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KERYX BIOPHARMACEUTICALS INC
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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): **January 28, 2013**

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 8.01 Other Events.

On January 28, 2013, Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") issued a press release announcing successful top-line results from the long-term Phase 3 study of Zerenex™ (ferric citrate), the Company's ferric iron-based phosphate binder drug candidate, for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with end-stage renal disease (ESRD) on dialysis. A copy of the press release is being filed as Exhibit 99.1 to this report.

Item 9.01 Financial Statements and Exhibits.

The following exhibit to this report shall be deemed filed under the Securities Exchange Act of 1934, as amended.

Exhibit Number	Description
99.1	Press Release dated January 28, 2013

SIGNATURES

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: January 28, 2013

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

INDEX TO EXHIBITS

Exhibit Number	Description
99.1	Press Release dated January 28, 2013

Keryx Biopharmaceuticals Announces Zerenex™ (ferric citrate) Meets Primary and All Key Secondary Endpoints in Phase 3 Long-Term Study as a Treatment for Hyperphosphatemia in End-Stage Renal Disease Patients on Dialysis

Zerenex Significantly Increases Iron Storage Parameters and Decreases Need for Intravenous Iron and Erythropoiesis-Stimulating Agents Versus Active Control

U.S. and European New Drug Application Submissions Anticipated in Second Quarter 2013

Conference Call to Be Held Today, Monday, January 28, 2013, at 8:00 am Eastern Time

New York, NY—(BUSINESS WIRE)—January 28, 2013—Keryx Biopharmaceuticals, Inc. (NASDAQ: KERX) today announced successful top-line results from the long-term Phase 3 study of Zerenex™ (ferric citrate), the Company's ferric iron-based phosphate binder drug candidate, for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with end-stage renal disease (ESRD) on dialysis. In this study, Zerenex met the study's primary endpoint, described below, demonstrating a highly statistically significant change in serum phosphorus versus placebo over the four-week Efficacy Assessment Period of the study. In addition, Zerenex met the key secondary endpoints of increasing ferritin and transferrin saturation (TSAT) and reducing the use of intravenous (IV) iron and erythropoiesis-stimulating agents (ESAs) versus the active control over the 52-week Safety Assessment Period of the study. This long-term study was the final component of the Company's Phase 3 registration program, which was conducted pursuant to a Special Protocol Assessment (SPA) with the Food and Drug Administration (FDA). In April 2011, the Company reported the positive final dataset from the short-term study component of this Phase 3 registration program. The Company expects to submit a New Drug Application (NDA) with the FDA and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for Zerenex in the second quarter of 2013.

Study Design

This Phase 3 long-term study was a multicenter, randomized, open-label, safety and efficacy clinical trial in 441 ESRD patients on hemodialysis or peritoneal dialysis. The study consisted of a 2-week washout period followed by a 52-week Safety Assessment Period in which subjects were randomized 2:1 to receive either Zerenex or an active control (Renvela® [sevelamer carbonate] and/or Phoslo® [calcium acetate]). The 52-week Safety Assessment Period was followed by a 4-week Efficacy Assessment Period. During the Efficacy Assessment Period, only those subjects randomized to treatment with Zerenex during the Safety Assessment Period were randomized in a 1:1 ratio to either continue treatment with Zerenex or switch to placebo for a 4-week treatment period. Subjects were titrated during the study to achieve serum phosphorus levels that ranged between 3.5 to 5.5 mg/dL.

The primary objectives of this study were to determine the long-term safety of KRX-0502 (ferric citrate) in subjects with ESRD undergoing either hemodialysis or peritoneal dialysis, and the efficacy of Zerenex following 52 weeks of treatment in a four-week, randomized, open-label, placebo-controlled Efficacy Assessment Period. Zerenex was administered using a 1 gram oral caplet formulation.

Oral iron therapy was not permitted during the course of the study. IV iron therapy was not permitted if a subject's serum ferritin level was greater than 1,000 ng/mL or the transferrin saturation (TSAT) was greater than 30%. The use of ESAs was at the physician's discretion.

