

KERYX BIOPHARMACEUTICALS INC

Form 8-K

October 25, 2018

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 24, 2018

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, 12th Floor

13-4087132
(IRS Employer

Identification No.)

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 1.01. Entry into a Material Definitive Agreement.

On October 24, 2018, Keryx Biopharmaceuticals, Inc., a Delaware corporation (Keryx), entered into a letter agreement with Panion & BF Biotech, Inc. (Panion) and Akebia Therapeutics, Inc. (Akebia) (the Letter Agreement) in connection with the Amended and Restated License Agreement between Keryx and Panion, dated March 17, 2008 as amended (the License Agreement), under which Keryx licenses certain intellectual property rights covering Auryxia[®] from Panion. Pursuant to the Letter Agreement, Panion agreed to rescind any and all prior termination threats or notices relating to the License Agreement and waived its rights to terminate the License Agreement based on any breach by Keryx of its obligation to use commercially reasonable efforts to commercialize Auryxia[®] outside the United States until the parties execute an amendment to the License Agreement, in accordance with the terms of the Letter Agreement, following consummation of the proposed business combination of Keryx and Akebia. These terms include establishing a joint steering committee consisting of Panion and Akebia representatives to oversee the development and commercialization of Fexeric[®] in Europe and providing Panion with an exclusive license under Keryx-owned patents covering the rights to make, use, sell, offer for sale and import ferric citrate in certain countries in the Asia-Pacific region. The parties will agree on a regulatory plan for Fexeric[®] in Europe within four months after execution of the Letter Agreement. The parties will also agree on a commercialization plan for Fexeric[®] in Europe following execution of the amendment. The amendment to the License Agreement will include alternatives in the event a commercialization plan is not agreed upon, such as payment of an annual license maintenance fee to Panion or the return of European intellectual property rights to Panion. In addition, Panion has agreed that Keryx will have the right, but not the obligation, to conduct any litigation against any infringer of patent rights under the License Agreement on the terms agreed upon in the Letter Agreement. In the event the proposed business combination of Keryx and Akebia is not consummated, Keryx and Panion are obligated to fulfill the terms of the Letter Agreement, including negotiating in good faith an amendment to the License Agreement. Keryx also agreed to make a \$500,000 payment to Panion promptly after execution of the Letter Agreement.

The foregoing description of the Letter Agreement does not purport to be complete and is qualified in its entirety by the full text of the Letter Agreement, a copy of which is expected to be filed as an exhibit to a subsequent filing with the U.S. Securities and Exchange Commission (the SEC).

Item 8.01. Other Events.

Merger Update

In addition to entering into the Letter Agreement discussed above in Item 1.01, Keryx and Akebia are filing an amendment with the SEC to their joint proxy statement/prospectus regarding their previously disclosed business combination through the merger of Alpha Therapeutics Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of Akebia (Merger Sub), with and into Keryx, with Keryx continuing after such merger as a wholly-owned subsidiary of Akebia (the Merger) pursuant to the Agreement and Plan of Merger, dated June 28, 2018, by and between Keryx, Akebia and Merger Sub, as amended, which contains important information about the proposed Merger and the two companies.

Additional Information and Where to Find It

In connection with the proposed Merger, Akebia and Keryx plan to file with the SEC and mail or otherwise provide to their respective stockholders a joint proxy statement/prospectus regarding the proposed transaction. BEFORE MAKING ANY VOTING DECISION, AKEBIA S AND KERYX S RESPECTIVE STOCKHOLDERS ARE URGED TO READ THE JOINT PROXY STATEMENT/PROSPECTUS IN ITS ENTIRETY WHEN IT BECOMES AVAILABLE AND ANY OTHER DOCUMENTS FILED BY EACH OF AKEBIA AND KERYX WITH THE SEC IN CONNECTION WITH THE PROPOSED MERGER OR INCORPORATED BY REFERENCE THEREIN BECAUSE THEY WILL CONTAIN IMPORTANT INFORMATION ABOUT THE PROPOSED TRANSACTION

AND THE PARTIES TO THE PROPOSED TRANSACTION. Investors and stockholders will be able to obtain a free copy of the joint proxy statement/prospectus and other documents containing important information about Akebia and Keryx, once such documents are filed with the SEC, through the website maintained by the SEC at www.sec.gov. Akebia and Keryx make available free of charge at www.akebia.com and www.keryx.com, respectively (in the Investors section), copies of materials they file with, or furnish to, the SEC.

