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): April 27, 2018

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.

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 2.02. Results of Operations and Financial Condition.

Preliminary Financial Data

On April 30, 2018, Keryx Biopharmaceuticals, Inc. (the "Company") announced that it expects to report total revenue for the quarter ended March 31, 2018 of between $21.0 million and $22.5 million, including between $20.0 million and $21.0 million in net Auryxia® U.S. product sales.

The preliminary financial data for the quarter ended March 31, 2018 set forth above are derived from preliminary internal financial reports. The Company has not yet finalized its complete results of operations for the quarter ended March 31, 2018. In connection with the finalization of its quarterly closing and reporting processes and the completion of its financial statements for the quarter ended March 31, 2018, the Company may identify items that would require the Company to make adjustments, some of which could be material, to the preliminary financial data set forth above.

The information in this Item 2.02 shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, except as shall be expressly set forth by specific reference in such a filing.

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

(b) On April 27, 2018, Gregory P. Madison notified the Board of Directors (the "Board") of the Company of his resignation as the President and Chief Executive Officer of the Company and as a member of the Board, effective immediately. The Company expects to provide Mr. Madison severance and other benefits subject to Mr. Madison signing a separation agreement. When such agreement is finalized, the Company expects to file a Current Report on Form 8-K with respect to such agreement.

In connection with Mr. Madison's resignation as a member of the Board, the Board reduced the size of the Board from eight directors to seven directors.

(c) In connection with Mr. Madison's resignation, on April 27, 2018, the Board appointed Jodie Morrison as Interim Chief Executive Officer of the Company while the Board conducts a search for the Company's next Chief Executive Officer. Ms. Morrison, age 42, has served on the Board since June 2016 and will continue to serve on the Board while she serves as the Interim Chief Executive Officer.

Ms. Morrison serves as a consultant to the industry. She served as President and Chief Executive Officer of Tokai Pharmaceuticals, Inc., a biopharmaceutical company focused on developing and commercializing novel therapies for prostate cancer and other hormonally-driven diseases, from March 2013 until May 2017. From December 2006 until March 2013, Ms. Morrison held other senior positions with Tokai, including Chief Operating Officer, Head of Clinical Affairs and Program Operations and Vice President of Clinical Affairs and Program Operations. Following her over 10 years of service at Tokai, she was the Chief Executive Officer of eGenesis, Inc., a privately held biotechnology company, in September and November 2017. Prior to joining Tokai, Ms. Morrison served as Director of Clinical Operations and Medical Affairs at Dyax Corporation, or Dyax. Prior to joining Dyax, Ms. Morrison held clinical management positions at both Curis, Inc. and at Diacrin, Inc. Ms. Morrison received a B.A. in neuroscience from Mount Holyoke College, her clinical research certification from the Boston University School of Medicine and her business training through the Greater Boston Executive Program at the MIT Sloan School of Management.

The Compensation Committee and the Board intend to review and approve compensation arrangements for Ms. Morrison at future meetings.

No family relationships exist between Ms. Morrison and any of the Company's directors or executive officers. There are no arrangements or understandings between Ms. Morrison and any other person pursuant to which Ms. Morrison was selected as the Interim Chief Executive Officer, nor are there any transactions to which the Company is or was a participant and in which Ms. Morrison has a material interest subject to disclosure under Item 404(a) of Regulation S-K.

In connection with the appointment of Ms. Morrison as the Company's Interim Chief Executive Officer, the Board also appointed current Board member Kevin Cameron to replace Ms. Morrison on the Audit Committee of the Board.

Item 7.01. Regulation FD Disclosure.