Primary Efficacy Endpoint

The primary efficacy endpoint of this trial was the mean change in serum phosphorus from baseline (Week 52) to end of the four-week Efficacy Assessment Period (Week 56) versus placebo in the Intent-to-Treat (ITT) group. The ITT group included 183 subjects, representing all subjects who took at least one dose of Zerenex or placebo in the Efficacy Assessment Period and provided at least one post-baseline efficacy assessment.

Zerenex met the primary efficacy endpoint with a highly statistically significant result (p<0.0001).

Mean Serum Phosphorus (mg/dL)	**Placebo (n=91)**	**Zerenex (n=92)**
Baseline (Week 52)	5.3	5.2
End of Treatment[1] (Week 56)	7.2	4.9
Change from Baseline at Week 56	1.9	-0.3
Least Squares (LS) Mean Difference from Placebo[2]		-2.3
p-value[2]		p<0.0001

1 Last observation carried forward was used for missing data.

2 The LS Mean treatment difference and p-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Key Secondary Efficacy Endpoints Related to Serum Phosphorus

During the 52-week Safety Assessment Period, Zerenex maintained serum phosphorus in the normal range, with highly statistically significant changes in mean serum phosphorus concentration at Weeks 12, 24, 36, 48, and 52 as compared to baseline (Day 0).

		Week				
n=277	**Baseline**	**12**	**24**	**36**	**48**	**52**
Zerenex Mean Serum Phosphorus (mg/dL)[1]	7.4	5.4	5.2	5.2	5.3	5.3
Change from Baseline		-2.0	-2.2	-2.2	-2.1	-2.1
% Change from Baseline		-27.0%	-29.7%	-29.7%	-28.4%	-28.4%
p-value		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

1 Last observation carried forward was used for missing data.

In addition, as agreed to with the European Medicines Agency (EMA), the treatment difference between Zerenex and Renvela® (sevelamer carbonate) at Week 12 of the Safety Assessment Period in terms of change from baseline (Day 0) in serum phosphorus was analyzed. Zerenex successfully achieved the non-inferiority endpoint versus Renvela®.

Key Secondary Efficacy Endpoints Related to Iron

The objectives of the key iron-related secondary endpoints, which were all pre-specified in the statistical analysis plan, were to corroborate prior data which suggested that Zerenex may increase iron storage parameters and reduce the need for IV iron and/or ESAs. Zerenex met all the key secondary efficacy endpoints related to iron with statistically significant treatment differences versus the active control group (Renvela® [sevelamer carbonate] and/or Phoslo® [calcium acetate]), as follows:

Mean Change in Ferritin

Zerenex demonstrated a statistically significant treatment difference versus the active control group in mean change in serum ferritin from baseline (Day 0) to Week 52.

Mean Ferritin (ng/mL)[1]	**Active Controls (n=134)**	**Zerenex (n=249)**
Baseline (Day 0)	616	595
Week 12	657	751
Week 24	658	847
Week 36	636	863
Week 48	627	882
Week 52	625	897
Change from Baseline at Week 52	9	302
% Change from Baseline	*1.5%*	*50.8%*
LS Mean Difference from Active Control Group at Week 52[2]		286
p-value[2]		p<0.0001

[1] Last observation carried forward was used for missing data.

[2] The LS Mean treatment difference and p-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Mean Change in TSAT

Zerenex demonstrated a statistically significant treatment difference versus the active control group in mean change in TSAT from baseline (Day 0) to Week 52.

Mean TSAT (%)[1]	**Active Controls (n=131)**	**Zerenex (n=244)**
Baseline (Day 0)	31	31
Week 12	31	40
Week 24	32	40
Week 36	30	40
Week 48	29	41
Week 52	30	39
Change from Baseline at Week 52	-1	8
% Change from Baseline	*-3.2%*	*25.8%*
LS Mean Difference from Active Control Group at Week 52[2]		10
p-value[2]		p<0.0001

[1] Last observation carried forward was used for missing data.

[2] The LS Mean treatment difference and p-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Cumulative IV iron Use

Each subject's average cumulative IV iron intake was calculated over the 52-week Safety Assessment Period. The ITT consisted of 278 subjects and 138 subjects for the Zerenex and active control groups, respectively. Zerenex demonstrated a 51.6% decrease in median IV iron intake as compared to the active control group ($p<0.0001$).