Participants in the Merger Solicitation

This document does not constitute a solicitation of proxy, an offer to purchase or a solicitation of an offer to sell any securities. Akebia, Keryx and their respective directors, executive officers and certain employees and other persons may be deemed to be participants in the solicitation of proxies from the stockholders of Akebia and Keryx in connection with the proposed merger. Security holders may obtain information regarding the names, affiliations and interests of Akebia's directors and officers in Akebia's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on March 12, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on April 30, 2018. Security holders may obtain information regarding the names, affiliations and interests of Keryx's directors and officers in Keryx's Annual Report on Form 10-K for the fiscal year ended December 31, 2017, which was filed with the SEC on February 21, 2018, and the Amendment No. 1 on Form 10-K/A, which was filed with the SEC on April 30, 2018, and its definitive proxy statement for the 2018 annual meeting of stockholders, which was filed with the SEC on May 31, 2018. To the extent the holdings of Akebia securities by Akebia's directors and executive officers or the holdings of Keryx securities by Keryx's directors and executive officers have changed since the amounts set forth in Akebia's or Keryx's

respective proxy statement for its 2018 annual meeting of stockholders, such changes have been or will be reflected on Statements of Change in Ownership on Form 4 filed with the SEC. Additional information regarding the interests of such individuals in the proposed merger will be included in the joint proxy statement/prospectus relating to the proposed merger when it is filed with the SEC. These documents (when available) may be obtained free of charge from the SEC's website at www.sec.gov, Akebia's website at www.akebia.com and Keryx's website at www.keryx.com.

Forward Looking Statements

Some of the statements included in this Current Report on Form 8-K, particularly those regarding Letter Agreement, the proposed amendment to the License Agreement and the proposed Merger, 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 are the following: Keryx's ability to successfully market Auryxia and whether Keryx can increase adoption of Auryxia in patients with chronic kidney disease on dialysis and for the treatment of iron deficiency anemia in patients with chronic kidney disease, not on dialysis; whether Keryx can maintain its operating expenses to projected levels while continuing its current clinical, regulatory and commercial activities; Keryx's ability to continue to supply Auryxia to the market; the risk that changes in the mix of payors between private and government sponsored insurers and other payors will increase Keryx's gross-to-net adjustment greater than Keryx anticipate; risks related to the Centers for Medicare & Medicaid Services' determinations with respect to Medicare Part D coverage for Auryxia; the risks associated with continued discussions among Keryx, Akebia and Panion pursuant to the Letter Agreement and the impact thereon on the License Agreement; the risk that the proposed Merger with Akebia does not close due to the failure to obtain stockholder or regulatory approval or otherwise; the risk that Akebia's or Keryx's respective businesses may suffer as a result of uncertainty surrounding the Merger and disruption of management's attention due to the Merger; risks that the Merger disrupts current plans and operations and the potential difficulties in employee retention as a result of the Merger; the risk that the expected benefits of the proposed Merger or other commercial opportunities may otherwise not be fully realized or may take longer to realize than expected; and other risk factors identified from time to time in Keryx's reports filed with the SEC and in the Registration Statement on Form S-4, as amended, filed by Akebia on the date hereof under the headings "Risk Factors-Risks Related to the Merger" and "Risk Factors-Risks Related to the Business of the Combined Company After the Merger", which risk factors are incorporated herein by reference. 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. 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.

Date: October 25, 2018

Keryx Biopharmaceuticals, Inc.
(Registrant)

By: /s/ Jodie P. Morrison
Jodie P. Morrison
Interim Chief Executive Officer