KERYX BIOPHARMACEUTICALS INC
Form 8-K
April 23, 2014

**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 23, 2014**

**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.)** |

**750 Lexington Avenue**

**New York, New York 10022**

**(Address of Principal Executive Offices)**

**(212) 531-5965**

**(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-2b under the Exchange Act.

¨ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act.

**Item 7.01. Regulation FD**

From time to time, Keryx Biopharmaceuticals, Inc. (the ***Company***) intends to conduct meetings with third parties in which the attached posters are presented. The posters are being presented today at the National Kidney Foundation 2014 Spring Clinical Meeting, taking place April 22-26, 2014 in Las Vegas, NV, and include the following:

- Phosphorus Binding with Ferric Citrate is Associated with Fewer Hospitalizations and Reduced Hospitalization Costs, R. Rodby, poster number 422;
- Economic Impact of Ferric Citrate Versus Standard of Care for Hemodialysis Patients, S. Brunelli, poster number 156;
- Phosphorus Binding with Ferric Citrate Reduces Erythropoiesis-Stimulating Agent (ESA) and IV Iron Usage and Cost in Patients with ESRD, R. Rodby, poster number 415; and
- Zerenex (Ferric Citrate Coordination Complex) for the Treatment of Iron-Deficiency Anemia and Reduction of Serum Phosphate in Non-Dialysis Dependent CKD, G. Block, poster number 423.

Copies of these posters are attached as Exhibits 99.1, 99.2, 99.3 and 99.4, respectively, to this Current Report on Form 8-K and the information contained therein is incorporated herein by reference.

The information in this Item 7.01 and Exhibits 99.1, 99.2, 99.3 and 99.4 shall not be deemed filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the Exchange Act) or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing.

**Item 9.01. Financial Statements and Exhibits.**

(d) Exhibits.

The Company hereby furnishes the following exhibits:

| Exhibit Number | Description |
|---|---|
| 99.1 | Phosphorus Binding with Ferric Citrate is Associated with Fewer Hospitalizations and Reduced Hospitalization Costs, R. Rodby, poster number 422. |
| 99.2 | Economic Impact of Ferric Citrate Versus Standard of Care for Hemodialysis Patients, S. Brunelli, poster number 156 |
| 99.3 | Phosphorus Binding with Ferric Citrate Reduces Erythropoiesis-Stimulating Agent (ESA) and IV Iron Usage and Cost in Patients with ESRD, R. Rodby, poster number 415. |
| 99.4 | Zerenex (Ferric Citrate Coordination Complex) for the Treatment of Iron-Deficiency Anemia and Reduction of Serum Phosphate in Non-Dialysis Dependent CKD, G. Block, poster number 423. |

**Forward-looking Statements**

Some of the statements included in this Form 8-K and the exhibit attached hereto, particularly those relating to the results of clinical trials, the clinical benefits to be derived from Zerenex (ferric citrate coordination complex), regulatory submissions and approvals, the commercial opportunity and competitive positioning, and any business

prospects for Zerenex, 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 the FDA PDUFA goal date for our Zerenex NDA is subject to change and does not guarantee that the review of the NDA will be completed on a timely basis; the risk that the FDA, and/or EMA ultimately deny approval of the U.S. NDA, and/or MAA, respectively; the risk that SPAs are not a guarantee that the FDA will ultimately approve a product candidate following filing acceptance; whether the FDA and EMA will concur with our interpretation of our Phase 3 study results, supportive data, or the conduct of the studies; whether, Zerenex, if approved by the FDA and/or EMA, will be successfully launched and marketed; 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 Form 8-K and the exhibit attached hereto speak only as of the date of this report. We do 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.

**Keryx Biopharmaceuticals, Inc.**
(Registrant)

Date: April 23, 2014

By: /s/ James F. Oliviero
James F. Oliviero, CFA
Chief Financial Officer

**INDEX TO EXHIBITS**

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