Cumulative Erythropoiesis-Stimulating Agent (ESA) Use

Each subject's average cumulative ESA intake was calculated over the 52-week Safety Assessment Period. The ITT consisted of 280 subjects and 141 subjects for the Zerenex and active control groups, respectively. Zerenex demonstrated a 27.1% decrease in median ESA intake as compared to the active control group ($p=0.0322$).

Mean Change in Hemoglobin

Zerenex demonstrated a statistically significant treatment difference versus the active control group in mean change in hemoglobin from baseline (Day 0) to Week 52.

Mean Hemoglobin (g/dL)[1]	**Active Controls (n=130)**	**Zerenex (n=244)**
Baseline (Day 0)	11.7	11.6
Week 52	11.1	11.4
Change from Baseline at Week 52	-0.6	-0.2
LS Mean Difference from Active Control Group at Week 52[2]		0.4
p-value[2]		p=0.0105

[1] Last observation carried forward was used for missing data.

[2] The LS Mean treatment difference and p-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Safety and Tolerability Profile

For reference, subjects previously intolerant to Renvela® (sevelamer carbonate) and/or Phoslo® (calcium acetate) were ineligible to participate in this study. Consistent with previous studies, Zerenex appeared safe and well tolerated in this study. Based on an analysis of safety data, the side-effect profile of Zerenex and the Active Control group appeared similar, with the most common adverse events gastrointestinal-related. The overall rate of gastrointestinal-related adverse events, excluding feces discoloration which is an asymptomatic Zerenex side effect, were 39% Zerenex vs. 44% Active Control. The most common gastrointestinal adverse events were: diarrhea, including soft stools (27% Zerenex vs. 14% Active Control), nausea (14% Zerenex vs. 14% Active Control), vomiting (9% Zerenex vs. 13% Active Control) and constipation (8% Zerenex vs. 5% Active Control). Adverse events were generally characterized as mild to moderate in nature.

The overall serious adverse event rates in the study were 34% Zerenex vs. 43% Active Control. Importantly, there were no clinically meaningful or statistically significant differences between Zerenex and the active control group in serum calcium levels and liver enzymes, as measured by alanine transaminase (ALT) and aspartate transaminase (AST).

The full efficacy and safety data from the study is expected to be presented at a future medical conference.

Dr. Julia Lewis, Professor of Medicine, Department of Nephrology, Vanderbilt University School of Medicine, member of the Executive Committee of the Collaborative Study Group and Study Chair of the Zerenex Phase 3 registration program, commented, "We are very excited by the results announced today. The data from this study confirm that Zerenex is a safe and effective phosphate binder with the added benefit of improving patients' iron levels while utilizing significantly less IV iron and ESAs. There is a clear need for viable alternatives to the marketed phosphate binders, and Zerenex can play a major role by not only providing adequate phosphate binding, but also providing additional benefits."

Ron Bentsur, Chief Executive Officer of Keryx, stated, "We are thrilled by the robust outcome of this pivotal study for Zerenex, particularly with the magnitude of the drug's effect on iron and anemia parameters, which should prominently differentiate Zerenex versus all the currently marketed phosphate binders. We believe that the ability to treat hyperphosphatemia, while also increasing iron storage parameters and reducing the need for IV iron and ESAs, sets a new paradigm for how a phosphate binder can be used to treat patients with end-stage renal disease on dialysis. We believe that these data position Zerenex to potentially become market leader in the phosphate binder market." Mr. Bentsur continued, "We sincerely thank the study investigators and coordinators, and are particularly grateful to the Collaborative Study Group for their expertise, guidance and dedication to the clinical development of Zerenex."

Zerenex is also in Phase 2 development in the U.S. for the management of phosphorus and iron deficiency in anemic patients with Stage 3 to 5 non-dialysis dependent chronic kidney disease.

Keryx holds a worldwide license (except for certain Asian Pacific countries) to Zerenex (ferric citrate) from Panion & BF Biotech, Inc. The Japanese rights are sublicensed by Keryx to Japan Tobacco Inc. (JT) and Torii Pharmaceutical Co., Ltd. (Torii). On January 7, 2013, JT announced the filing of its NDA with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD). The NDA filing is supported by efficacy and safety data from several successfully completed Phase 3 studies in CKD patients with hyperphosphatemia in Japan.