On April 30, 2018, the Company issued a press release announcing the preliminary financial data and the management changes described above. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Forward-Looking Statements

Some of the statements included in this Current Report on Form 8-K, particularly those regarding the preliminary financial data and the management transition, may be forward-looking statements that involve a number of risks and uncertainties. For those statements, the Company 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 the Company's actual results to differ materially are the following: the risk that the Company may identify items that would require the Company to make adjustments, some of which could be material, to the preliminary financial data; the Company's ability to successfully transition the chief executive role to Ms. Morrison and to a full-time chief executive; the Company's ability to successfully market Auryxia and whether the Company can increase adoption of Auryxia in patients with chronic kidney disease on dialysis and successfully launch Auryxia for the treatment of iron deficiency anemia in patients with chronic kidney disease, not on dialysis; whether the Company can maintain its operating expenses to projected levels while continuing its current clinical, regulatory and commercial activities; the Company's ability to continue to supply Auryxia to the market; the risk that increased utilization by Medicare Part D subscribers will increase the Company's gross-to-net adjustment greater than the Company anticipates; and other risk factors identified from time to time in the Company's reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this Current Report on Form 8-K speak only as of the date of this Current Report on Form 8-K. The Company 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 April 30, 2018.

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: April 30, 2018

By: /s/ Scott A. Holmes
Scott A. Holmes
Chief Financial Officer

Keryx Biopharmaceuticals Announces Changes to Management and Preliminary First Quarter 2018 Revenue

- Gregory Madison resigned as president and chief executive officer of the company and from its board of directors
- Jodie Morrison, current Keryx board member, named interim chief executive officer
- Company expects to report first quarter 2018 total revenue of $21.0 million - $22.5 million, including Auryxia® net U.S. product sales of $20.0 million - $21.0 million

BOSTON, MA, April 30, 2018 – Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), a biopharmaceutical company focused on bringing innovative medicines to people with kidney disease, today announced that Gregory Madison has resigned as president and chief executive officer of the company and his seat on its board of directors, effective immediately. Jodie Morrison, a member of the company's board of directors, has been named interim chief executive officer. The company also announced preliminary first quarter 2018 revenue.

"On behalf of the entire board I would like to thank Greg for his contributions to Keryx over the past four years, in particular for his role in transitioning Keryx from a development-stage organization to a commercial entity, and wish him well in his future endeavors," said Michael Rogers, chairman of Keryx's board of directors. "We are fortunate to have Jodie – a fellow director – step into a management role and help lead Keryx as we continue to execute on our strategic priorities. We look forward to her continued contributions both as an ongoing member of our board and as interim CEO while we conduct the search for a permanent chief executive officer."

"We have a very talented leadership team at Keryx and I look forward to working with them to review our business in the coming weeks," said Jodie Morrison, interim chief executive officer of Keryx. "Auryxia is an important therapy with the potential to benefit millions of people in the U.S. living with chronic kidney disease (CKD) and iron deficiency anemia or hyperphosphatemia. The board and the entire leadership team at Keryx are focused on ensuring that we maximize the value of Auryxia and help as many patients as possible who are living with these complications of CKD."

Jodie Morrison has served on Keryx's board of directors since June 2016. From 2013 to 2017, she served as president and chief executive officer of Tokai Pharmaceuticals, Inc., where she took the company through its initial public offering in 2014. From December 2006 until March 2013, Ms. Morrison held other senior positions with Tokai, including chief operating officer, head of clinical affairs and program operations and vice president of clinical affairs and program operations. Ms. Morrison received a B.A. in neuroscience from Mount Holyoke College, her clinical research certification from the Boston University School of Medicine and her business training through the Greater Boston Executive Program at the MIT Sloan School of Management.

Preliminary Financial Data

The company expects to report total revenue for the first quarter of 2018 of between $21.0 million and $22.5 million, including between $20.0 million and $21.0 million in net Auryxia U.S. product sales. The company will announce its full first quarter 2018 financial results in the coming weeks and plans to host a conference call at that time.

The preliminary financial data for the first quarter of 2018 set forth above are derived from preliminary internal financial reports. The company has not yet finalized its complete results of operations for the quarter ended March 31, 2018. In connection with the finalization of its quarterly closing and reporting processes and the completion of its financial statements for the quarter ended March 31, 2018, the company may identify items that would require the company to make adjustments, some of which could be material, to the preliminary financial data set forth above.

About Auryxia® (ferric citrate) Tablets

Auryxia (ferric citrate) was approved by the U.S. Food and Drug Administration (FDA) on September 5, 2014 for the control of serum phosphorus levels in patients with chronic kidney disease on dialysis and approved by the FDA on November 6, 2017 for the treatment of iron deficiency anemia in patients with chronic kidney disease not on dialysis. Auryxia tablets were designed to contain 210 mg of ferric iron, equivalent to 1 gram of ferric citrate, and offers convenient mealtime dosing. The starting dose of Auryxia for the treatment of hyperphosphatemia for patients on dialysis is six tablets per day (two per meal) and for the treatment of iron deficiency anemia in patients not on dialysis is three tablets per day (one per meal). For more information about Auryxia and the U.S. full prescribing information, please visit www.Auryxia.com.

