KERYX BIOPHARMACEUTICALS INC
Form 10-K
March 13, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2013.

OR

¨ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____.

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4087132**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**
750 Lexington Avenue	
New York, New York	**10022**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (212) 531-5965

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, Par Value $0.001 Per Share	**NASDAQ Capital Market**
(Title of Class)	**(Name of Each Exchange on Which Registered)**

Securities registered pursuant to Section 12(g) of the Act:

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ¨ No x

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ¨ No x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No ¨

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant s knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ¨

Indicate by check mark whether the registrant is a large accelerated filed, an accelerated filer, a non-accelerated filer or a smaller reporting company. See definitions of large accelerated filer, accelerated filer, and smaller reporting company in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer ¨	Accelerated filer x
Non-accelerated filer ¨	Smaller reporting company ¨

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ¨ No x

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are affiliates) was $597,771,011 as of June 28, 2013, based on the closing sale price of such stock as reported on the NASDAQ Capital Market.

There were 90,912,023 shares of the registrant s common stock outstanding as of March 1, 2014.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the 2014 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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KERYX BIOPHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE FISCAL YEAR ENDED DECEMBER 31, 2013

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This Annual Report on Form 10-K contains trademarks and trade names of Keryx Biopharmaceuticals, Inc., including our name and logo. All other trademarks, service marks, and trade names referenced in this Annual Report on Form 10-K are the property of their respective owners.

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations, may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words anticipate, believe, estimate, may, expect a similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the pre-clinical and clinical development, manufacturing, regulatory approval, and commercialization (including market acceptance) of Zerenex™ (ferric citrate coordination complex) or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Zerenex;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidate;

estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows to finance our operating requirements, including expectations regarding the value and liquidity of our investments;

expected losses;

expectations for future capital requirements; and

ability to estimate costs related to litigation.

The forward-looking statements contained in this report reflect our views and assumptions only as of the date that this report is signed. Except as required by law, we assume no responsibility for updating any forward-looking statements.

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

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PART I

Unless the context requires otherwise, references in this report to Keryx, Company, we, us and our and similar designations refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries.

ITEM 1. BUSINESS.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of pharmaceutical products for the treatment of renal disease. We are developing Zerenex™ (ferric citrate coordination complex), an oral, ferric iron-based compound. We have completed a U.S.-based Phase 3 clinical program for Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with chronic kidney disease, or CKD, on dialysis, conducted pursuant to a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA. Our New Drug Application, or NDA, is currently under review by the FDA with an assigned Prescription Drug User Fee Act, or PDUFA, goal date of June 7, 2014. In addition, in March 2014, we submitted a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, seeking the approval of Zerenex as a treatment for hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD, or NDD-CKD.

We have also completed a U.S.-based Phase 2 study of Zerenex for the management of elevated serum phosphorus levels and iron deficiency anemia in subjects with Stage 3 to 5 NDD-CKD.

In January 2014, our Japanese partner, Japan Tobacco Inc., or JT, and Torii Pharmaceutical Co., Ltd., or Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, to be marketed in Japan by JT s subsidiary, Torii, under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD.

Currently, our only drug candidate is Zerenex. We may engage in business development activities that include seeking strategic relationships for Zerenex, as well as evaluating compounds and companies for in-licensing or acquisition. To date, we have not received approval for the sale of any drug candidate in any market. Therefore, we have not generated any product sales from any drug candidate. We have generated, and expect to continue to generate, revenue from the sublicensing of rights to Zerenex in Japan to our Japanese partner, JT and Torii.

OUR STRATEGY

Our mission is to create long-term stockholder value by acquiring, developing and commercializing pharmaceutical products for the treatment of life-threatening diseases. Our strategy to achieve this mission is to:

- utilize our clinical development capabilities to manage and progress Zerenex, and any drug candidates we may in-license or acquire, through the clinical development and regulatory processes to approval;

- identify and explore licensing, partnership and other business development opportunities for Zerenex, and any drug candidates we may in-license or acquire;

seek to acquire medically important drug candidates in early clinical development; and

commercialize our drug candidate(s), either alone or in partnership, which we believe can provide maximum stockholder value.

CORPORATE INFORMATION

We were incorporated in Delaware in October 1998. We commenced operations in November 1999, following our acquisition of substantially all of the assets and certain of the liabilities of Partec Ltd., our predecessor company that began its operations in January 1997. Our executive offices are located at 750 Lexington Avenue, New York, New York 10022. Our telephone number is 212-531-5965, and our e-mail address is info@keryx.com.

We maintain a website with the address www.keryx.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into,

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this report. You may read and copy any materials we file at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC s website address is http://www.sec.gov.

PRODUCT UNDER DEVELOPMENT

Zerenex (ferric citrate coordination complex)

Overview

Zerenex (ferric citrate coordination complex) is an oral, ferric iron-based compound that has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes and can potentially also treat iron deficiency anemia.

In April 2011, we reported the final results from the Phase 3 short-term efficacy study of Zerenex for the treatment of hyperphosphatemia in patients with CKD on dialysis. Positive top-line results from this Phase 3 short-term study were announced in November 2010.

In January 2013, we announced successful top-line results from our long-term Phase 3 study of Zerenex for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with CKD on dialysis. Updated results were presented in June 2013 at the World Congress of Nephrology. In this study, Zerenex met the study s primary endpoint, 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, or TSAT, and reducing the use of intravenous, or IV, iron and erythropoiesis-stimulating agents, or ESAs, versus the active control group over the 52-week Safety Assessment Period of the study. This long-term Phase 3 study was the final component of our Phase 3 registration program, which was conducted pursuant to an SPA agreement with the FDA. In August 2013, we submitted an NDA to the FDA seeking approval for the marketing and sale of Zerenex. In October 2013, our NDA was accepted for filing by the FDA and was assigned a PDUFA goal date of June 7, 2014. The acceptance for filing of the NDA indicates the determination by the FDA that the application is sufficiently complete to permit a substantive review.

In May 2011, we announced positive Scientific Advice from the EMA for the development of Zerenex for the management and control of serum phosphorus in CKD patients undergoing dialysis, and in NDD-CKD patients. The Scientific Advice from the EMA indicates that our completed Phase 3 program in the U.S., in conjunction with safety data generated from other clinical studies with Zerenex, is considered sufficient to support a European MAA for this indication in CKD patients on dialysis. The Scientific Advice also provided us with a regulatory path forward in the NDD-CKD setting in Europe. As a result, following the successful completion of our Phase 3 program in CKD patient on dialysis, and our Phase 2 study in NDD-CKD patients, we believe that we will not need to conduct any additional clinical trials with Zerenex in order to obtain European approval in the dialysis and NDD-CKD settings. Accordingly, in March 2014, we submitted a MAA with the EMA, for marketing approval in Europe for both dialysis and NDD-CKD.

In January 2013, we announced that JT filed its NDA with the Japanese Ministry of Health, Labour and Welfare, or MHLW, for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD. The Japanese NDA filing was supported by efficacy and safety data from several successfully completed Phase 3 studies in CKD patients with hyperphosphatemia in Japan. In January 2014, JT received manufacturing and

marketing approval of ferric citrate from the MHLW. Ferric citrate, to be marketed in Japan by JT s subsidiary, Torii, under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD.

In November 2013, we announced successful top-line results from the U.S.-based Phase 2 study of Zerenex in managing serum phosphorus and iron deficiency anemia in patients with NDD-CKD. The Phase 2 study was a multicenter, randomized, double-blind, placebo-controlled clinical trial in subjects with Stage 3 to 5 NDD-CKD, with elevated serum phosphorus ³4.0 mg/dL and iron deficiency anemia. The study consisted of a 2-week washout period (for subjects on a phosphate binder at screening) followed by a 12-week treatment period in which subjects were randomized 1:1 to receive either Zerenex or placebo. One hundred forty-nine (149) subjects were randomized into the study from 20 sites in the U.S. In this study, Zerenex met both co-primary endpoints, demonstrating highly statistically significant changes in serum phosphorus and TSAT versus placebo over the 12-week treatment period. In addition, Zerenex met the key secondary endpoints of increasing ferritin and hemoglobin, and decreasing fibroblast growth factor-23, or FGF-23, versus placebo.

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Market Opportunity

In the U.S., 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 continue to rise in the future. The majority of ESRD patients, over 400,000, require dialysis. Worldwide, there are approximately 3 million patients with ESRD, with the majority of ESRD patients, over 2.3 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.

Aluminum-type phosphate binders were widely used in the past. However, the systemic absorption of aluminum from these agents and the potential toxicity associated with their use no longer make this type of binder a viable long-term treatment option.

Calcium-type phosphate binders are commonly used to bind dietary phosphate; however, they promote positive net calcium balance and an increased risk of metastatic calcification in many patients, especially in those patients taking vitamin D analogs and those with adynamic bone disease. Calcification of the cardiovascular system is believed to represent a significant risk factor for morbidity and mortality in patients with CKD.

Non-calcium-based, non-absorbed phosphate binders, including sevelamer hydrochloride and sevelamer carbonate are among the most prescribed phosphate binders in the U.S. Compared to the calcium-type binders, fewer coronary and aortic calcifications have been documented, however, there is a risk of metabolic acidosis with sevelamer hydrochloride, as well as the potential for gastrointestinal problems, and sevelamer can affect concomitant vitamin K and vitamin D treatment.

Lanthanum-type phosphate binders are another alternative. Lanthanum is a rare earth element and is minimally absorbed in the gastrointestinal tract. Lower level tissue deposition, particularly in bone and liver, has been observed in animals. However, the long-term, potentially harmful, effects due to the accumulation of lanthanum in these tissues have not been clearly determined.

The need for alternative phosphate-binding agents has long been recognized, especially given the increasing prevalence of ESRD and shortcomings with current therapies available to such patients.

In addition, it is estimated that more than 10% of the U.S. adult population is affected by NDD-CKD, a condition generally characterized by greater than 50% reduction of normal kidney function. In addition, elevated levels of serum phosphorus become more prevalent in Stage 3 to 5 NDD-CKD patients. Several studies have shown that higher serum phosphorus concentrations may be associated with increased mortality and morbidity in CKD, however, no phosphate binders are currently FDA approved for NDD-CKD.

Iron deficiency anemia, which develops early in the course of CKD and worsens with disease progression, is extremely prevalent in the NDD-CKD population and is associated with fatigue, lethargy, decreased quality of life and is also believed to be associated with cardiovascular complications, hospitalizations, and increased mortality. Based on data contained in a 2009 publication in the Journal of the American Society of Nephrology, it is estimated that over 1.5 million adults with NDD-CKD in the U.S. alone are also afflicted with iron deficiency anemia. To combat this anemia, iron replacement therapy is essential to increase iron stores, which is reflected in ferritin and TSAT levels, and raise hemoglobin levels. Currently available oral iron supplements are associated with limited efficacy and dose-limiting tolerability issues. No oral iron agents are currently FDA approved to treat iron deficiency anemia in NDD-CKD. ESAs and IV iron are not frequently administered in NDD-CKD due to both the FDA boxed warning

label of potential cardiovascular risk for ESAs and logistical complications associated with administering IV medicines in office settings which lack the necessary facilities, such as emergency equipment and/or emergency medical access. Consequently, the NDD-CKD patient population remains underserved.

Zerenex has the potential to be an effective and safe treatment for lowering and/or maintaining serum phosphorus levels, and treating iron deficiency anemia, in patients with CKD on dialysis and NDD-CKD.

CKD on Dialysis: Phase 3 Registration Clinical Program Short-Term Study

In April 2011, we reported the final results from the Phase 3 short-term clinical trial of Zerenex for the treatment of hyperphosphatemia in CKD patients on dialysis. Top-line results from this Phase 3 short-term study were announced in November 2010. The final results were presented at the National Kidney Foundation Spring Clinical Meetings held in Las Vegas, Nevada, in an oral presentation. In this study, conducted pursuant to a SPA agreement with the FDA, Zerenex met the study s primary endpoint, described below, demonstrating a highly statistically significant dose response. In addition, key secondary endpoints were also met.

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Study Design

The Phase 3 short-term study was a multicenter, randomized, open-label trial with a two-week washout period, following which patients were randomized 1:1:1 to receive a fixed dose of Zerenex of either 1 gram, 6 grams or 8 grams per day for a treatment period of 28 days. Zerenex was administered using a 1 gram oral tablet formulation, and the fixed-dose arms of 1 gram, 6 grams and 8 grams per day represented 1, 6 and 8 pills per day, respectively. One hundred fifty-one dialysis patients were enrolled into the study. The ITT group included 146 patients, representing all patients who took at least one dose of Zerenex and provided a Baseline (at the end of washout) and at least one post-Baseline efficacy assessment. Efficacy assessments were taken weekly starting at Baseline and subsequently at days 7, 14, 21 and 28.

Study Results

The primary endpoint of the study was to determine whether there was a dose response in the change in serum phosphorus from Baseline to Day 28 in the ITT group, using a regression analysis to evaluate this objective. The study met the primary endpoint, with the regression analysis indicating a highly statistically significant dose response ($p<0.0001$). Additional efficacy results are as follows:

Mean Serum Phosphorus (mg/dL) ITT (n=146)	**1g/Day (n=50)**	**6g/Day (n=51)**	**8g/Day (n=45)**
Baseline (End of Washout)	7.3	7.6	7.5
Day 28 (End of Treatment)	7.4	5.6	5.3
Change from Baseline at Day 28	0.1	-2.0	-2.2
P-Value		*<0.0001*	*<0.0001*
% Change from Baseline at Day 28	0.5%	-25.7%	-29.6%

In addition, a statistically significant dose response increase in serum bicarbonate was observed in the study, indicating the potential ability of Zerenex to address metabolic acidosis. Metabolic acidosis is a condition that occurs in many dialysis patients when the kidneys do not remove sufficient acid from the body, leading to low blood pH. The consequences of metabolic acidosis can be severe. The inability to manage metabolic acidosis is believed to be a drawback for some of the currently marketed phosphate binders.

Importantly, no clinically meaningful change in serum calcium was observed in the study. Additionally, a statistically significant dose response reduction in calcium-phosphorus product was also observed in the study. Elevated levels of serum calcium, or hypercalcemia, and high levels of calcium-phosphorus product, both of which are believed to be drawbacks from the use of some of the currently marketed phosphate binders, increase the risk of soft tissue calcification and may contribute to the substantial morbidity and mortality seen in patients with ESRD.

