

KERYX BIOPHARMACEUTICALS INC  
Form 8-K  
January 09, 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): January 6, 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, 12<sup>th</sup> 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-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 January 8, 2017, Keryx Biopharmaceuticals, Inc. ( Keryx ) issued a press release announcing business progress and certain preliminary unaudited financial data for the quarter and year ended December 31, 2016. Keryx also announced that on January 11, 2017 at 2:30 p.m. PST (5:30 p.m. EST), it will webcast its corporate presentation and breakout session at the 35<sup>th</sup> Annual J.P. Morgan Healthcare Conference. A copy of such press release is being furnished as Exhibit 99.1 to this report and is incorporated herein by reference. A copy of the investor presentation to be used on the webcast is being furnished as Exhibit 99.2 to this report and is incorporated herein by reference.

The information set forth in Exhibits 99.1 and 99.2 shall not be deemed to be filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act ), 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.**

(c) On January 6, 2017, Keryx entered into an employment agreement with Christine A. Carberry (the Employment Agreement ) to serve as Keryx s Chief Operating Officer. Ms. Carberry is expected to start with Keryx on or about January 16, 2017 and her employment with Keryx under the Employment Agreement will be on an at will basis.

Ms. Carberry, age 56 years, brings to Keryx approximately 30 years of biotech and pharmaceutical leadership, including most recently as an executive team member and Senior Vice President, Quality, Technical Operations, Program and Alliance Management at Forum Pharmaceuticals Inc. Prior to Forum, Ms. Carberry spent 25 years at Biogen Inc. and held roles of increasing responsibility, culminating as Vice President, Program and Alliance Management.

Under the Employment Agreement, Ms. Carberry s base salary will be equal to \$385,000 per year, subject to increases by the Compensation Committee of Keryx s Board of Directors (the Committee ) at any time in its sole discretion. Ms. Carberry is also eligible to receive an annual discretionary bonus, not to exceed 40% of her base salary, if certain performance goals are met in the discretion of the Committee.

Under the Employment Agreement, Ms. Carberry is also entitled to 85,000 shares of restricted common stock (the Stock Grant ) and options to purchase an additional 170,000 shares of common stock (the Option Grant ), all issuable upon commencement of employment with Keryx. The Stock Grant and the Option Grant will vest over three years with the first one-third of the shares under each grant vesting on the first anniversary of Ms. Carberry s start date with Keryx and thereafter the remaining two-thirds of the shares under each grant will vest in equal quarterly installments through the third anniversary of Ms. Carberry s start date with Keryx, in each case conditioned upon Ms. Carberry s continued employment with Keryx.

Under the Employment Agreement, Ms. Carberry will be entitled to cash severance payments if Keryx terminates her employment without cause (as defined in the Employment Agreement) or if Ms. Carberry resigns her employment for good reason (as defined in the Employment Agreement).

In connection with the execution of the Employment Agreement, Ms. Carberry agreed to maintain Keryx s confidential information and trade secrets (as defined in the Employment Agreement) and also to adhere to certain covenants of non-competition.

The foregoing summary of the Employment Agreement is qualified in its entirety by the copy of such agreement filed as Exhibit 10.1 hereto and incorporated by reference.

No family relationships exist between Ms. Carberry and any of our directors or other executive officers. There are no arrangements or understandings between Ms. Carberry and any other person pursuant to which Ms. Carberry was selected as an officer, nor are there any transactions to which Keryx is or was a participant and in which Ms. Carberry has a material interest subject to disclosure under Item 404(a) of Regulation S-K.

**Item 8.01. Other Events.**

*Auryxia® (ferric citrate) Commercial Progress*

On January 8, 2017, Keryx reported prescription demand for Auryxia for the fourth quarter of 2016 was approximately 8,700 prescriptions, which included 4,500 prescriptions for the month of December, the first full month of sales post resupply of Auryxia following the previously announced supply interruption. This compares to approximately 5,000 prescriptions for the month of July 2016, the last full month of sales prior to the interruption.

Keryx also announced that the U.S. Food and Drug Administration ( FDA ) has approved Patheon s manufacturing facility in France to manufacturer supply of Auryxia for the United States. The approval of this site provides Keryx with a third manufacturing site for finished Auryxia drug product.

*Submission of Supplemental New Drug Application*

On January 8, 2017, Keryx also announced that it submitted a supplemental new drug application to the FDA seeking to expand the label of ferric citrate to include the treatment of iron deficiency anemia in adults with stage 3-5 non-dialysis dependent chronic kidney disease.

*Preliminary Unaudited Financial Data*

On January 8, 2017, Keryx announced the following preliminary unaudited financial data for the quarter and year ended December 31, 2016:

**Total revenues** for the quarter ended December 31, 2016 are expected to be approximately \$9.5 million, compared with \$5.8 million during the same period in 2015. Total revenue expectations for the fourth quarter of 2016 consist of approximately \$8.2 million in ex-factory Auryxia net U.S. product sales, compared to \$4.8 million in the fourth quarter of 2015, which were recorded based on actual prescriptions written during the period. Total expected revenues for the fourth quarter of 2016 also include \$1.3 million in license revenues as compared to \$1.0 million during the same period in 2015.

For the year ended 2016, total revenues are expected to be approximately \$31.9 million as compared to \$13.7 million in 2015. Total expected revenues for 2016 include \$27.1 million of Auryxia net U.S. product sales and \$4.8 million in license revenues as compared to \$10.1 million and \$3.5 million, respectively, in 2015.

**Cost of goods sold** for the quarter ended December 31, 2016 are expected to be approximately \$13.3 million, compared with \$1.1 million during the same period in 2015. Expected cost of goods sold for the fourth quarter of 2016 include an approximately \$11.8 million write-off of work-in-process inventory that was determined to no longer be suitable for commercial manufacture. For the year ended 2016, total cost of goods sold are expected to be approximately \$37.7 million, as compared to \$4.5 million in 2015. Total expected 2016 cost of goods sold includes approximately \$25.6 million in write-offs of work-in-process inventory that was determined to no longer be suitable for commercial manufacture and approximately \$2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production at the company's third-party drug product manufacturers. Total 2015 cost of goods sold included \$2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production at the company's third-party drug product manufacturers.

**Cash and cash equivalents** as of December 31, 2016 totaled approximately \$112.1 million.

The preliminary unaudited financial data for the quarter and the year ended December 31, 2016 set forth above is derived from preliminary internal financial reports. Keryx has not yet finalized its complete results of operations for the year ended December 31, 2016. In connection with the finalization of its year-end closing and reporting processes, the completion of its financial statements for the year ended December 31, 2016 and the completion of the audit of its financial statements for the year ended December 31, 2016, Keryx and its auditors may identify items that would require Keryx to make adjustments, some of which could be material, to the preliminary unaudited financial data set forth above.

**Item 9.01. Financial Statements And Exhibits.**

(d) Exhibits.

- 10.1 Employment Agreement with Christine A. Carberry dated January 6, 2017.
- 99.1 Press release issued by Keryx Biopharmaceuticals, Inc. dated January 8, 2017.
- 99.2 Investor presentation of Keryx Biopharmaceuticals, Inc. dated January 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: January 9, 2017

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

**INDEX TO EXHIBITS**

**Exhibit**

**Number**

**Description**

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