IMPORTANT U.S. SAFETY INFORMATION FOR AURYXIA® (ferric citrate)

CONTRAINDICATION

AURYXIA® (ferric citrate) is contraindicated in patients with iron overload syndromes, e.g., hemochromatosis.

WARNINGS AND PRECAUTIONS

- **Iron Overload:** Increases in serum ferritin and transferrin saturation (TSAT) were observed in clinical trials with AURYXIA in patients with chronic kidney disease (CKD) on dialysis treated for hyperphosphatemia, which may lead to excessive elevations in iron stores. Assess iron parameters prior to initiating AURYXIA and monitor while on therapy. Patients receiving concomitant intravenous (IV) iron may require a reduction in dose or discontinuation of IV iron therapy.
- **Risk of Overdosage in Children Due to Accidental Ingestion:** Accidental ingestion and resulting overdose of iron-containing products is a leading cause of fatal poisoning in children under 6 years of age. Advise patients of the risks to children and to keep AURYXIA out of the reach of children.

ADVERSE REACTIONS

Most common adverse reactions with AURYXIA were:

- Hyperphosphatemia in CKD on Dialysis: Diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%)
- Iron Deficiency Anemia in CKD Not on Dialysis: Discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%)

SPECIFIC POPULATIONS

- **Pregnancy and Lactation:** There are no available data on AURYXIA use in pregnant women to inform a drug-associated risk of major birth defects and miscarriage. However, an overdose of iron in pregnant women may carry a risk for spontaneous abortion, gestational diabetes and fetal malformation. Data from rat studies have shown the transfer of iron into milk, hence, there is a possibility of infant exposure when AURYXIA is administered to a nursing woman.

To report suspected adverse reactions, contact Keryx Biopharmaceuticals at 1-844-445-3799.

Please **click here** to view the Full Prescribing Information for Auryxia.

Forward-Looking Statements

Some of the statements included in this press release, particularly those regarding the preliminary financial data and the management transition, may be forward-looking statements that involve a number of risks and uncertainties. For those statements, we claim 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 our actual results to differ materially are the following: the risk that we may identify items that would require us to make adjustments, some of which could be material, to the preliminary financial data; our ability to successfully

transition the chief executive role to Ms. Morrison and to a full-time chief executive; our ability to successfully market Auryxia and whether we can increase adoption of Auryxia in patients with chronic kidney disease on dialysis and successfully launch Auryxia for the treatment of iron deficiency anemia in patients with chronic kidney disease, not on dialysis; whether we can maintain our operating expenses to projected levels while continuing our current clinical, regulatory and commercial activities; our ability to continue to supply Auryxia to the market; the risk that increased utilization by Medicare Part D subscribers will increase our gross-to-net adjustment greater than we anticipate; and other risk factors identified from time to time in our reports filed with the Securities and Exchange Commission. Any forward-looking statements set forth in this press release speak only as of the date of this press release. We do not undertake to update any of these forward-looking statements to reflect events or circumstances that occur after the date hereof. This press release and prior releases are available at http://www.keryx.com. The information found on our website is not incorporated by reference into this press release and is included for reference purposes only.

About Keryx Biopharmaceuticals, Inc.

Keryx Biopharmaceuticals, Inc., with headquarters in Boston, Massachusetts, is focused on the development and commercialization of innovative medicines that provide unique and meaningful advantages to people with kidney disease. The Keryx team consists of approximately 200 committed people working with passion to advance the care of people with this complex disease. This dedication has resulted in two FDA-approved indications for Keryx's first medicine, Auryxia® (ferric citrate) tablets. For more information about Keryx, please visit www.keryx.com.

KERYX BIOPHARMACEUTICALS CONTACT
Amy Sullivan
Senior Vice President, Corporate Affairs
T: 617.466.3519
amy.sullivan@keryx.com