Certain iron parameters, including ferritin and TSAT, were measured in the study. Over the 28-day treatment period, modest upward trends in ferritin and TSAT levels were observed in the 6 grams/day and 8 grams/day dose groups.

We believe that Zerenex appeared to be safe and well-tolerated in this clinical study, with no serious adverse events deemed to be drug-related by the Data Safety Monitoring Committee.

CKD on Dialysis: Phase 3 Registration Clinical Program Long-Term Study

In January 2013, we announced successful top-line results from the long-term Phase 3 study of Zerenex for the treatment of hyperphosphatemia in patients with CKD 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 TSAT and reducing the use of IV iron and ESAs versus the active control group (Renvela® [sevelamer carbonate] and/or Phoslo® [calcium acetate]) over the 52-week Safety Assessment Period of the study. This long-term study was the final component of our Phase 3 registration program, which was conducted pursuant to a SPA agreement with the FDA.

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Study Design

This Phase 3 long-term study was a multicenter, randomized, open-label, safety and efficacy clinical trial in 441 CKD 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 Zerenex in subjects with CKD 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 tablet 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 1000 ng/mL or TSAT was greater than 30%. The use of ESAs was at the physician s discretion.

Top line results were as follows:

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, or ITT, group. The ITT group included 182 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=91)**
Baseline (Week 52)	5.4	5.1
End of Treatment[1] (Week 56)	7.2	4.9
Mean Change from Baseline at Week 56	1.8	-0.2
Least Squares (LS) Mean Difference from Placebo[2]		-2.2
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=281	**Baseline**	**12**	**24**	**36**	**48**	**52**
Zerenex Mean Serum Phosphorus (mg/dL)[1]	7.4	5.4	5.3	5.2	5.3	5.4
Mean Change from Baseline		-2.0	-2.1	-2.2	-2.1	-2.0
% Change from Baseline		-27.0%	-28.4%	-29.7%	-28.4%	-27.0%
p-value		<0.0001	<0.0001	<0.0001	<0.0001	<0.0001

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

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In addition, as agreed to with the 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 in a sequential strategy to control overall Type I error rate, 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 pre-defined 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=137)**	**Zerenex (n=253)**
Baseline (Day 0)	610	593
Week 12	649	750
Week 24	651	847
Week 36	633	864
Week 48	622	886
Week 52	632	895
Mean Change from Baseline at Week 52	22	302
% Change from Baseline	*3.6%*	*50.9%*
LS Mean Difference from Active Control Group at Week 52[2]		274
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=137)**	**Zerenex (n=252)**

Baseline (Day 0)	31	31
Week 12	31	40
Week 24	31	40
Week 36	31	40
Week 48	29	41
Week 52	30	39
Mean 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]		9
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.

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Cumulative IV iron Use

Each subject s average cumulative IV iron intake was calculated over the 52-week Safety Assessment Period. The ITT group consisted of 271 subjects and 138 subjects for the Zerenex and active control groups, respectively. Zerenex demonstrated a 51% decrease in median IV iron intake as compared to the active control group (median 1.87 mg/day for Zerenex versus 3.83 mg/day for active control, $p<0.0001$).

Cumulative Erythropoiesis-Stimulating Agent (ESA) Use

Each subject s average cumulative ESA intake was calculated over the 52-week Safety Assessment Period. The ITT group consisted of 273 subjects and 141 subjects for the Zerenex and active control groups, respectively. Zerenex demonstrated a 24% decrease in median ESA intake as compared to the active control group (median 756 units/day for Zerenex versus 993 units/day for active control, $p<0.05$).

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=133)**	**Zerenex (n=248)**
Baseline (Day 0)	11.7	11.6
Week 52	11.2	11.4
Mean Change from Baseline at Week 52	-0.6	-0.2
LS Mean Difference from Active Control Group at Week 52[2]		0.3
p-value[2]		p<0.05

[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, we believe that Zerenex appeared safe and well tolerated in this clinical 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 most common gastrointestinal adverse events were: diarrhea, including soft stools (26% Zerenex vs. 14% Active Control), nausea (14% Zerenex vs. 14% Active Control), feces discoloration (17% Zerenex vs. 0% Active Control), vomiting (9% Zerenex vs. 15% 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 39% Zerenex vs. 49% 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, or ALT, and aspartate transaminase, or AST.

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CKD on Dialysis: Open-Label Safety Extension Study

In November 2013, we announced preliminary, unaudited data from an ongoing 48-week safety extension study of Zerenex for the treatment of hyperphosphatemia in patients with CKD on dialysis. Only patients who had participated in, and successfully completed the 58-week, long-term Phase 3 study were eligible for enrollment into this safety extension study. This extension study, which is not a regulatory requirement, is being conducted in 35 sites in the U.S. The study commenced enrollment in August 2012 and is anticipated to be completed in the first half of 2014.

Patients in the OLE study are titrated to achieve and maintain normal serum phosphorus levels (3.5 to 5.5 mg/dL) for a period of 48 weeks. This study, together with the 58-week, long-term Phase 3 safety and efficacy study, represents potential cumulative exposure to Zerenex of up to 2 years. Enrollment in the study included 168 patients, of which 166 patients were dosed with Zerenex, consisting of 114 and 52 patients from the Zerenex and Active Control arms of the completed long-term Phase 3 study, respectively. The data presented was through October 31, 2013, and appear to corroborate the data observed in the completed long-term Phase 3 study. Key efficacy-related highlights from this preliminary data include:

- Effective control of serum phosphorus within the normal range of 3.5 to 5.5 mg/dL;
- Increase and plateau of TSAT and ferritin at weeks 12 and 24, respectively, with ferritins decreasing after week 36;
- Limited use of IV iron in the study, with 69% of patients not receiving any IV iron throughout the study; and
- Substantially lower use of IV iron and ESAs as compared to national averages, while maintaining hemoglobin.

The data presented appeared to corroborate the results observed in the completed long-term Phase 3 study.

NDD-CKD: Phase 2 Clinical Study

In November 2013, we announced successful top-line results from the U.S.-based Phase 2 study of Zerenex in managing serum phosphorus and iron deficiency anemia in patients with Stage 3 to 5 NDD-CKD. In this study, Zerenex met both co-primary endpoints, demonstrating highly statistically significant changes in serum phosphorus and TSAT versus placebo over the 12-week treatment period. In addition, Zerenex met the key secondary endpoints of increasing ferritin and hemoglobin, and decreasing fibroblast growth factor-23, or FGF-23, versus placebo.

Study Design

This Phase 2 study was a multicenter, randomized, double-blind, placebo-controlled clinical trial in subjects with stage 3 to 5 NDD-CKD, with elevated serum phosphorus ³4.0 mg/dL and iron deficiency anemia. The study consisted of a 2-week washout period (for subjects on a phosphate binder at screening) followed by a 12-week treatment period in which subjects were randomized 1:1 to receive either Zerenex or placebo. One hundred forty-nine (149) subjects were randomized into the study from 20 sites in the United States.

The use of IV iron and ESAs were not permitted within 8 weeks and 4 weeks prior to the study, respectively, and not permitted during the course of the study. Oral iron therapy was also not permitted during the course of the study.

Top line results were as follows:

Co-Primary and Key Secondary Endpoints

Zerenex met both co-primary and all key secondary endpoints with highly statistically significant results. The Intent-to Treat (ITT) group included 141 subjects, representing all subjects who took at least one dose of Zerenex or placebo and provided at least one post-baseline efficacy assessment. The co-primary efficacy endpoints of this trial were the mean changes in serum phosphorus and TSAT from baseline to the end of the 12-week treatment period versus placebo in the ITT group.

Mean Serum Phosphorus (mg/dL)	**Placebo (n=69)**	**Zerenex (n=72)**
Baseline	4.7	4.5
End of Treatment[1] (Week 12)	4.4	3.9
Treatment Difference p-value[2]		p<0.001

[1] Last observation carried forward was used for missing data.
[2] P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

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TSAT (%)	Placebo (n=69)	Zerenex (n=72)
Baseline	21	22
End of Treatment[1] (Week 12)	20	32
Treatment Difference p-value[2]		p<0.001

[1] Last observation carried forward was used for missing data.
[2] P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

The key secondary endpoints of the study were the mean changes in ferritin, hemoglobin and FGF-23 from baseline to the end of the 12-week treatment period versus placebo in the ITT group.

Mean Ferritin (ng/mL)	Placebo (n=69)	Zerenex (n=72)
Baseline	110	116
End of Treatment[1] (Week 12)	106	189
Treatment Difference p-value[2]		p<0.001

[1] Last observation carried forward was used for missing data.
[2] P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Mean Hemoglobin (g/dL)	Placebo (n=69)	Zerenex (n=72)
Baseline	10.6	10.5
End of Treatment[1] (Week 12)	10.4	11.0
Treatment Difference p-value[2]		p<0.001

[1] Last observation carried forward was used for missing data.
[2] P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Mean Intact FGF-23 (pg/mL)	Placebo (n=60)	Zerenex (n=63)
Baseline	263	319
End of Treatment[1] (Week 12)	293	200
Treatment Difference p-value[2]		P=0.017

[1] Last observation carried forward was used for missing data. Intact FGF-23 was assessed at baseline, Week 6 and Week 12.
[2] P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

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Mean C-Terminal FGF-23 (pg/mL)	Placebo (n=60)	Zerenex (n=63)
Baseline	511	468
End of Treatment[1] (Week 12)	579	316
Treatment Difference p-value[2]		p<0.001

[1] Last observation carried forward was used for missing data. C-Terminal FGF-23 was assessed at baseline, Week 6 and Week 12.

[2] P-value is created via an ANCOVA model with treatment as the fixed effect and baseline as the covariate.

Zerenex was also highly statistically significant in its mean changes at Week 12 versus baseline for all the above-mentioned co-primary and key secondary endpoints.

Treatment Failures

Patients were discontinued from the study if they had hemoglobin measurements <9.0 g/dL on two consecutive visits or serum phosphorus measurements ³6.0 mg/dL on two consecutive visits following randomization. Treatment Failures in the study were as follows:

Treatment Failures n (%)	Placebo (n=74)	Zerenex (n=75)
Hemoglobin <9.0 g/dL	9 (12%)	1 (1%)
Serum Phosphorus ³6.0 mg/dL	2 (3%)	0 (0%)

Safety and Tolerability Profile

The safety population in the study included all randomized patients who took at least one dose of study drug. We believe that Zerenex appeared to be safe and well-tolerated in this Phase 2 study, with discontinuation rates of 19% and 32% in the Zerenex and placebo groups, respectively, including Treatment Failures. There were no study discontinuations due to hypophosphatemia in the study.

Serious adverse events occurred in six Zerenex subjects (8%) versus nine placebo subjects (12%). Two deaths were recorded in the study, both from the placebo group. There were no clinically meaningful or statistically significant differences in serum calcium levels and liver enzymes as measured by ALT and AST.

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

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete such development for Zerenex, which is currently our only product candidate. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 1A under the heading Risks Associated with Our Product Development Efforts.

Product candidate	Target indication	Development status	Expected completion of phase	Estimated cost to complete phase
Zerenex (ferric citrate coordination complex)	Hyperphosphatemia in CKD on dialysis	U.S. NDA filed and under review	Mid-2014	$1 - $2 million
Zerenex (ferric citrate coordination complex)	Hyperphosphatemia in CKD	EU MAA submitted	Mid-2015	$2 - $4 million
Zerenex (ferric citrate coordination complex)	Management of serum phosphorus and iron deficiency anemia in NDD-CKD	Phase 3 initiation pending	Mid-2015	$8 - $10 million

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Completion dates and costs in the above table are estimates and are subject to the uncertainties associated with regulatory submissions, clinical trials and the related requirements of development. In the cases where the requirements for regulatory submissions, clinical trials and development programs have not been fully defined, or are dependent on the success of other trials, we cannot estimate trial completion or cost with any certainty. The actual spending on each trial during the year is also dependent on our ability to fund such clinical trials. We therefore direct your attention to Item 7 under the heading Liquidity and Capital Resources.

INTELLECTUAL PROPERTY AND PATENTS

General

Patents and other proprietary rights are very important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents supported by regulatory exclusivity, or are effectively maintained as trade secrets. It is our intention to seek and maintain patent and trade secret protection for our drug candidates and our proprietary technologies. As part of our business strategy, our policy is to actively file patent applications in the U.S. and, when appropriate, internationally to cover methods of use, processes of manufacture, new chemical compounds, pharmaceutical compositions, dosing of the compounds and compositions, and improvements in each of these areas. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. We have a number of patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the U.S. are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability to be extended through the Patent Term Extension program available under 35 U.S.C. § 156, although any such extension could still be minimal.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of a litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope

and validity of third-party proprietary rights. Litigation would involve substantial costs.

Pursuant to our license for Zerenex (ferric citrate coordination complex) with Panion & BF Biotech, Inc., or Panion, we have the exclusive commercial rights to a series of patent applications worldwide, excluding certain Asian-Pacific countries. These patents and patent applications include claims directed to compositions of matter, pharmaceutical compositions, methods of treatment, as well as methods for the manufacture of ferric citrate. We have also filed a patent application directed to formulations of certain ferric citrate drug products.

The patent rights that we own or have licensed relating to Zerenex are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market Zerenex. In particular:

- The first composition of matter and method patent relating to Zerenex in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We cannot assure you that we can obtain any extension of the term of this

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patent for delays caused by FDA regulatory review (the maximum amount of term extension available under the Patent Term Extension provisions of 35 U.S.C. § 156 would extend the term of this patent to February 2022). We have additional composition of matter and use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient (API) of Zerenex), pharmaceutical compositions that include the API, pharmaceutical compositions having ferric citrate in an amount effective to reduce serum phosphate levels, and methods of treating hyperphosphatemia and metabolic acidosis. Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are key, non-interchangeable components of the pharmaceutical product. Upon expiration of U.S. Patent No. 5,753,706, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition as our product, so long as the competitors do not infringe any other patents that we may hold, such as other composition of matter patents and/or method of use patents.

Our methods of use patents only protect the product when used or sold for the claimed methods. However, these types of patents do not limit a competitor from making and marketing a product that is identical to our product that is labeled for an indication that is outside of our patented methods, or for which there is a substantial use in commerce outside of our patented methods.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product(s) or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our product.

Because any potential date for regulatory approval is currently unknown, it is possible that the life of these patents following regulatory approval will be minimal, even if the above-discussed Patent Term Extension is obtained.

