxia and the expected timing of when Keryx will have adequate supply of Auryxia to make it available to patients again following the supply interruption, 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; 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; whether Keryx will be able to identify and negotiate acceptable terms with a commercialization partner in the E.U.; whether Keryx or a partner can successfully launch Fexeric® in the E.U.; whether Riona® will be successfully marketed in Japan by Keryx s Japanese partner, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd; 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.

Item 9.01. Financial Statements And Exhibits.

(d) Exhibits.
The following exhibit is furnished herewith:

99.1 Press release issued by Keryx Biopharmaceuticals, Inc., dated August 1, 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: August 1, 2016

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

INDEX TO EXHIBITS

Exhibit Number	**Description**
99.1	Press release issued by Keryx Biopharmaceuticals, Inc., dated August 1, 2016.