

KERYX BIOPHARMACEUTICALS INC
Form 425
October 01, 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 1, 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 1, 2018, Keryx Biopharmaceuticals, Inc., a Delaware corporation (Keryx), entered into the First Amendment to Agreement and Plan of Merger (the First Amendment) with Akebia Therapeutics, Inc. (Akebia), a Delaware corporation, and Alpha Therapeutics Merger Sub Inc., a Delaware corporation and wholly-owned subsidiary of Akebia (Merger Sub), amending the Agreement and Plan of Merger, dated June 28, 2018, by and between Akebia, Keryx and Merger Sub (the Merger Agreement). As previously disclosed, pursuant to the Merger Agreement, Keryx and Akebia will combine their respective businesses through the merger of Merger Sub with and into Keryx, with Keryx continuing after such merger as a wholly-owned subsidiary of Akebia (the Merger).

The First Amendment provides that, as of the effective time of the Merger (the Effective Time), Akebia must take all necessary corporate action to cause an increase in the size of the board of directors of Akebia (the Akebia Board) to ten (10) directors, comprising (i) four (4) directors designated by the Akebia Board, each of whom shall be a director of Akebia prior to the Effective Time and be reasonably acceptable to Keryx (the Continuing Directors), (ii) five (5) directors designated by the board of directors of Keryx (the Keryx Board), each of whom shall be a director of Keryx prior to the Effective Time and be reasonably acceptable to Akebia (the Keryx Board Designees), and (iii) one (1) additional independent director to be designated by the Akebia Board and the Keryx Board (the Additional Director), who is neither a member of the Akebia Board nor a member of the Keryx Board prior to the Effective Time. The Additional Director shall serve as chairperson of the Akebia Board as of the Effective Time. Pursuant to the First Amendment, Akebia and Keryx shall designate the Continuing Directors, the Keryx Board Designees and the Additional Director, as applicable, as soon as practicable, but no later than immediately prior to the Effective Time. The First Amendment also provides that, as of the Effective Time, the Continuing Directors, the Keryx Board Designees and the Additional Director shall be allocated among three classes of directors as follows:

Class II (up for re-election in 2019): 1 Continuing Director, 2 Keryx Board Designees;

Class III (up for re-election in 2020): Additional Director, 1 Continuing Director, 1 Keryx Board Designee; and

Class I (up for re-election in 2021): 2 Continuing Directors, 2 Keryx Board Designees.

Other than as expressly modified pursuant to the First Amendment, the Merger Agreement remains in full force and effect as originally executed on June 28, 2018. The foregoing description of the First Amendment is not complete and is subject to and qualified in its entirety by reference to the First Amendment, a copy of which is filed as Exhibit 2.1 to this Current Report on Form 8-K and is incorporated herein by reference.

Item 8.01. Other Events.

Merger Update

In addition to entering into the First Amendment, Keryx and Akebia are filing a joint proxy statement/prospectus regarding the Merger with the U.S. Securities and Exchange Commission (the SEC) today, which contains important information about the proposed Merger and the two companies. In connection with of the filing of the joint proxy statement/prospectus, Keryx is filing this Current Report on Form 8-K to provide certain updates on its business.

Auryxia Formulary Status

Keryx has completed contract negotiations with Part D sponsors for the 2019 calendar year, and has secured coverage for Auryxia[®] (ferric citrate) on two additional Part D formularies. In 2019, Keryx expects Auryxia will be on formulary at nine of the ten major Part D plans.

The Centers for Medicare & Medicaid Services (CMS) recently communicated to Medicare Part D sponsors that Auryxia is considered by CMS a Part D drug when it is used for its FDA-approved indication for the control of serum phosphorus levels. CMS also indicated that it does not consider use of Auryxia covered under Part D when it is used solely for the treatment of iron deficiency anemia (IDA) in patients with chronic kidney disease not on dialysis, which is Auryxia s other FDA-approved indication. CMS expects Part D sponsors to utilize a prior authorization edit (PA), or other process, to ensure that Auryxia is being used for a Part D covered indication. Keryx expects Part D sponsors will implement a PA for Auryxia no later than January 2019. Keryx expects to interact with CMS and Part D sponsors further on this matter.

Keryx believes that the vast majority of the Part D prescriptions written for Auryxia today are for the treatment of hyperphosphatemia and therefore will continue to be covered by Part D plans in the future.

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 Medicare Part D coverage for Auryxia and the expectations thereof on Keryx and Medicare Part D sponsors, 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 IDA 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; 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 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.

Item 9.01. Financial Statements And Exhibits.

(d) Exhibits.

The following exhibit is filed herewith:

- 2.1 First Amendment to Agreement and Plan of Merger dated October 1, 2018, by and among Akebia Therapeutics, Inc., Alpha Therapeutics Merger Sub Inc. and Keryx Biopharmaceuticals, Inc.

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 1, 2018

Keryx Biopharmaceuticals, Inc.
(Registrant)

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