Obtaining proof of direct infringement by a competitor for a method of use patent can be difficult because the competitors making and marketing a product may not engage in the patented use. Additionally, obtaining proof that a competitor contributes to, or induces, infringement of a patented method by another can be difficult because an off-label use of a product could prohibit a finding of contributory infringement. In addition, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Zerenex if we obtain regulatory approval, increase the risk that a generic version of Zerenex could enter the market to compete with Zerenex, limit our development and commercialization of Zerenex, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Zerenex. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

Moreover, physicians may prescribe a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent or prosecute.

In addition, any limitations of our patent protection described above may adversely affect the value of our product candidate and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations, pediatric exclusivity or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, such as new chemical entity exclusivity or new formulation

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exclusivity, to provide market exclusivity for a drug candidate. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity provides an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired. We may also seek to utilize market exclusivities in other territories, such as in the EU. We cannot assure that our drug candidate, Zerenex, or any drug candidates we may acquire or in-license, will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

LICENSING AGREEMENTS AND COLLABORATIONS

We have formed strategic alliances with a number of companies for the development, manufacture and commercialization of Zerenex. Our current key strategic alliances are discussed below.

Panion & BF Biotech, Inc.

In November 2005, we entered into a license agreement with Panion. Under the license agreement, we have acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of Zerenex. To date, we have paid an aggregate of $6.6 million to Panion, and Panion is eligible to receive additional payments of up to an aggregate of $5.0 million upon our successful achievement of FDA and EMA market approval, in addition to royalty payments based on a mid-single digit percentage of net sales of Zerenex. The license agreement terminates upon the expiration of our obligations to pay royalties thereunder. In addition, we may terminate the license agreement (i) in its entirety or (ii) with respect to one or more countries of the territory covered by the agreement, in either case upon 90 days notice. We and Panion also have the right to terminate the license agreement upon the occurrence of a breach of a material provision of the license agreement and certain insolvency events.

Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd.

In September 2007 (amended and restated in June 2009), we entered into a sublicense agreement with JT and Torii, JT s pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive rights for the development and commercialization of Zerenex in Japan. The licensing arrangement calls for JT and Torii to pay us up to $100 million in up-front license fees and payments upon the achievement of pre-specified milestones, of which we have received $45 million, including the milestone payment of $10.0 million received in February 2014 for the achievement of the Japanese marketing approval milestone. In addition, upon commercialization, JT and Torii will make royalty payments to us based on a tiered double-digit percentage of net sales of ferric citrate in Japan escalating up to the mid-teens. JT and Torii are responsible for the development and commercialization costs in Japan. The sublicense terminates upon the expiration of all underlying patent rights. Also, JT and Torii may terminate the sublicense agreement with or without cause upon at least six months prior written notice to us. Additionally, either party may terminate the sublicense agreement for cause upon 60 days prior written notice after the breach of any material provision of the sublicense agreement, or after certain insolvency events.

COMPETITION

The pharmaceutical and biotechnology industries are highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Zerenex, currently our only drug candidate, will have to compete with existing therapies. In addition, other companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting with Zerenex, including the treatment of hyperphosphatemia and iron deficiency anemia. Other companies have products or drug

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candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop drug products. Some of these potential competing drugs are further advanced in development than Zerenex and other potential drug candidates we may acquire or in-license, and may be commercialized earlier. Additional information can be found under Item 1A Risk Factors Other Risks Related to Our Business within this report.

SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug candidate for use in clinical trials and for future sales.

We believe that we have established contract manufacturing relationships for the supply of Zerenex to ensure that we will have sufficient material for clinical trials and commercial launch. In addition, we are establishing the basis for long-term commercial production capabilities. We have committed to build inventory in anticipation for the launch of Zerenex in 2014. As with any supply program, obtaining raw materials of the required quality and quantity cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

Prior to the time of commercial sale, to the extent possible and commercially practicable, we intend to seek to engage additional suppliers for Zerenex to produce Zerenex under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which Zerenex can be produced and will have limited experience in manufacturing Zerenex in quantities sufficient for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Administration and corresponding state and foreign government agencies to ensure strict compliance with cGMP and other state and federal regulations and corresponding foreign standards. Any of our contractors in Europe face similar challenges from the numerous European Union and member state regulatory agencies and authorized bodies. We do not have control over third-party manufacturers compliance with these regulations and standards, other than through contractual obligations and periodic auditing. If they are deemed out of compliance with cGMPs, approvals could be delayed, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

If we need to change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay, and disruption of supply. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

GOVERNMENT AND INDUSTRY REGULATION

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidate(s), as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have, or previously had, marketing rights. Before marketing in the U.S., any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the FDCA. The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, testing, packaging, labeling, storage, recordkeeping, distribution, adverse event reporting, advertising, promotion, and the import and export of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical, clinical and manufacturing data and supporting information to the FDA for each indication or use to establish a drug candidate s safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. The approval process takes many years, requires the expenditure of substantial resources including ongoing requirements for post-market surveillance and possibly post-marketing studies. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

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The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the new drug application, or NDA. To receive Fast Track designation, an applicant must demonstrate:

that the drug is intended to treat a serious or life-threatening condition; and

that the drug demonstrates the potential to address unmet medical needs.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. If the FDA determines that the conditions for fast track designation have been met, the FDA will provide a designation letter stating that fast track designation has been granted for development of the drug product for use in treating serious or life-threatening conditions, and informing the sponsor that development studies must show that the product fulfills unmet medical needs. A fast track designation applies to the product coupled with the specific indication for which it is being studied, but not to a product alone.

If the fast track request is incomplete, or the drug development program fails to meet the criteria for fast track designation, the FDA will issue a nondesignation determination. If the sponsor submits a subsequent request for consideration, the FDA will respond to that request within 60 calendar days of receipt of the subsequent request.

Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review of a completed application in six months or less, if the application submission is supported by clinical data, and also may be permitted to submit portions of a NDA to the FDA for review before the complete application is submitted.

Sponsors of drugs designated as fast track also may seek approval under the FDA s accelerated approval regulations. Under this authority, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or an effect on a clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality, taking into account the threat posed by the condition and whether the drug provides a meaningful advantage over available therapies. Accelerated approval based on a surrogate endpoint or an effect on a clinical endpoint other than survival or irreversible morbidity will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence. Failure to conduct such studies, or conducting such studies that do not establish the required safety and efficacy may result in revocation of the original approval. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. In addition, the FDA currently requires as a condition for accelerated approval pre-approval of promotional materials, which could adversely impact the timing of the commercial launch or subsequent marketing of the product.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

Phase 1: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology. In the case of some products for severe or life-threatening diseases, the initial human testing is often conducted in patients having the specific disease.

Phase 2: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

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Phase 3: Studies further evaluate dosage, and establish safety and efficacy in an expanded patient population. Generally, at least two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval.

Phase 4: The FDA may require Phase 4 post-marketing studies to find out more about the drug s long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study, competing clinical trials or other factors;

inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site s review board;

longer treatment time required to demonstrate efficacy or determine the appropriate product dose;

insufficient supply of the drug candidates;

high drop-out rate in the clinical trial;

adverse medical events or side effects in treated patients; and

lack of efficacy of the drug candidates.

In addition, the FDA, equivalent foreign regulatory authority, or a data safety monitoring committee for a trial may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk, or for futility. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Sponsors of drugs may apply for a Special Protocol Assessment (SPA) from the FDA. Through the SPA process, 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. However, final marketing approval depends on the results of efficacy, the

adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in Phase 3 trials. 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 safety or efficacy.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product. Whether or not the FDA requests additional information, there is no assurance that the NDA will be approved.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy, or REMS, as part of a NDA. A REMS plan may contain post-market obligations of the sponsor to, among other things, train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

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As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer s quality control and manufacturing procedures conform to current good manufacturing practices (cGMPs), which are established under FDA regulations. Manufacturers must expend significant time, money and effort to ensure continued compliance, and, in addition to preapproval inspections, the FDA conducts periodic inspections to evaluate continued compliance with cGMP and other requirements. It may be difficult for our manufacturers or us to comply with applicable cGMPs, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may not allow us to market products that have been affected by the failure to comply.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is deemed by the FDA to be safe and effective, as determined by the FDA s review of the clinical studies and other data submitted in the NDA. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any significant changes to manufacturing, drug product, or labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing monitoring and regulation by the FDA, including compliance with cGMPs and the reporting of field alerts and adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in FDA approved labeling, and the promotion and advertising of our products will be subject to comprehensive monitoring, review and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to the FDA. Claims exceeding or deemed inconsistent with those contained in approved labeling, or deemed to be false or misleading, will be deemed by FDA to constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in recalls, warning letters or enforcement actions, including withdrawal of approval, seizure of products, injunctions, fines and/or civil or criminal penalties. In addition, there may be instances in which the U.S. Department of Justice or Office of Inspector General at the U.S. Department of Health & Human Services pursues an enforcement action against our company or our contract manufacturers due to manufacturing or marketing activities or due to alleged kickbacks to health care professionals or false claims to the government if we are able to obtain reimbursement for our product. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products outside the U.S., we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies may apply for foreign marketing authorizations at a national level. However, within the European Union, registration procedures are available to companies wishing to market a product in more than one European Union member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the U.S. or abroad.

RESEARCH AND DEVELOPMENT

Company sponsored research and development expenses (excluding non-cash compensation and discontinued operations) totaled $26,209,000 in 2011, $19,369,000 in 2012 and $32,387,000 in 2013. Other research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-launch inventory, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. See Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations Overview.

EMPLOYEES

As of March 1, 2014, we had 41 full and part-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

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ITEM 1A. RISK FACTORS.

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition and/or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks related to our business

We have a limited operating history and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred substantial operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2013, we had an accumulated deficit of $439.3 million. As we continue our research and development and pre-commercial efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate, Zerenex (ferric citrate coordination complex).

We have not yet commercialized any drug candidate and cannot be sure that we will ever be able to do so. Even if we commercialize Zerenex, or a future drug candidate, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug candidate.

Risks associated with our product development efforts

If we do not receive regulatory approvals to market our product candidate in a timely manner, or at all, our business will be materially harmed and our stock price may be adversely affected.

We are developing Zerenex (ferric citrate coordination complex), an oral, ferric iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. We have completed a U.S.-based Phase 3 clinical program for Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with chronic kidney disease, or CKD, on dialysis, conducted pursuant to a Special Protocol Assessment, or SPA, agreement with the Food and Drug Administration, or FDA, and the Company s New Drug Application, or NDA, was submitted to the FDA for review in August 2013. On October 7, 2013, the FDA accepted for review the NDA that we submitted for Zerenex. We subsequently received the Filing Review Notification, also referred to as the Day 74 letter, which designated a standard 10-month review timeline and a FDA Prescription Drug User Fee Act, or PDUFA, goal date of June 7, 2014, which is the date by which the FDA intends to complete its review and issue a determination. The FDA is not bound by, and has in the past missed, its PDUFA goals, and it is unknown whether the review of our NDA filing for Zerenex will be completed within the FDA review goal or will be delayed.

In May 2011, we announced positive Scientific Advice from the European Medicines Agency, or EMA, for the development of Zerenex for the management and control of serum phosphorus in CKD patients undergoing dialysis, and in non-dialysis dependent CKD patients. The Scientific Advice from the EMA indicates that our successful Phase 3 program in dialysis in the U.S., in conjunction with safety data generated from other clinical studies with Zerenex, will be considered sufficient to support a European marketing authorization application, or MAA, to the EMA for the indication in CKD patients on dialysis. The Scientific Advice also provided us with a regulatory path forward in the non-dialysis dependent CKD setting in Europe. As a result, we believe that since our Phase 3 program in dialysis, and

Phase 2 study in non-dialysis dependent CKD, in the U.S. were successful, we will not need to conduct any additional clinical trials to assess the safety or efficacy of Zerenex in order to obtain European approval in CKD, including the dialysis and non-dialysis dependent CKD settings. Accordingly, in March 2014, we submitted a MAA with the EMA for both dialysis and NDD-CKD. Scientific Advice is legally non-binding and is based on the current scientific knowledge, which may be subject to future changes. Many companies which have been provided with positive Scientific Advice by the EMA have ultimately failed to obtain approval of an MAA for their drugs. Additionally, even if the primary endpoint in a Phase 3, or other pivotal, clinical trial is achieved, the Scientific Advice does not guarantee approval. The EMA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power and analyses, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision, which may delay or prevent EMA approval of Zerenex.

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Obtaining approval of a NDA and MAA by the FDA and EMA, respectively, is highly uncertain and like many product candidates, we may fail to obtain the respective approvals even though our NDA for Zerenex has been filed and accepted for review by the FDA. The NDA and MAA review processes are extensive, lengthy, expensive and uncertain, and the FDA and/or EMA may delay, limit or deny approval of Zerenex for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the respective regulatory authority that Zerenex is safe and effective for any indication;

- the data arising from the clinical trials, including the Phase 3 results for dialysis patients and our recent Phase 2 results for non-dialysis dependent CKD, the development program or the NDA and/or MAA for Zerenex may not be satisfactory to the FDA and/or EMA;

- the respective regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials or conclude that the data fails to meet statistical or clinical significance;

- the respective regulatory authority may not find the data from preclinical and clinical studies sufficient to demonstrate that Zerenex s clinical and other benefits outweigh its safety risks;

- the respective regulatory authority may disagree with our interpretation of data from preclinical studies or clinical trials, and may reject conclusions from preclinical studies or clinical trials, or determine that primary or secondary endpoints from clinical trials were not met, or reject safety conclusions from such studies;

- the respective regulatory authority may not accept data generated at one or more of our clinical trial sites;

- the respective regulatory authority may determine that we did not properly oversee our clinical trials or follow the regulatory authority s advice or recommendations in conducting our clinical trials;

- an advisory committee, if convened by the respective regulatory authority, may recommend against approval of our application or may recommend that the respective regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve Zerenex; and

- the respective regulatory authority may identify deficiencies in the chemistry, manufacturing and controls, or CMC, sections of our NDA, our manufacturing processes, facilities or analytical methods

or those of our third party contract manufacturers, and this may lead to significant delays in the approval of Zerenex or to the rejection of the Zerenex NDA.

