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): May 25, 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 7.01. Regulation FD Disclosure.

On May 25, 2018, Keryx Biopharmaceuticals, Inc. (the "Company") issued a press release announcing data from an investigator sponsored study of ferric citrate in patients with chronic kidney disease. The Company also announced that on May 25, 2018 at 8:30 a.m. ET, it will host an investor conference call to discuss the data. A copy of such press release is being furnished as Exhibit 99.1 to this report and is incorporated herein by reference.

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 May 25, 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: May 25, 2018

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

Keryx Biopharmaceuticals Announces Data from an Investigator Sponsored Trial of Ferric Citrate in Patients with Advanced Chronic Kidney Disease in a Late-Breaking Presentation at the 55th Annual ERA/EDTA Today in Copenhagen

Conference Call Today at 8:30 a.m. EST

Copenhagen, Denmark, May 25, 2018 - Keryx Biopharmaceuticals, Inc. (Nasdaq: KERX), a company focused on bringing innovative medicines to people with kidney disease, announced today that data from an investigator sponsored study that evaluated the use of ferric citrate in patients with advanced chronic kidney disease (CKD) was presented as a late-breaking oral presentation at the 55th annual ERA/EDTA congress in Copenhagen.

The open-label, single-center study evaluated use of ferric citrate compared to standard of care treatment (SOC) in late-stage non-dialysis dependent CKD patients. Patients with eGFR < 20 ml/min who were not anticipated to start renal replacement therapy (dialysis) within 8 weeks of study initiation were randomized 2:1 to receive a fixed dose of ferric citrate (two tablets per meal) or SOC. The data presented today are based on the 199 evaluable patients (133 in the ferric citrate-treated arm, and 66 in the SOC arm) who were seen for at least one follow up visit. Of those randomized to the standard of care arm, 37 percent received phosphate binders during the pre-dialysis period. Patients enrolled in the study were seen monthly for 9 months, or, for those who started dialysis treatment, for three months post dialysis initiation. The data presented today are related to the non-dialysis period of the study (9 months for those who did not progress to dialysis or the time leading up to dialysis for patients who progressed).

“The data from this study suggest that administering ferric citrate to late-stage pre-dialysis patients not only improves biochemical parameters associated with chronic kidney disease, but also has the potential to delay the need for dialysis,” said Geoffrey Block, M.D, Director of Clinical Research at Denver Nephrology. “With the impact of ferric citrate across multiple aspects of CKD, it is worth further investigation to determine which of these many factors is contributing to the reduced risk of renal replacement therapy observed in this study.”

The study evaluated many biochemical parameters associated with CKD, including hemoglobin, transferrin saturation (TSAT), ferritin, phosphorus, and intact-FGF23 in study patients. At baseline, these parameters were consistent between the treatment groups. There were however more patients with diabetes randomly assigned to the standard of care arm. In the ferric citrate treatment group, 76 of the 133 patients completed the full nine months of the study, 30 initiated renal replacement therapy, 16 terminated early, 8 received a transplant and 3 died. In the SOC treatment group, 29 of the 66 patients completed nine months of the study, 31 initiated renal replacement therapy, 4 terminated early and 2 died. At nine months, patients receiving ferric citrate in the non-dialysis period had significant improvements compared to those in the SOC arm in all biochemical parameters measured in this study, as listed in the table below:

Non-Dialysis Period	**Hg (g/dL) mean**		**TSAT (%) mean**		**Ferritin (ng/mL) mean**		**Phosphate (mg/dL) mean**		**Intact FGF23 (pg/mL) median**	
	FC	SOC	FC	SOC	FC	SOC	FC	SOC	FC	SOC
Baseline (FC n=133, SOC n=66)	11.3	11.1	25	23	202	170	4.5	4.4	354	337
Month 9 (FC n = 76, SOC n = 29)	12.1	11.1	32	25	371	220	4.4	4.5	321	558
p-value (Wilcoxon Rank-Sum test, FC vs. SOC at 9 months)	**P=0.002**		**P=0.005**		**P=0.0002**		**P=0.007**		**P=0.01**	

Additionally, the study evaluated the number of patients in each arm that progressed to death, dialysis or transplant in each cohort over the 9 month period. After adjusting for baseline characteristics, patients in the ferric citrate treated arm were less likely to reach this endpoint (for all patients, Cox proportional hazards: HR 0.44, p=0.006, CI 0.25, 0.79; for diabetic patients, HR 0.41, p=0.02, CI 0.2, 0.85).

Conference Call Information

Keryx Biopharmaceuticals will host an investor conference call today, May 25, 2018, at 8:30 a.m. ET to discuss these data. To participate in the conference call, please dial 1-800-263-0877, 1-323-794-2094 (international) and refer to conference ID: 4339584. The call will also be webcast with slides, which will be accessible through the Investors & Media section of the company's website at www.keryx.com. The audio replay will be available at http://www.keryx.com for approximately 15 days after the call.

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 adult patients with chronic kidney disease on dialysis and approved by the FDA on November 6, 2017 for the treatment of iron deficiency anemia in adult 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: Patients with iron overload syndrome, e.g., hemochromatosis, should not take AURYXIA® (ferric citrate).

Iron Overload: Iron absorption from AURYXIA may lead to increased iron in storage sites. Iron parameters should be monitored prior to and while on AURYXIA. 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 overdose of iron containing products is a leading cause of fatal poisoning in children under 6 years of age. Keep AURYXIA away from children. Call a poison control center or your physician in case of an accidental overdose in a child.

Adverse Events: The most common adverse events occurring in at least 5% of patients treated with AURYXIA were, diarrhea, constipation, nausea, vomiting, cough, abdominal pain, and high levels of potassium in the blood.

AURYXIA contains iron and may cause dark stools, which is considered normal with oral medications containing iron.

Please click here to see full Prescribing Information.

About Keryx Biopharmaceuticals, Inc.

Keryx Biopharmaceuticals, Inc., headquartered 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.

Forward-Looking Statements

Some of the statements included in this press release, particularly those regarding the post-hoc analysis and the effectiveness of Auryxia, 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 benefit seen by patients using Auryxia outside of the clinical setting; as well as our ability to successfully market Auryxia and whether we can increase adoption of Auryxia in patients with CKD 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.

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