Conference Call Information

Keryx will host a conference call today, January 28, 2013 at 8:00 a.m. Eastern Time to present the top-line results from this long-term Phase 3 study for Zerenex. The conference call can be accessed by dialing 1-877-869-3847 (U.S.), 1-201-689-8261 (outside the U.S.), call-in ID: KERYX. The rebroadcast of the conference call will be available for replay at http://www.keryx.com, for a period of 15 days after the call.

About Special Protocol Assessments

The Special Protocol Assessment (SPA) process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. Final marketing approval depends on the efficacy and safety results, including the adverse event profile, and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 clinical program. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product efficacy or safety. For more information on Special Protocol Assessment, please visit: http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm080571.pdf.

About Hyperphosphatemia

In the United States, according to data from the U.S. Renal Data System, there are approximately 600,000 patients with end-stage renal disease, or ESRD, and the number of ESRD patients is projected to rise in the future. The majority of ESRD patients in the United States, over 400,000, require dialysis. Worldwide, there are approximately 2.8 million patients with ESRD, with the majority of ESRD patients, over 2 million, requiring dialysis. Phosphate retention and the resulting hyperphosphatemia in patients with ESRD on dialysis are usually associated with secondary hyperparathyroidism, renal osteodystrophy, soft tissue mineralization and the progression of renal failure. ESRD patients usually require treatment with phosphate-binding agents to lower and maintain serum phosphorus at acceptable levels. The need for alternative phosphate-binding agents has long been recognized, especially given the increasing prevalence of ESRD as well as shortcomings with current therapies. Zerenex has the potential to be an effective and safe treatment in lowering and/or maintaining normal serum phosphorus levels in patients with ESRD and hyperphosphatemia.

The market for phosphate binders to treat hyperphosphatemia in ESRD patients is approaching $1.5 billion worldwide.

About Keryx Biopharmaceuticals, Inc.

Keryx Biopharmaceuticals is focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of renal disease. Keryx is developing Zerenex (ferric citrate), an oral, ferric iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex has completed a U.S.-based Phase 3 clinical program for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, conducted pursuant to a Special Protocol Assessment (SPA) agreement with the FDA, and Keryx expects to submit an NDA with the FDA and a MAA with the EMA in the second quarter of 2013. Zerenex is also in Phase 2 development in the U.S. for the management of phosphorus and iron deficiency in anemic patients with Stage 3 to 5 non-dialysis dependent chronic kidney disease. In addition, Keryx's Japanese partner, Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd. has filed its New Drug Application for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with chronic kidney disease. Keryx is headquartered in New York City.

Forward-Looking Statements

Some of the statements included in this press release, particularly those relating to the results of clinical trials, and the clinical benefits to be derived from Zerenex (ferric citrate), as well as 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: risks related to the timing for submission of the NDA and MAA and whether the FDA and EMA, respectively, will accept such submissions for review following submission and ultimately approve them; whether the FDA and EMA will concur with the our interpretation of our Phase 3 study results or the conduct of the study; our ability to successfully and cost-effectively complete clinical trials, submit new drug applications and obtain marketing approvals for Zerenex; top-line results are based on a preliminary analysis of then available data (both safety and efficacy) and there is the risk that such findings and conclusions could change following a more comprehensive review of the data; the risk that the data (both safety and efficacy) from the ongoing Phase 2 study in non-dialysis dependent chronic kidney disease will be negative or inconclusive; our ability to meet anticipated development timelines for Zerenex due to clinical trial results, manufacturing capabilities or other factors; our Japanese partner's ability to successfully obtain marketing approval for ferric citrate in Japan; uncertainties related to the regulatory process; whether, if Zerenex receives approval, it will be successfully distributed and marketed; whether the patents and patent applications owned or licensed by the Company will protect the Company's technology and prevent others from infringing it; 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, and the FDA.gov website, is not incorporated by reference into this press release and is included for reference purposes only.