Additionally, our March 2014 MAA submission to the EMA was our first MAA filing in Europe. The EMA s review of our MAA submission has not yet commenced and we can provide no assurance that our MAA submission will be accepted for review by the EMA. In addition, during the regulatory review process, regulatory agencies will typically ask questions of drug sponsors. To date, in the NDA review process by the FDA, we have endeavored to answer all such questions in a timely and complete fashion; however, we cannot assure you that our answers to such questions were, and will continue to be, complete and to the satisfaction of the FDA. If certain questions asked by the FDA have not been fully and satisfactorily answered by us, our target PDUFA date may be delayed or our NDA filing may be rejected.

We have conducted two Phase 3 clinical trials initiated in May 2010 and September 2010 for Zerenex as a treatment of hyperphosphatemia in patients with end-stage renal disease pursuant to a SPA agreement with the FDA. Many companies which have been granted SPAs have ultimately failed to obtain final approval to market their drugs. Since we are seeking approval for Zerenex under a SPA, based on protocol designs negotiated with, and agreed to by, the FDA, we may be subject to enhanced scrutiny. Regardless of the success of our Phase 3 clinical trials, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power and analyses, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Additionally, the regulatory approval of new therapies, and other clinical trial results from potential competitors in our proposed indication, could invalidate our SPA agreement, or require us to conduct additional, expensive clinical trials in order to obtain regulatory approval.

Accordingly, we may not receive the regulatory approvals needed to market Zerenex. Any failure or delay in completion of the development program or the FDA and/or EMA review processes would delay or foreclose commercialization of Zerenex and severely harm our business and financial condition.

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete our clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze

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the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same disease that we are studying. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner or at all. In addition, conducting multi-national studies adds another level of complexity and risk. As a result, we may be subject to events affecting countries outside the U.S.

Negative or inconclusive results from the clinical trials we conduct or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials. For example, in May 2012, we abandoned our development efforts and terminated our license for KRX-0401 (perifosine) following negative results from the Phase 3 trial. We may also opt to change the delivery method, formulation or dosage which could affect efficacy results for the drug candidate. Accordingly, we may not be able to complete our current or future clinical trials within an acceptable time frame, if at all.

Pre-clinical testing and clinical development are long, expensive and uncertain processes. If our drug candidate does not receive the necessary regulatory approvals, we will be unable to commercialize our drug candidate, Zerenex.

We have not received, and may never receive, regulatory approval for the commercial sale of any drug candidate. We may need to conduct significant additional research and human testing before we receive product approvals with the FDA, EMA or with regulatory authorities of other countries. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product. It requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. The FDA, EMA or a regulatory authority of another country, as applicable, may pose additional questions or request further toxicological, drug-drug interaction, pre-clinical or clinical data or substantiation. For example, while ferric citrate is a Generally Recognized as Safe, or GRAS, substance in the U.S., and the FDA and EMA have not requested us to conduct a two-year carcinogenicity study in animals, there is no assurance that the FDA, EMA or some other regulatory authority will not ask us to conduct such a study in order to obtain regulatory approval. In addition, the FDA and EMA have not requested us to conduct reproductive toxicity, genotoxicity and single-dose toxicity studies and we are referencing such studies from the published scientific literature in our regulatory submissions. However, we can provide no assurance that the FDA or EMA will not ask us to conduct additional studies. Similarly, while the results of drug-drug interaction studies conducted in vitro have been submitted in the NDA and the MAA, we are currently in the process of conducting additional in-vitro drug-drug interaction studies as requested by the FDA during the NDA review process, which need to be completed prior to the target PDUFA date. While we believe that we will be able to complete these in-vitro studies, as requested, prior to the target PDUFA date, we cannot assure you that such studies will be completed to the satisfaction of the FDA, which could extend the target PDUFA date. In addition, while no requests have been made by the FDA or EMA for in-vivo (human) drug-drug interaction studies, we cannot assure you that the FDA or EMA will not request such studies in the future. Consequently, it may take us many years to complete the testing of our drug candidate and failure can occur at any stage of this process. Negative, inconclusive, or insufficient results or medical events during a pre-clinical or clinical trial could cause us to delay or terminate our development efforts. Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies.

Safety signals detected during clinical studies and pre-clinical animal studies, such as the gastrointestinal bleeding and liver toxicities that have been seen in some high-dose, ferric citrate canine studies, may require us to perform additional safety studies or analyses, which could delay the development of the drug or lead to a decision to discontinue development of the drug. We have submitted to the FDA data from our short-term and long-term rat and canine pre-clinical studies for Zerenex. While the FDA has reviewed the data from these studies and we have conducted our Phase 3 clinical program for CKD patients on dialysis, and Phase 2 study in non-dialysis dependent CKD patients, we can provide no assurance that the FDA will not raise any safety concerns in the future from these studies. Drug candidates in the later stages of clinical development may fail to show the desired traits of safety and efficacy despite positive results in earlier clinical testing. Moreover, the risk remains that the safety and efficacy data from our pivotal Phase 3 program for dialysis dependent CKD patients may be insufficiently persuasive for the approval of the drug, or may raise safety concerns that may prevent approval of the drug, for the indication sought. The risk also remains that a clinical program conducted by one of our partners may raise efficacy or safety concerns that may prevent approval of the drug. In addition, qualitative, quantitative and statistical interpretation of any of the prior pre-clinical and clinical safety and efficacy data of our drug candidate may be viewed as flawed by the FDA, EMA or any other regulatory agency. In addition, there can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted by us or our consultants, which in subsequent, larger studies might appear and prevent approval of such drug candidate. In addition, top-line results reported on completed clinical trials are based on a preliminary analysis of

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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 by a regulatory authority. For example, in January 2013, we announced successful top-line results from our long-term Phase 3 study of Zerenex for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with ESRD on dialysis. Updated results were presented in June 2013 at the World Congress of Nephrology. We can provide no assurance that our findings and conclusions from our long-term Phase 3 study of Zerenex will not change following a more comprehensive review of the data by a regulatory authority.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving what appeared to be promising results in earlier trials. We experienced such a setback with our Phase 3 KRX-0401 (perifosine) results in April 2012, and we can provide no assurance that we will not experience such setbacks with Zerenex or any other drug candidate we develop. If we experience delays in the testing or approval process for our existing drug candidate or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidate may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the U.S. and abroad. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we engage, from time to time, clinical research organizations with experience in conducting regulatory trials, errors in the conduct, monitoring, data capture and analysis, and/or auditing could potentially invalidate the results.

Because all of our proprietary technologies are licensed or sublicensed to us by third parties, termination of these license rights would prevent us from developing and commercializing Zerenex.

We do not own our drug candidate, Zerenex. We have licensed and sublicensed the rights, patent or otherwise, to Zerenex from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Zerenex from one of the inventors of Zerenex. The license agreement with Panion requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Zerenex) and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreement (including upon certain insolvency events), Panion could terminate the agreement, and we would lose the rights to Zerenex. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Zerenex, Panion could lose its license, which could impair or delay our ability to develop and commercialize Zerenex. From time to time, we may have disagreements with our licensors or collaborators, or they and/or we may have disagreements with the original inventors, regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our current, and any future, drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drug candidates. Finally, our rights to develop and commercialize Zerenex, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Zerenex and the licenses and sublicenses we grant to others.

We rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not successfully manufacture and test our drug candidate, our business will be harmed.

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug candidate for use in clinical trials and for future sales. We may not be able to enter into future contract agreements with these third-parties on terms acceptable to us, if at all.

Our ability to conduct clinical trials, manufacture and commercialize our drug candidate will depend on the ability of such third parties to manufacture our drug candidate on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices, or cGMP, and other regulatory requirements, including requirements from federal, state and local environmental and safety regulatory agencies and foreign regulatory requirements, if applicable. Prior to approval, the FDA must review and approve our validation studies for drug substance and drug product. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional validation studies that the FDA must review and approve. Contract manufacturers often encounter difficulties in scaling up production, including problems involving raw material supplies, production yields, technical difficulties, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, changing priorities within the contract manufacturers, compliance with

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FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. Any of these difficulties, if they occur, and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for our drug candidate. These risks become more acute as we scale up for commercial quantities, where a reliable source of raw material supplies and drug substance and drug product processes become critical to commercial success. For example, given the large quantity of materials required for Zerenex production and the large quantities of Zerenex that will be required for commercial success, the commercial viability of Zerenex, if approved, will also depend on adequate supply of starting materials that meet quality, quantity and cost standards and the ability of our contract manufacturers to produce drug substance and drug product in large scale. Failure to achieve this level of supply can jeopardize and prevent the successful commercialization of the product. Moreover, issues that may arise in our current transition to commercial batch sizes with our third party manufacturers of Zerenex can lead to significant delays in our development timelines.

Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidate. In addition, our contract manufacturers will be subject to ongoing periodic and unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with cGMP, as well as other governmental regulations and corresponding foreign standards. While we periodically audit our contractors for adherence to regulatory requirements, and are ultimately held responsible for their regulatory compliance, we cannot assure you that unforeseen changes at these contractors will not occur that could change their regulatory standing. The same issues apply to contract analytical services which we use for quality, impurity and release testing of our drug candidate. We are required by law to have adequate control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract and through periodic oversight, but unforeseen circumstances could affect our third-party manufacturers compliance with applicable regulations and standards. As we continue to scale up production, we continue to develop analytical tools for ferric citrate drug substance and drug product testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to obtain FDA approval. Moreover, even with effective analytical methods available, there is no assurance that we will be able to analyze all the raw materials and qualify all impurities to the satisfaction of the FDA, possibly requiring additional analytical studies, analytical method development, or preclinical studies, which could significantly delay our ability to receive regulatory approval for our drug candidate. Additionally, changes in the analytical specifications required by the FDA or other regulatory authority, such as United States Pharmacopeial Convention standards, from time to time, could delay our ability to receive regulatory approval for our drug candidate. Switching or engaging multiple third-party contractors to produce our drug substance or drug product may be difficult and time consuming because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance or drug product must meet established specifications at each manufacturing facility. It may be difficult and time consuming for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Zerenex, the loss of any of our drug substance or drug product manufacturers would result in significant additional costs and delays in our development program. Moreover, if we need to add or change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties, we may be unable to commercialize our products.

We do not possess all of the capabilities to fully commercialize our product on our own. From time to time, we may need to contract with additional third parties, or renew or revise contracts with existing third parties, to:

manufacture our product candidate;

assist us in developing, testing and obtaining regulatory approval for and commercializing our compound and technologies; and

market and distribute our drug product.

We can provide no assurance that we will be able to successfully enter into agreements with such third parties on terms that are acceptable to us, if at all. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our product independently, which could result in significant delays. Furthermore, such failure could result in the termination of license rights to our product. If these manufacturing, development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our product. We cannot predict the form or scope that any such collaboration might take, and we may

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pursue other strategic alternatives if terms or proposed collaborations are not attractive. To the extent that we rely on third parties to research, develop or commercialize our product, we are unable to control whether such product will be scientifically or commercially successful. Additionally, if these third parties fail to perform their obligations under our agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor and ensure the quality of such work, we may face delays in achieving the business or regulatory milestones required for commercialization of our current, and any future, drug candidate.

Our reliance on third parties, such as clinical research organizations, or CROs, may result in delays in completing, or a failure to complete, clinical trials if such CROs fail to perform under our agreements with them.

In the course of product development, we engage CROs and other vendors to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. If the CROs or applicable vendors fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory or timely manner, we may face significant delays in completing our clinical trials, submitting our regulatory filings, or approval, as well as the commercialization of one or more drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidate(s).

Other Risks Related to Our Business

If we are unable to develop adequate sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to commercialize our product effectively.

In the event our drug candidate is approved by the FDA and or EMA, we may conduct our own sales and marketing effort to support the drug. We currently have limited experience in sales, marketing or distribution. To directly market and distribute any product, we must build and train a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build and train such a sales and marketing organization on our own or with the assistance of a contract sales organization. For some market opportunities, we may want or need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our product. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our product, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive and time consuming than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

From time to time we may consider offers or hold discussions with companies for partnerships or the acquisition of our company or any of our current or future products. Any accepted offer may preclude us from commercializing our product(s) effectively.

Even if we obtain regulatory approval to market Zerenex, if it fails to achieve market acceptance, we may never record meaningful revenues.

Even if Zerenex is approved for sale, it may not be commercially successful in the marketplace. Market acceptance of our drug product will depend on a number of factors, including:

perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidate, including, but not limited to, the perception of the long-term effects of the potential absorption and/or accumulation of ferric iron or citrate resulting from the use of Zerenex;

the marketing claims that the FDA will permit us to make in the labeling and advertising of Zerenex, including potential marketing claims related to the effect of Zerenex on iron storage parameters and on the reduction in the use of IV iron and ESAs;

the rates of adoption of our product by medical practitioners and the target populations for our product;

the potential advantages that our product offers over existing treatment methods and competing products;

the cost-effectiveness of our product relative to competing products, which may be exacerbated as existing treatments go off-patent;

the pricing and pricing strategies for our product;

the availability of government or third-party payor reimbursement for our product;

the side effects or unfavorable publicity concerning our product or similar products; and

the effectiveness of our sales, marketing and distribution efforts.

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Because we expect sales of our product, if approved, to generate substantially all of our revenues in the long-term, the failure of our drug to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue. In addition, our estimates regarding market size and projected growth are based on third party studies, which while we believe them to be reasonable, may not prove to be accurate when Zerenex becomes available in the market. Some of the studies have also observed a slowdown of growth in the incidence of renal disease and patients on dialysis.

In addition, we can provide no assurance that Riona® will be successfully launched and marketed in Japan by our Japanese partner, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd.

If our competitors develop and market products that are less expensive, more effective or safer than our drug product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our drug product obsolete or noncompetitive. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

Zerenex, if approved in the U.S., would have to compete with other FDA approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Genzyme Corporation (a wholly-owned subsidiary of Sanofi), PhosLo® (calcium acetate), marketed by Fresenius Medical Care, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum and magnesium. Our strategy to compete against these existing treatments depends in part on physicians and patients accepting that Zerenex is differentiated in the marketplace versus these FDA approved phosphate binders. In addition, we may have to compete against existing treatments on price, which becomes more challenging as generic versions of these existing treatments come to market. For example, a generic formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the U.S. in October 2008. In addition, upon the expiration of their core patents, generic formulations of Renagel® and Renvela® (expected in the U.S. beginning in March 2014), and generic formulations of Fosrenol®, may be launched, which could have a material effect on the pricing of phosphate binders.

In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug product. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidate and may be commercialized earlier. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors.

If we lose our key personnel or are unable to attract and retain additional personnel, our operations could be disrupted and our business could be harmed.

As of March 1, 2014, we had 41 full and part-time employees. To successfully develop our drug candidate, we must be able to attract and retain highly skilled personnel. Our limited resources may hinder our efforts to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Ron Bentsur, our Chief Executive Officer and Greg Madison, our Chief Operating Officer, our ability to continue to execute on our business plan could be materially impaired. Although we have employment agreements with Mr. Bentsur and Mr. Madison, such agreements do not prevent either of them from terminating their respective employment with us.

Any acquisitions we make may require a significant amount of our available cash and may not be scientifically or commercially successful.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

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Acquisitions involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company s relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to the acquisition;
- the diversion of our management s attention from our core business; and
- the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit our ability to generate revenue.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from:

- government and health administration authorities;
- private health insurers;
- managed care programs; and
- other third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved health care products. Third-party payors, including Medicare and Medicaid, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which for the first time established prescription drug coverage for Medicare beneficiaries, under Medicare Part D. Under this program,

beneficiaries purchase insurance coverage from private insurance companies to cover the cost of their prescription drugs. However, third-party insurance coverage may not be available to patients for our product, if approved. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our product, its market acceptance may be significantly reduced.

Health care reform measures could adversely affect our business.

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the U.S. and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the pricing of healthcare products and services in the U.S. or internationally, the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third party payors. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services, or HHS, in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services, or CMS, issued a proposed regulation covering the calculation of Average Manufacturer Price, or AMP, which is the key variable in the calculation of these rebates.

Furthermore, in the U.S., health care reform legislation titled the Patient Protection and Affordable Care Act, or PPACA, was signed into law in March 2010. The impact of this legislation on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court s decision allows implementation of key provisions impacting drug and device manufacturers to go forward. This includes PPACA changes to the Medicare Part D Program (including closing the donut hole), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the Biologics Price Competition and Innovation Act and the Physician Payments Sunshine Act, both of which were enacted as part of the PPACA. Regulations to implement PPACA could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our product.

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For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The final rule delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, delays by two years the implementation of oral-only end-stage renal disease related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2016. If phosphate binders are included in the bundle beginning in 2016, separate Medicare reimbursement will no longer be available for phosphate binders, as it is today under Medicare Part D. While it is too early to project the impact bundling may have on the phosphate binder industry, the impact could potentially cause dramatic price reductions for phosphate binders, which could significantly reduce the commercial potential of our drug candidate, if approved.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and post-marketing clinical trials related to serious risks, labeling changes based on new safety information, and compliance with risk evaluation and mitigation strategies approved by the FDA. The FDA s exercise of this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA restrictions on the sale or distribution of approved products. Finally, on July 9, 2012, the Food and Drug Administration Safety and Innovation Act was enacted to, among other things, renew the drug user fee program, expand the FDA s inspection records access and require manufacturers to establish appropriate oversight and controls over their suppliers and the supply chain, including raw material suppliers and contract manufacturers, as a part of cGMP compliance.

We face product liability risks and may not be able to obtain adequate insurance.

The use of our drug candidate in clinical trials, and the future sale of any approved drug candidate and new technology, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidate or limit commercialization of any approved product.

We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for a product;

injury to our reputation;

our inability to continue to develop a drug candidate;

withdrawal of clinical trial volunteers; and

loss of revenues.

Consequently, a product liability claim or product recall may result in losses that could be material.

Our corporate compliance efforts cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sale, marketing, and reimbursement of our product(s), together with our general operations, are subject to extensive regulation by federal, state and other authorities within the U.S. and numerous entities outside of the U.S. We are a relatively small company with 41 full and part-time employees as of March 1, 2014. We also have significantly fewer employees than many other companies that have a product candidate in clinical development, and we rely heavily on third parties to conduct many important functions. While we believe that our corporate compliance program is sufficient to ensure compliance with applicable regulations, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, issuance of an enforcement or warning letter, restrictions on our product or manufacturing processes, withdrawal of product(s) from the market, significant fines, or other sanctions or litigation.

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Risks related to our financial condition

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate our business plan. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with the build-up of pre-launch/launch inventory and capacity expansion, the timing and expenditures associated with the respective regulatory review processes for our U.S. NDA and EU MAA filings, the timing and expenditures associated with pre-commercial/commercial activities related to Zerenex, and the timing, design and conduct of clinical trials for Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- the timing and expenditures associated with the build-up of pre-launch/launch inventory and capacity expansion;
- the timing and expenditures associated with the respective regulatory review processes for our U.S. NDA and EU MAA filings;
- the timing and expenditures associated with pre-commercial/commercial activities related to Zerenex;
- the timing, design and conduct of, and results from, clinical trials for Zerenex;
- the timing of expenses associated with manufacturing and product development of Zerenex and those proprietary drug candidates that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under our licensing arrangement;

- the timing and expenses associated with capital expenditures to expand our manufacturing capabilities;

- the timing and expenses associated with building our own commercial infrastructure to manufacture, market and sell our drug candidate and those that may be in-licensed, partnered or acquired;

- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and

- the costs related to litigation.

If our cash is insufficient to meet future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

Risks related to our intellectual property and third-party contracts

If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection on our drug product and technologies, and to successfully defend these patents against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug product and technologies which may have an adverse effect on our business. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus

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reducing any advantage of the patent. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage. As many of the patents we use are licensed or sublicensed from third parties, we may not be able to enforce such licensed patents against third party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. In addition, in jurisdictions outside the U.S. where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

We also rely on trade secrets and know-how to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, licensees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to our drug product and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

The intellectual property that we own or have licensed relating to our drug candidate, Zerenex, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Zerenex.

The patent rights that we own or have licensed relating to Zerenex are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market Zerenex. In particular:

Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are key, non-interchangeable components of the pharmaceutical product. The first composition of matter and method patent relating to Zerenex in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We cannot assure you that we can obtain any extension of the term of this patent for delays caused by FDA regulatory review (the maximum amount of term of extension available under the Patent Term Extension provisions of 35 U.S.C. § 156 would extend the term of this patent to February 2022). Upon expiration of U.S. Patent No. 5,753,706, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition as our product, so long as the competitors do not infringe any other patents that we may hold, such as other composition of matter patents and/or method of use patents. We license additional composition of matter and use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient, or API, of Zerenex), pharmaceutical compositions that include the API, pharmaceutical compositions having ferric citrate in an amount effective to reduce serum phosphate levels, and methods of treating hyperphosphatemia and metabolic acidosis.

Our methods of use patents only protect the product when used or sold for the claimed methods. However, these types of patents do not limit a competitor from making and marketing a product that is identical to our product that is labeled for an indication that is outside of our patented methods, or for which there is a substantial use in commerce outside of our patented methods.

Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product(s) or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our product.

Because any potential date for regulatory approval is currently unknown, it is possible that the life of these patents following regulatory approval will be minimal, even if the above-discussed Patent Term Extension is obtained.

Obtaining proof of direct infringement by a competitor for a method of use patent can be difficult because the competitors making and marketing a product may not engage in the patented use. Additionally, obtaining proof that a competitor contributes to, or induces, infringement of a patented method by another can be difficult because, for example, an off-label use of a product could prohibit a finding of contributory infringement. In addition, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Zerenex if we obtain regulatory approval, increase the risk that a generic version of Zerenex could enter the market to compete with Zerenex, limit our development and commercialization of Zerenex, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Zerenex. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

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Moreover, physicians may prescribe a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may directly infringe or contribute to or induce infringement of method of use patents, such infringement is difficult to prevent or prosecute.

In addition, any limitations of our patent protection described above may adversely affect the value of our product candidate and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

In addition to patent protection, we may utilize orphan drug regulations, pediatric exclusivity or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, such as new chemical entity exclusivity, or NCE, or new formulation exclusivity, to provide market exclusivity for a drug candidate.

Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product.

In the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity provides an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired.

The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a New Chemical Entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full ANDA; however, an applicant submitting a full ANDA would be required to conduct sufficient studies to demonstrate that their generic product is bioequivalent to Zerenex.

We may also seek to utilize market exclusivities in other territories, such as in the EU.

We cannot assure that our drug candidate, Zerenex (ferric citrate coordination complex), or any drug candidates we may acquire or in-license, will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

Litigation or third-party claims could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our product.

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. In addition, third parties may have or may obtain patents in the future and claim that Zerenex or any other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management s attention may be diverted from operating our business. In addition, any legal action against our licensor or us that seeks damages or an injunction of our commercial activities relating to Zerenex or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development,

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marketing and sale of Zerenex or such technologies, and/or require our licensor or us to obtain a license to continue to use Zerenex or other technologies. We cannot predict whether our licensor or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Risks Related to Our Common Stock

Future sales or other issuances of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

On August 2, 2013, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-190353), which the SEC declared effective on August 16, 2013, providing for the offering of up to $150 million of our common stock and warrants to purchase our common stock. Subsequent to the underwritten public offering that was completed on January 23, 2014, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement.

Future issuances of common stock could depress the market for our common stock.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders holdings may be significantly diluted. In addition, stockholders holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

Our stock price can be volatile, which increases the risk of litigation, and may result in a significant decline in the value of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- developments concerning our drug candidate, including the safety and efficacy results from clinical trials and regulatory filings and approvals;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments involving us or our competitors;
- changes in financial estimates by securities analysts;

actual or anticipated variations in quarterly or annual operating results;

expectations regarding our financial condition;

expiration or termination of licenses, research contracts or other collaboration agreements;

developments relating to our intellectual property and those of our competitors, including but not limited to, the commercialization of generic products;

expectations or investor speculation regarding the strength of our intellectual property position, or the availability of regulatory exclusivity;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

changes in the market valuations of similar companies;

negative comments and sentiment in the media; and

additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management s attention and resources, which could seriously harm our business.

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Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

ITEM 1B. UNRESOLVED STAFF COMMENTS.

None.

ITEM 2. PROPERTIES.

Our corporate and executive office is located in New York, New York. Our New York facility consists of approximately 18,500 square feet of leased space at 750 Lexington Avenue, New York, New York 10022, with a lease term through September 30, 2016. We are a party to an office sharing agreement with a third-party for a portion of our leased space through September 29, 2014.

ITEM 3. LEGAL PROCEEDINGS.

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings, except as stated below.

On February 1, 2013, a lawsuit was filed against us and our chief executive officer on behalf of a putative class of all of our shareholders (other than the defendants) who acquired our shares between June 1, 2009 and April 1, 2012. Smith v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-0755-TPG (S.D.N.Y.). On February 26, 2013, a substantially similar lawsuit was filed against us and our chief executive officer as well as our chief financial officer. Park v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-1307-TPG (S.D.N.Y.). On June 10, 2013, the Court entered an Order consolidating the two lawsuits and appointing a lead plaintiff. The case is now styled In re Keryx Biopharmaceuticals, Inc. Securities Litigation, Case No. 1:13-CV-0755-KBF (S.D.N.Y.). On July 10, 2013, the lead plaintiff filed a Consolidated Amended Complaint that, in substance, repeated the claims alleged in the consolidated lawsuits. The Consolidated Amended Complaint asserts claims against (i) us for alleged violations of Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act) and Rule 10b-5 promulgated thereunder and (ii) our chief executive officer for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. The claims in the Consolidated Amended Complaint are premised on general allegations that we and the individual defendant participated directly or indirectly in the preparation and/or issuance of purportedly false and misleading earnings reports, SEC filings, press releases, and other public statements, which allegedly caused our stock to trade at artificially inflated prices. The lead plaintiff seeks an unspecified amount of damages. On August 26, 2013, we filed a motion to dismiss the Consolidated Amended Complaint. On October 10, 2013, lead plaintiff filed an opposition to our motion to dismiss. Our reply in further support of our motion to dismiss was filed on November 12, 2013. On February 14, 2014, the Court entered an Opinion and Order granting the motion to dismiss. The Court

entered Judgment for the Defendants on February 24, 2014. We believe the claims made in this action are without merit, and intend to defend the consolidated action vigorously. We cannot, however, predict the outcome or effect, if any, of the lawsuit on our business.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable

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PART II

ITEM 5. MARKET FOR REGISTRANT S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES.

Market Information

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol KERX.

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

	High	Low
Fiscal Year Ended December 31, 2013		
Fourth Quarter	$ 14.68	$ 8.76
Third Quarter	$ 10.22	$ 7.87
Second Quarter	$ 8.75	$ 6.92
First Quarter	$ 9.08	$ 2.73

	High	Low
Fiscal Year Ended December 31, 2012		
Fourth Quarter	$ 3.14	$ 2.31
Third Quarter	$ 2.83	$ 1.79
Second Quarter	$ 2.16	$ 1.28
First Quarter	$ 5.07	$ 2.51

Holders

The number of record holders of our common stock as of February 14, 2014 was 51.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2013, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1999 Stock Option Plan, as amended, the 2004 Long-Term Incentive Plan, the 2007 Incentive Plan, the 2009 CEO Incentive Plan and the 2013 Incentive Plan.

	Equity Compensation Plan Information		
Plan Category	**Number of securities to be**	**Weighted-average exercise**	**Number of securities**

	issued upon exercise of outstanding options	price of outstanding options	remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	3,245,370	$ 6.75	3,125,002
Equity compensation plans not approved by security holders	600,000	0.35	
Total	3,845,370	$ 5.75	3,125,002

For information about all of our equity compensation plans, see Note 11 to our Consolidated Financial Statements included in this report.

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COMMON STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2008 through December 31, 2013, with the cumulative total return over such period on (i) the U.S. Index of The NASDAQ Stock Market and (ii) the Biotechnology Index of The NASDAQ Stock Market. The graph assumes an investment of $100 on December 31, 2008, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of all dividends. Measurement points are December 31 of each year.

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ITEM 6. SELECTED FINANCIAL DATA.

The following Statement of Operations Data for the years ended December 31, 2013, 2012, 2011, 2010 and 2009, and Balance Sheet Data as of December 31, 2013, 2012, 2011, 2010 and 2009, as set forth below are derived from our audited consolidated financial statements. This financial data should be read in conjunction with Item 7. Management s Discussion and Analysis of Financial Condition and Results of Operations and Item 8. Financial Statements and Supplementary Data.

	Years ended December 31,				
	2013	**2012**	**2011**	**2010**	**2009**
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue:					
License revenue	$ 7,000	$	$ 5,000	$	$ 21,616
Other revenue					3,575
Total revenue	7,000		5,000		25,191
Operating expenses:					
Research and development:					
Non-cash compensation	2,347	662	803	1,236	1,233
Other research and development	32,387	19,369	26,209	13,728	7,372
Total research and development	34,734	20,031	27,012	14,964	8,605
General and administrative:					
Non-cash compensation	3,606	1,505	1,289	1,237	1,867
Other general and administrative	15,743	5,543	5,448	5,014	4,904
Total general and administrative	19,349	7,048	6,737	6,251	6,771
Total operating expenses	54,083	27,079	33,749	21,215	15,376
Operating (loss) income	(47,083)	(27,079)	(28,749)	(21,215)	9,815
Other income:					
Interest and other income, net	351	1,719	380	764	667
(Loss) income from continuing operations before income taxes	(46,732)	(25,360)	(28,369)	(20,451)	10,482
Income taxes					
(Loss) income from continuing operations	(46,732)	(25,360)	(28,369)	(20,451)	10,482

Gain from discontinued operations			246	120	3
(Loss) income before extraordinary gain	(46,732)	(25,360)	(28,123)	(20,331)	10,485
Extraordinary gain		2,639			
Net (loss) income	$ (46,732)	$ (22,721)	$ (28,123)	$ (20,331)	$ 10,485
Basic and diluted (loss) income per common share:					
Continuing operations	$ (0.58)	$ (0.36)	$ (0.42)	$ (0.34)	$ 0.21
Discontinued operations			*	*	*
Extraordinary gain		0.04			
Basic and diluted (loss) income per common share	$ (0.58)	$ (0.32)	$ (0.42)	$ (0.34)	$ 0.21

* Amount less than one cent per share.

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	As of December 31,				
	2013	2012	2011	2010	2009
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents, interest receivable and short-term investment securities	$ 55,696	$ 14,677	$ 39,470	$ 28,512	$ 34,000
Long-term investment securities					1,914
	$ 55,696	$ 14,677	$ 39,470	$ 28,512	$ 35,914
Working capital	$ 41,600	$ 7,068	$ 30,237	$ 22,520	$ 29,489
Total assets	60,766	18,569	43,488	32,114	40,818
Other liabilities	38	36	35	35	50
Contingent equity rights			2,639	2,639	2,639
Total stockholders equity	45,400	10,494	31,047	23,248	32,097

ITEM 7. MANAGEMENT S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in Item 1A. Risk Factors. See also the Special Cautionary Notice Regarding Forward-Looking Statements set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with Item 6. Selected Financial Data, Item 8. Financial Statements and Supplementary Data, and our consolidated financial statements beginning on page F-1 of this report.

Overview

We are a biopharmaceutical company focused on the acquisition, development and commercialization of pharmaceutical products for the treatment of renal disease. We are developing Zerenex™ (ferric citrate coordination complex), an oral, ferric iron-based compound that has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes.

In August 2013, we submitted an NDA to the FDA seeking approval for the marketing and sale of Zerenex in patients with CKD on dialysis. Our NDA submission was based primarily on the datasets derived from our Phase 3 registration program, which was conducted pursuant to an SPA agreement with the FDA, and is also supported by safety and efficacy data from several additional studies, including four Phase 3 studies conducted in Japan in CKD patients on dialysis. In October 2013, our NDA was accepted for filing by the FDA and was assigned a PDUFA goal date of June 7, 2014. The acceptance for filing of the NDA indicates the determination by the FDA that the application is sufficiently complete to permit a substantive review. In addition, in March 2014, we submitted a MAA with the EMA.

In November 2013, we announced successful top-line results from its Phase 2 study of Zerenex in non-dialysis dependent chronic kidney disease patients with elevated serum phosphorus and iron deficiency anemia. In this study, Zerenex met both co-primary endpoints, demonstrating highly statistically significant changes in serum phosphorus and transferrin saturation versus placebo over the 12-week treatment period. In addition, Zerenex met the key

secondary endpoints of increasing ferritin and hemoglobin, and decreasing fibroblast growth factor-23 versus placebo.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, to be marketed in Japan by JT s subsidiary, Torii, under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD.

We may engage in business development activities that include seeking strategic relationships for Zerenex, as well as evaluating compounds and companies for in-licensing or acquisition. To date, we have not received approval for the sale of any drug candidate in any market. Therefore, we have not generated any product sales from any drug candidate. We have generated, and expect to continue to generate, revenue from the sublicensing of rights to Zerenex in Japan to JT and Torii.

In April 2012 we announced that our Phase 3 trial for KRX-0401 (perifosine) for refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine and placebo. Following these results, we abandoned our development efforts and terminated our license relating to the KRX-0401 (perifosine) drug candidate, and re-focused our development efforts on our drug candidate, Zerenex.

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We have devoted substantially all of our efforts to the identification, in-licensing, development and partnering of drug candidates. We have incurred negative cash flow from operations each year since our inception. We anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our product development efforts, our clinical trials, pre-commercial/commercial, partnership and licensing activities.

Our license revenues currently consist of license fees and milestone payments arising from our agreement with JT and Torii. We recognize license revenue in accordance with the revenue recognition guidance of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or the Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

Our other revenues consist of fees and payments arising from technology transfer, termination and settlement agreements related to our prior license agreements.

We have not earned any revenues from the commercial sale of any drug candidate.

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-launch inventory, regulatory, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred. Other research and development expenses, which exclude non-cash compensation and discontinued operations, for the years ended December 31, 2013, 2012 and 2011 were $32,387,000, $19,369,000 and $26,209,000, respectively.

The following table sets forth the other research and development expenses per project, for the periods presented.

	Years ended December 31,		
	2013	**2012**	**2011**
Zerenex (ferric citrate coordination complex)	$ 32,001,000	$ 15,494,000	$ 13,007,000
Other	1,017,000	641,000	1,102,000
Terminated programs (primarily KRX-0401)	(631,000)	3,234,000	12,100,000
Total	$ 32,387,000	$ 19,369,000	$ 26,209,000

Amounts in the above table exclude discontinued operations.

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities, pre-commercial activities and facilities-related expenses.

Our results of operations include non-cash compensation expense as a result of the grants of stock options and restricted stock. Compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual awards. The expense is included in the respective categories of expense in the consolidated statements of operations. We expect to continue to incur significant non-cash compensation expenses.

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the measurement date. The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value

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of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

In addition, certain options and restricted stock issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, therefore the total expense is uncertain until the milestone is met.

Clinical trials are lengthy and expensive. Even though our trials demonstrated that Zerenex is effective in treating certain diseases or conditions, there is no guarantee that we will be able to record commercial sales of Zerenex in the future. In addition, we expect losses to continue as we continue to fund the development of Zerenex, including, but not limited to, new drug application submissions, building of inventory, pre-commercial activities, ongoing and additional clinical trials, and the potential acquisition and development of additional drug candidates in the future. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we are continuing to establish the commercial infrastructure required to manufacture, market and sell Zerenex following approval, if any, by the FDA or regulatory authorities of other countries, which will result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

Corporate

In September 2013, the Board of Directors increased the total number of board members to seven and appointed Daniel P. Regan as a director to fill the newly-created position.

In September 2013, we extended our lease on our corporate and executive office located in New York City, adding approximately 6,800 square feet of additional leased space and extending its term through September 30, 2016.

In January 2014, we formed a subsidiary in the United Kingdom, Keryx Biopharma UK Ltd., related to the submission of our MAA in Europe.

In February 2014, Greg Madison was appointed as Executive Vice President and Chief Operating Officer.

RESULTS OF OPERATIONS

Years Ended December 31, 2013 and 2012

License Revenue. License revenue for the year ended December 31, 2013 was $7.0 million due to the recognition of a non-refundable milestone payment received in January 2013 from JT and Torii following their filing of their 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 CKD. There was no license revenue for the year ended December 31, 2012. We expect to recognize additional license revenue in future periods from our sublicense agreement with JT and Torii. In February 2014, we received a non-refundable milestone payment of $10.0 million related to JT and Torii s achievement of marketing approval in Japan in January 2014. We will also receive royalty payments based on a tiered double-digit percentage of net sales in Japan, as well as up to an additional $55 million upon the achievement of certain annual net sales milestones.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants increased by $1,685,000 to $2,347,000 for the year ended December 31, 2013, as compared to $662,000 for the year ended December 31, 2012. The increase in non-cash compensation expense in the year ended December 31, 2013, as compared to December 31, 2012, was primarily due to the recording of $1.2 million of non-cash compensation expense associated with the vesting of 17,500 stock options and 100,000 shares of restricted stock in October 2013 upon the filing acceptance of our NDA for Zerenex, and also related to the recording of the fair value of equity awards granted to research and development personnel, which are expensed over the vesting periods of the individual awards. We expect our non-cash compensation expense (research and development) to increase in 2014 due to higher fair values of awards granted as compared to those awards granted in previous years and the potential for vesting of additional milestone-based awards.

Other Research and Development Expenses. Other research and development expenses increased by $13,018,000 to $32,387,000 for the year ended December 31, 2013, as compared to $19,369,000 for the year ended December 31, 2012. The

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increase in other research and development expenses was due primarily to a $16,507,000 increase in research and development expenses related to our Zerenex program, including costs associated with the filing of our NDA, preparation of our MAA submission, and manufacturing of pre-launch inventory, partially offset by a $3,866,000 decrease in research and development expenses related to KRX-0401, which license agreement was terminated in May 2012. The year ended December 31, 2013, includes a $1.0 million one-time milestone payment to Panion & BF Biotech, Inc., the licensor of Zerenex, related to our submission of the NDA in August 2013. We expect our other research and development expenses in 2014 to increase modestly due to the build-up of pre-launch inventory and capacity expansion for Zerenex, the $2.0 million one-time milestone payment to Panion for JT and Torii s achievement of the marketing approval milestone in January 2014, and anticipated additional milestone payments to Panion, partially offset by decreased clinical trial and regulatory submission costs.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense (general and administrative) related to equity incentive grants increased by $2,101,000 to $3,606,000 for the year ended December 31, 2013, as compared to $1,505,000 for the year ended December 31, 2012. The increase in non-cash compensation expense in the year ended December 31, 2013, as compared to December 31, 2012, was primarily due to the recording of $1.6 million of non-cash compensation expense associated with the vesting of 150,000 shares of restricted stock in October 2013 upon the filing acceptance of our NDA for Zerenex, and was also related to the recording of the fair value of equity awards granted to general and administrative personnel and directors, which are expensed over the vesting periods of the individual awards. We expect our non-cash compensation expense (general and administrative) to increase in 2014 due to increased general and administrative personnel related to the potential commercialization of Zerenex, higher fair values of awards granted as compared to those awards granted in previous years, and the potential for vesting of additional milestone-based awards.

Other General and Administrative Expenses. Other general and administrative expenses increased by $10,200,000 to $15,743,000 for the year ended December 31, 2013, as compared to $5,543,000 for the year ended December 31, 2012. The increase was primarily related to a $7.2 million increase in pre-commercial activities as we scale-up our operations and infrastructure to prepare to commercialize Zerenex, and a $1.5 million increase in legal fees. We expect our other general and administrative costs to increase in 2014 related to the potential commercialization of Zerenex.

Interest and Other Income, Net. Interest and other income, net, decreased by $1,368,000 to $351,000 for the year ended December 31, 2013, as compared to $1,719,000 for the year ended December 31, 2012. During the year ended December 31, 2012, we were awarded $1.5 million in compensatory damages, net of fees and legal expenses, related to a statement of claim we filed with FINRA against an SEC registered broker-dealer for damages arising from that broker-dealer s recommendations and purchases of certain securities for our cash management account.

Extraordinary Gain. For the year ended December 31, 2012, we recorded a non-cash extraordinary gain of $2,639,000 related to a write-off of the contingent equity rights liability following the termination of the license agreement for KRX-0401.

Years Ended December 31, 2012 and 2011

License Revenue. There was no license revenue for the year ended December 31, 2012. License revenue for the year ended December 31, 2011 was $5.0 million due to the recognition of a non-refundable milestone payment received in April 2011 from JT and Torii for their commencement of a Phase 3 clinical program in Japan.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants decreased by $141,000 to $662,000 for the year ended December 31,

2012, as compared to $803,000 for the year ended December 31, 2011. The decrease in non-cash compensation expense in 2012, as compared to 2011, was primarily related to the recording of the fair value of equity awards granted to research and development personnel, which are expensed over the vesting periods of the individual awards.

Other Research and Development Expenses. Other research and development expenses decreased by $6,840,000 to $19,369,000 for the year ended December 31, 2012, as compared to $26,209,000 for the year ended December 31, 2011. The decrease in other research and development expenses was due primarily to a $8,885,000 decrease in research and development expenses related to the completion in April 2012 of the KRX-0401 Phase 3 study in metastatic colorectal cancer and subsequent termination of the clinical development program and license agreement for KRX-0401 in May 2012. The decrease was partially offset by a $2,487,000 increase in research and development expenses related to our Zerenex Phase 3 clinical program.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense (general and administrative) related to equity incentive grants increased by $216,000 to $1,505,000 for the year ended December 31, 2012, as compared to $1,289,000 for the year ended December 31, 2011. The increase in non-cash compensation expense in 2012, as compared to 2011, was primarily related to the recording of the fair value of equity awards granted to general and administrative personnel and directors, which are expensed over the vesting periods of the individual awards.

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Other General and Administrative Expenses. Other general and administrative expenses increased by $95,000 to $5,543,000 for the year ended December 31, 2012, as compared to $5,448,000 for the year ended December 31, 2011. The increase was due primarily to increased miscellaneous general and administrative expenses, including market research initiatives.

Interest and Other Income, Net. Interest and other income, net, increased by $1,339,000 to $1,719,000 for the year ended December 31, 2012, as compared to $380,000 for the year ended December 31, 2011. The increase was due to the award of $1.5 million in compensatory damages, net of fees and legal expenses, relating to the statement of claim we filed with FINRA against an SEC registered broker-dealer for damages arising from that broker-dealer s recommendations and purchases of auction rate securities for our cash management account.

Gain from Discontinued Operations. For the year ended December 31, 2011, we recorded a $246,000 reversal of previously recorded estimated liabilities associated with the discontinued operations of our services business.

Extraordinary Gain. For the year ended December 31, 2012, we recorded a non-cash extraordinary gain of $2,639,000 relating to a write-off of the contingent equity rights liability following the termination of the license agreement for KRX-0401 in May 2012.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, interest income, and from the upfront and milestone payments from our sublicense agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. We have not yet commercialized a drug candidate and cannot be sure if we will ever be able to do so. Even if we commercialize a drug candidate, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug candidate. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate.

On January 30, 2013, we announced the pricing of an underwritten public offering, whereby we sold 9,469,100 shares of our common stock at a price of $8.49 per share for gross proceeds of approximately $80.4 million. Net proceeds from this offering were approximately $74.8 million, net of underwriting discounts and offering expenses of approximately $5.6 million. The shares were sold under Registration Statements (Nos. 333-171517 and 333-186332) on Form S-3 and Form S-3MEF, respectively, as filed by us with the Securities and Exchange Commission.

As of December 31, 2013, we had $55.7 million in cash and cash equivalents, an increase of $41.0 million from December 31, 2012. On January 22, 2014, we announced the pricing of an underwritten public offering, whereby we sold 7,935,000 shares of our common stock at a price of $14.50 per share for gross proceeds of approximately $115.1 million. Net proceeds from this offering were approximately $107.6 million, net of underwriting discounts and offering expenses of approximately $7.5 million. The shares were sold under a Registration Statement (No. 333-190353) on Form S-3, filed by us with the Securities and Exchange Commission.

We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate our business plan. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with the build-up of prelaunch/launch inventory and capacity expansion, the timing and expenditures associated with the respective regulatory review processes for our U.S. NDA and EU MAA filings, the timing and expenditures associated with pre-commercial/commercial activities

related to Zerenex, and the timing, design and conduct of clinical trials for Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

In accordance with the licensing arrangement with JT and Torii, we may receive payments upon the achievement of pre-specified milestones. In January 2013, JT and Torii filed 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 CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of $7.0 million in January 2013 for the achievement of their NDA filing milestone, which is included as license revenue in our consolidated statement of operations. In February 2014, we received a non-refundable milestone payment of $10.0 million for JT and

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Torii s achievement of the Japanese marketing approval milestone in January 2014. We will also receive royalty payments based on a tiered double-digit percentage of net sales in Japan, as well as up to an additional $55 million upon the achievement of certain annual net sales milestones.

On August 2, 2013, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-190353), which the SEC declared effective on August 16, 2013, providing for the offering of up to $150 million of our common stock and warrants to purchase our common stock. Subsequent to the underwritten public offering that was completed on January 23, 2014, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement. We may offer the securities under our shelf registration statement from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in our best interests and the best interests of our stockholders.

Net cash used in operating activities for the year ended December 31, 2013 was $34.3 million, as compared to $24.8 million for the year ended December 31, 2012. This increase in net cash used in operating activities was primarily related to increased Zerenex development and pre-commercial expenditures, partially offset by the $7.0 million non-refundable milestone payment received from JT and Torii in January 2013 and an increase of $6.8 million in accounts payable and accrued expenses.

For the year ended December 31, 2013, net cash used in investing activities was $346,000, as compared to $4.2 million provided by investing activities for the year ended December 31, 2012. The change was primarily due to the timing of our investments in, and maturities of, held-to-maturity short-term securities.

For the year ended December 31, 2013, net cash provided by financing activities was $75.7 million as compared to no net cash provided by financing activities for the year ended December 31, 2012. The increase was primarily related to net proceeds of $74.8 million received from the public offering of common stock in January 2013.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support, or engages in leasing, hedging, or research and development services on our behalf.

OBLIGATIONS AND COMMITMENTS

As of December 31, 2013, we have known contractual obligations, commitments and contingencies of $22,769,000. Of this amount, $19,921,000 relates to research and development agreements (relating to our Zerenex clinical and manufacturing programs), of which $19,629,000 is due within the next year. Most of these commitments are contingent upon our continuing development of our drug candidate. The additional $2,848,000 relates to our operating lease obligations.

		Payment due by period			
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Research and development agreements	$ 19,921,000	$ 19,629,000	$ 292,000	$	$

Operating leases	2,848,000	949,000	1,899,000		
Total	$ 22,769,000	$ 20,578,000	$ 2,191,000	$	$

The above table includes a $14,817,000 commitment for inventory build expected to be paid in less than one year. The capitalization of inventory for our product candidate will commence when it is probable that our product will be approved for commercial marketing.

Our lease on our corporate and executive office located in New York City extends through September 30, 2016. Our office sharing agreement with a third party for a portion of our leased space extends through September 29, 2014, whereby the third party pays us $13,400 per month. This sublet income is not included as an offset to our operating lease obligations in the table above.

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We have undertaken to make contingent milestone payments to the licensor of Zerenex of up to $7.0 million over the life of the license, which will be due upon the regulatory approvals of Zerenex in the U.S., EU and Japan. The uncertainty relating to the timing of regulatory approvals prevents us from including the entire commitment in the table above. Subsequent to December 31, 2013, we paid a $2.0 million milestone payment to the licensor of Zerenex relating to the marketing approval of ferric citrate in Japan in January 2014, which is not included in the above table.

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our consolidated financial statements, which have been prepared in accordance with GAAP. The preparation of these financial statements requires us to make estimates and judgments that affect the reported amount of assets and liabilities and related disclosure of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

We define critical accounting policies as those that are reflective of significant judgments and uncertainties and which may potentially result in materially different results under different assumptions and conditions. In applying these critical accounting policies, our management uses its judgment to determine the appropriate assumptions to be used in making certain estimates. These estimates are subject to an inherent degree of uncertainty. Our critical accounting policies include the following:

Stock Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. For employee and director grants, the value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock and our assessment of future volatility; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those equity awards expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

Total compensation expense for options and restricted stock issued to consultants is determined at the measurement date. The expense is recognized over the vesting period for the options and restricted stock. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record stock-based compensation expense based on the fair value of the equity awards at the reporting date. These equity awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the

amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Revenue Recognition. We recognize license revenue in accordance with the revenue recognition guidance of the Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified

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objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

We recognize other revenues at the time such fees and payments are earned.

Accounting for Pre-Approval Inventory Expenditures. Pre-approval inventory expenditures are recorded as research and development expenses as incurred. The capitalization of inventory for our product candidate will commence when it is probable that our product will be approved for commercial marketing.

Accounting Related to Goodwill. As of December 31, 2013, there was approximately $3.2 million of goodwill on our consolidated balance sheet. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit s carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit s goodwill is compared with the carrying amount of the unit s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

Accounting For Income Taxes. In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in maintaining the valuation allowance.

RECENTLY ISSUED ACCOUNTING STANDARDS

None.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK.

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We currently invest in government and investment-grade corporate debt in accordance with our investment policy, which we may change from time to time. The securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of December 31, 2013, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA.

Our consolidated financial statements and the notes thereto, included in Part IV, Item 15(a), part 1, are incorporated by reference into this Item 8.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE.

None.

ITEM 9A. CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2013, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2013, our disclosure controls and procedures were effective.

Management s Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework (1992). Our management has concluded that, as of December 31, 2013, our internal control over financial reporting was effective based on these criteria. UHY LLP, our independent registered public accounting firm, has audited the accompanying consolidated balance sheets as of December 31, 2013 and 2012, and the related consolidated statements of operations, comprehensive loss, stockholders equity and cash flows for each of the years in the three-year period ended December 31, 2013, included in this annual report on page F-1. UHY LLP has issued an attestation report on our internal control over financial reporting as of December 31, 2013, which is found below.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal control over financial reporting during the quarter ended December 31, 2013, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

Report of Independent Registered Public Accounting Firm

To the Board of Directors and

Stockholders of Keryx Biopharmaceuticals, Inc.

We have audited Keryx Biopharmaceuticals, Inc. s (the Company) internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting included in Part II, Item 9A of this Form 10-K. Our responsibility is to express an opinion on the Company s internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal

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control over financial reporting was maintained in all material respects. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company s internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company s internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company s assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, Keryx Biopharmaceuticals, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

We have also audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets and the related consolidated statements of operations, stockholders equity, and cash flows of Keryx Biopharmaceuticals, Inc., and our report dated March 13, 2014, expressed an unqualified opinion.

/s/ UHY LLP

New York, New York

March 13, 2014

ITEM 9B. OTHER INFORMATION.

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2014 Annual Meeting of Stockholders.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2014 Annual Meeting of Stockholders.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2014 Annual Meeting of Stockholders.

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ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS AND DIRECTOR INDEPENDENCE.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2014 Annual Meeting of Stockholders.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2014 Annual Meeting of Stockholders.

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PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

(a) 1. Consolidated Financial Statements

The following consolidated financial statements of Keryx Biopharmaceuticals, Inc. are filed as part of this report.

2. Consolidated Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. Exhibits

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007, filed as Exhibit 3.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 and incorporated herein by reference.
3.4	Amendment Number 3 to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated June 18, 2013, filed as Exhibit 3.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed on August 2, 2013 and incorporated herein by

reference.

4.1 Specimen Common Stock Certificate, filed as Exhibit 4.1 to the Registrant s First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein by reference.

10.1 1999 Stock Option Plan, as amended, filed as Exhibit 10.2 to the Registrant s Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.

10.2 Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan, filed with the Registrant s Definitive Proxy Statement for the Annual Meeting of Stockholders on June 10, 2004, filed on April 29, 2004, and incorporated herein by reference.

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10.3!	License Agreement between Keryx Biopharmaceuticals, Inc. and Panion & BF Biotech, Inc. dated as of November 7, 2005, filed as Exhibit 10.21 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2005, filed on March 8, 2006, and incorporated herein by reference.
10.4	Amendment to the Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan dated April 11, 2006, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, filed on August 9, 2006, and incorporated herein by reference.
10.5	2007 Incentive Plan, filed as Annex D to the Registrant s Definitive Proxy Statement on Schedule 14A (File No. 000-30929) filed on April 30, 2007, and incorporated herein by reference.
10.6	Keryx Biopharmaceuticals, Inc. 2013 Incentive Plan, filed with the Registrant s Definitive Proxy Statement for the Annual Meeting of Stockholders on June 18, 2013, filed on April 30, 2013, and incorporated herein by reference.
10.7!	Sub-license Agreement by and among Keryx Biopharmaceuticals, Inc., Japan Tobacco Inc., and Torii Pharmaceutical Co., Ltd. dated September 26, 2007, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed on November 9, 2007, and incorporated herein by reference.
10.8!	Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed on May 12, 2008, and incorporated herein by reference.
10.9!	First Amendment to Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008, filed as Exhibit 10.16 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2008, filed on March 31, 2009, and incorporated herein by reference.
10.10!	Amended and Restated License Agreement dated June 8, 2009, by and between Keryx Biopharmaceuticals, Inc., Japan Tobacco, Inc. and Japan Torii Pharmaceutical Co. Ltd., filed as Exhibit 10.1 to the Registrant s quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed on August 8, 2009, and incorporated herein by reference.
10.11!	License Termination and Technology Transfer Agreement dated May 4, 2012, among AOI Pharma, Inc., Keryx Biopharmaceuticals, Inc., AEterna Zentaris GmbH, filed as Exhibit 10.1 to the Registrant s quarterly report on Form 10-Q for the quarter ended March 31, 2012, filed on May 9, 2012, and incorporated herein by reference.
10.12	Employment Agreement with Ron Bentsur dated September 14, 2009, filed as Exhibit 10.1 to the Registrant s Form 8-K filed on September 16, 2009, and incorporated herein by reference.
10.13	First Amendment to Employment Agreement with Ron Bentsur dated January 13, 2012, filed as Exhibit 10.1 to the Registrant s Form 8-K filed on January 19, 2012, and incorporated herein by reference.
10.14	Second Amendment to Employment Agreement with Ron Bentsur dated June 11, 2013, filed as Exhibit 10.1 to the Registrant s Form 8-K filed on June 13, 2013, and incorporated herein by reference.
10.15	Second Amended and Restated Directors Equity Compensation Plan, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2010, filed on August 9, 2010 and incorporated herein by reference.
10.16	

Change in Control Agreement with James F. Oliviero dated October 31, 2011, as amended on November 3, 2011, filed as Exhibit 10.20 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2011, filed on March 2, 2012, and incorporated herein by reference.

10.17 Second Amendment to Change in Control Agreement with James F. Oliviero dated June 10, 2013, filed as Exhibit 10.2 to the Registrant s Form 8-K filed on June 13, 2013, and incorporated herein by reference.

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21.1	List of subsidiaries of Keryx Biopharmaceuticals, Inc.
23.1	Consent of UHY LLP.
24.1	Power of Attorney of Director and Officers of Keryx Biopharmaceuticals, Inc. (included herein).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
101	The following financial information from Keryx Biopharmaceuticals, Inc. s Annual Report on Form 10-K for the year ended December 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, (v) the Notes to Consolidated Financial Statements.

! Confidential treatment has been granted with respect to the omitted portions of this exhibit.
Indicates management contract or compensatory plan or arrangement.

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Keryx Biopharmaceuticals, Inc.

Consolidated Financial Statements as of December 31, 2013

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and

Stockholders of Keryx Biopharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheets of Keryx Biopharmaceuticals, Inc. (the Company) as of December 31, 2013 and 2012, and the related consolidated statements of operations, stockholders equity, and cash flows for each of the years in the three-year period ended December 31, 2013. The Company s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the consolidated financial position of Keryx Biopharmaceuticals, Inc. as of December 31, 2013 and 2012, and the results of its consolidated operations and its cash flows for each of the years in the three-year period ended December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company s internal control over financial reporting as of December 31, 2013, based on criteria established in *Internal Control Integrated Framework (1992)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated March 13, 2014, expressed an unqualified opinion thereon.

/s/ UHY LLP

New York, New York

March 13, 2014

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Keryx Biopharmaceuticals, Inc.

Consolidated Balance Sheets as of December 31,

(in thousands, except share and per share amounts)

	2013	2012
Assets		
Current assets:		
Cash and cash equivalents	$ 55,696	$ 14,677
Other current assets	1,232	430
Total current assets	56,928	15,107
Property, plant and equipment, net	349	56
Goodwill	3,208	3,208
Other assets, net	281	198
Total assets	$ 60,766	$ 18,569
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,004	$ 7,212
Accrued compensation and related liabilities	1,324	827
Total current liabilities	15,328	8,039
Other liabilities	38	36
Total liabilities	15,366	8,075
Commitments and contingencies (Notes 14 and 15)		
Stockholders equity:		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)		
Common stock, $0.001 par value per share (130,000,000 and 95,000,000 shares authorized, 82,723,145 and 72,002,949 shares issued, 82,643,197 and 71,923,001 shares outstanding at December 31, 2013 and 2012, respectively)	83	72
Additional paid-in capital	485,014	403,387
Treasury stock, at cost, 79,948 shares at December 31, 2013 and 2012, respectively	(357)	(357)
Accumulated deficit	(439,340)	(392,608)

Total stockholders equity	45,400	10,494
Total liabilities and stockholders equity	$ 60,766	$ 18,569

The accompanying notes are an integral part of the consolidated financial statements.

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Operations for the Year Ended December 31,

(in thousands, except share and per share amounts)

	2013	2012	2011
Revenue:			
License revenue	$ 7,000	$	$ 5,000
Total revenue	7,000		5,000
Operating expenses:			
Research and development:			
Non-cash compensation	2,347	662	803
Other research and development	32,387	19,369	26,209
Total research and development	34,734	20,031	27,012
General and administrative:			
Non-cash compensation	3,606	1,505	1,289
Other general and administrative	15,743	5,543	5,448
Total general and administrative	19,349	7,048	6,737
Total operating expenses	54,083	27,079	33,749
Operating loss	(47,083)	(27,079)	(28,749)
Interest and other income, net	351	1,719	380
Loss from continuing operations before income taxes	(46,732)	(25,360)	(28,369)
Income taxes			
Loss from continuing operations	(46,732)	(25,360)	(28,369)
Gain from discontinued operations			246
Loss before extraordinary gain	(46,732)	(25,360)	(28,123)
Extraordinary gain		2,639	

Net loss	$ (46,732)	$ (22,721)	$ (28,123)
Basic and diluted net loss per common share:			
Continuing operations	$ (0.58)	$ (0.36)	$ (0.42)
Discontinued operations			*
Extraordinary gain		0.04	
Basic and diluted net loss per common share	$ (0.58)	$ (0.32)	$ (0.42)
Weighted average shares used in computing basic and diluted net loss per common share	81,009,561	71,633,464	67,370,354

* Amount less than one cent per share.

The accompanying notes are an integral part of the consolidated financial statements.

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Stockholders Equity

for the Years Ended December 31, 2013, 2012 and 2011

(in thousands, except share amounts)

	Common stock		Additional paid-in	Treasury stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	deficit	Total
Balance at January 1, 2011	61,521,483	$ 62	$ 365,307	79,948	$ (357)	$ (341,764)	$ 23,248
Issuance of common stock in public offering (net of offering costs of $2,266)	7,021,277	7	30,727				30,734
Issuance of restricted stock	206,450	*					*
Forfeiture of restricted stock	(28,338)	( )*					( )*
Issuance of common stock in connection with the exercise of options	2,382,027	2	3,094				3,096
Compensation in respect of options and restricted stock granted to employees, directors and third-parties			2,092				2,092
Net loss						(28,123)	(28,123)
Balance at December 31, 2011	71,102,899	$ 71	$ 401,220	79,948	$ (357)	$ (369,887)	$ 31,047
Issuance of restricted stock	997,300	1					1
Forfeiture of restricted stock	(97,250)	( )*					( )*
Compensation in respect of options and restricted stock granted to employees, directors and third-parties			2,167				2,167
Net loss						(22,721)	(22,721)
Balance at December 31, 2012	72,002,949	$ 72	$ 403,387	79,948	$ (357)	$ (392,608)	$ 10,494
Issuance of common stock in public offering (net of offering	9,469,100	10	74,743				74,753

costs of $5,640)							
Issuance of restricted stock	831,020	1					1
Forfeiture of restricted stock	(23,737)	( )*					( )*
Issuance of common stock in connection with the exercise of options	443,813	*	931				931
Compensation in respect of options and restricted stock granted to employees, directors and third-parties			5,953				5,953
Net loss						(46,732)	(46,732)
Balance at December 31, 2013	82,723,145	$ 83	$ 485,014	79,948	$ (357)	$ (439,340)	$ 45,400

* *Amount less than one thousand dollars.*

The accompanying notes are an integral part of the consolidated financial statements.

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Cash Flows for the Year Ended December 31,

(in thousands)

	2013	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (46,732)	$ (22,721)	$ (28,123)
Gain from discontinued operations			246
Extraordinary gain		2,639	
Loss from continuing operations	(46,732)	(25,360)	(28,369)
Adjustments to reconcile loss from continuing operations to cash flows used in operating activities of continuing operations:			
Stock compensation expense	5,953	2,167	2,092
Depreciation and amortization	54	35	47
Changes in assets and liabilities, net of effects of acquisitions:			
(Increase) decrease in other current assets	(802)	104	(334)
Decrease (increase) in accrued interest receivable		7	(7)
Increase in security deposits			(51)
(Increase) decrease in other assets	(83)	11	(21)
Increase (decrease) in accounts payable and accrued expenses	6,792	(1,658)	3,592
Increase (decrease) in accrued compensation and related liabilities	497	(70)	228
Increase in other liabilities	2	1	
Net cash used in operating activities of continuing operations	(34,319)	(24,763)	(22,823)
Net cash provided by operating activities of discontinued operations			1
Net cash used in operating activities	(34,319)	(24,763)	(22,822)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(346)	(24)	(57)
Investment in held-to-maturity short-term securities	(24,403)	(11,263)	(9,941)
Proceeds from maturity of held-to-maturity short-term securities	24,403	15,475	5,830
Net cash (used in) provided by investing activities	(346)	4,188	(4,168)
CASH FLOWS FROM FINANCING ACTIVITIES			

Proceeds from public offerings, net	74,753		30,734
Proceeds from exercise of options	931		3,096
Net cash provided by financing activities	75,684		33,830
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	41,019	(20,575)	6,840
Cash and cash equivalents at beginning of year	14,677	35,252	28,412
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 55,696	$ 14,677	$ 35,252

The accompanying notes are an integral part of the consolidated financial statements.

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Keryx Biopharmaceuticals, Inc.

Notes to the Consolidated Financial Statements

Unless the context requires otherwise, references in this report to Keryx, Company, we, us and our refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries.

NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF BUSINESS

We are a biopharmaceutical company focused on the acquisition, development and commercialization of pharmaceutical products for the treatment of renal disease. Currently, our only drug candidate is Zerenex™ (ferric citrate coordination complex), an oral, ferric iron-based compound. Our New Drug Application (NDA), for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with chronic kidney disease (CKD) on dialysis, is currently under review by the Food and Drug Administration (FDA) with an assigned Prescription Drug User Fee Act (PDUFA) goal date of June 7, 2014. In addition, in March 2014, we submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) seeking the approval of Zenerex as a treatment for hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD.

We own a 100% interest in each of ACCESS Oncology, Inc. (ACCESS Oncology), Neryx Biopharmaceuticals, Inc., and Accumin Diagnostics, Inc. (ADI), all inactive U.S. corporations incorporated in the State of Delaware. Most of our biopharmaceutical development and substantially all of our administrative operations during 2013, 2012 and 2011 were conducted in the U.S.

LIQUIDITY AND CAPITAL RESOURCES

Except for 2009, we have incurred substantial operating losses since our inception, and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2013, we have an accumulated deficit of $439.3 million.

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, interest income, and from the upfront and milestone payments from our Sublicense Agreement with Japan Tobacco Inc. (JT) and Torii Pharmaceutical Co., Ltd. (Torii) and miscellaneous payments from our other prior licensing activities. We have not yet commercialized any drug candidate and cannot be sure if we will ever be able to do so. Even if we commercialize a drug candidate, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug candidate alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate, if approved.

In January 2013, we raised approximately $74.8 million, net of underwriting discounts and offering expenses of approximately $5.6 million, in an underwritten public offering. In January 2014, we raised approximately $107.6 million, net of underwriting discounts and offering expenses of approximately $7.5 million, in an underwritten public

offering. We have a shelf registration statement on Form S-3 filed and declared effective by the Securities and Exchange Commission in August 2013, which provides for the offering of up to $150 million of common stock and warrants in the aggregate. Subsequent to the underwritten public offerings that were completed in January 2013 and January 2014, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement.

We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate our business plan. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with the build-up of prelaunch/launch inventory and capacity expansion, the timing and expenditures associated with the respective regulatory review processes for our U.S. NDA and EU MAA filings, the timing and expenditures associated with pre-commercial/commercial activities related to Zerenex, and the timing, design and conduct of clinical trials for Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

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Our common stock is listed on the NASDAQ Capital Market and trades under the symbol KERX.

CORPORATE

In September 2013, the Board of Directors increased the total number of board members to seven and appointed Daniel P. Regan as a director to fill the newly-created position.

In February 2014, Greg Madison was appointed as Executive Vice President and Chief Operating Officer.

RECENTLY ISSUED ACCOUNTING STANDARDS

None.

PRINCIPLES OF CONSOLIDATION

The consolidated financial statements include our financial statements and those of our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

USE OF ESTIMATES

The preparation of financial statements in conformity with U.S. generally accepted accounting principles (GAAP) requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to the financial statements.

CASH AND CASH EQUIVALENTS

We treat liquid investments with original maturities of three months or less when purchased as cash and cash equivalents.

INVESTMENT SECURITIES

We were not invested in investment securities at December 31, 2013 and 2012, respectively.

PROPERTY, PLANT AND EQUIPMENT

Property, plant and equipment are stated at historical cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets:

	Estimated useful life (years)
Office furniture and equipment	3-7
Computers, software and related equipment	3

Leasehold improvements are amortized over the shorter of their useful life or the remaining term of the lease exclusive of renewal options.

PATENT COSTS

We expense patent maintenance costs as incurred. We have classified our patent expenses in other general and administrative.

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REVENUE RECOGNITION

We recognize license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification (the Codification). We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract (see Note 9 License Agreements).

Other revenue consists of fees and payments arising from technology transfer, termination and settlement agreements related to our prior license agreements. Other revenues are recognized at the time such fees and payments are earned.

RESEARCH AND DEVELOPMENT COSTS

Research and development costs are expensed as incurred. Pre-approval inventory expenditures are recorded as research and development expense as incurred. The capitalization of inventory for our product candidate will commence when it is probable that our product will be approved for commercial marketing. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations (CROs) and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

INCOME TAXES

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in operations in the period that includes the enactment date. If the

likelihood of realizing the deferred tax assets or liability is less than more likely than not, a valuation allowance is then created.

We, and our subsidiaries, file income tax returns in the U.S. federal jurisdiction and in various states. We have tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they were generated for tax purposes. Since a portion of these net operating loss carryforwards may be utilized in the future, many of these net operating loss carryforwards will remain subject to examination.

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We are continuing our practice of recognizing interest and penalties related to uncertain income tax positions in income tax expense.

STOCK - BASED COMPENSATION

We recognize all share-based payments to employees and to non-employee directors for service on our board of directors as compensation expense in the consolidated financial statements based on the grant date fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For share-based payments to consultants and other third-parties, compensation expense is determined at the measurement date. The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. The awards to consultants and other third-parties are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date.

BASIC AND DILUTED NET LOSS PER COMMON SHARE

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options outstanding as of December 31, 2013, 2012 and 2011, which are not included in the computation of net loss per share amounts, were 3,845,370, 3,401,671 and 3,517,000, respectively. No warrants were outstanding during each of these periods.

SEGMENT REPORTING

Following the discontinuation of the Services segment in December 2011, we have determined that we operate in only one reportable segment: the Products segment.

ACQUISITIONS

We adopted ASC Topic 805, Business Combinations, as of January 1, 2009. The adoption of ASC Topic 805 was effective on a prospective basis. Prior to the adoption of ASC Topic 805, we accounted for acquired businesses using the purchase method of accounting which required that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Our consolidated financial statements and results of operations through 2008 reflected an acquired business after the completion of the acquisition and were not retroactively restated. The cost to acquire a business, including transaction costs, was allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired was recorded as goodwill. Any excess of the net assets acquired over the purchase price represented negative goodwill.

IMPAIRMENT

Long lived assets are reviewed for an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management s policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as

well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized.

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Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit s carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit s goodwill is compared with the carrying amount of the unit s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. As of December 31, 2011, 2012 and 2013, management conducted its annual assessments of goodwill and concluded that there were no impairments. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

CONCENTRATIONS OF CREDIT RISK

We do not have significant off-balance-sheet risk or credit risk concentrations. We maintain our cash and cash equivalents and held-to-maturity investments, when applicable, with multiple financial institutions that invest in investment-grade securities with average maturities of less than twelve months. See Note 3 Investment Securities and Note 4 Fair Value Measurements.

NOTE 2 - CASH AND CASH EQUIVALENTS

(in thousands)	December 31, 2013	December 31, 2012
Money market funds	$ 29,904	$ 7,137
Checking and bank deposits	25,792	7,540
Total	$ 55,696	$ 14,677

A significant portion of our cash is maintained in Federal Deposit Insurance Corporation (FDIC) insured accounts at credit qualified financial institutions. At times, such amounts may exceed the FDIC insurance limits. At December 31, 2013, uninsured cash balances totaled approximately $55.4 million.

NOTE 3 - INVESTMENT SECURITIES

We were not invested in investment securities at December 31, 2013 and 2012, respectively.

NOTE 4 - FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

Level 1 quoted prices in active markets for identical assets and liabilities;

Level 2 inputs other than Level 1 quoted prices that are directly or indirectly observable; and

Level 3 unobservable inputs that are not corroborated by market data.

We review investment securities for impairment and to determine the classification of the impairment as temporary or other-than-temporary. Losses are recognized in our consolidated statement of operations when a decline in fair value is determined to be other-than-temporary. We review our investments on an ongoing basis for indications of possible impairment. Once identified, the determination of whether the impairment is temporary or other-than-temporary requires significant judgment.

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The following table provides the fair value measurements of applicable financial assets as of December 31, 2013 and 2012:

(in thousands)	Financial assets at fair value as of December 31, 2013 Level 1	Level 2	Level 3
Money market funds (1)	$ 29,904	$	$
Total	$ 29,904	$	$

(in thousands)	Financial assets at fair value as of December 31, 2012 Level 1	Level 2	Level 3
Money market funds (1)	$ 7,137	$	$
Total	$ 7,137	$	$

(1) Included in cash and cash equivalents on our consolidated balance sheet. The carrying amount of money market funds is a reasonable estimate of fair value.

NOTE 5 - PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2013	December 31, 2012
Leasehold improvements	$ 32	$ 20
Office furniture and equipment	556	329
Computers, software and related equipment	638	530
	1,226	879
Accumulated depreciation and amortization	(877)	(823)
Net book value	$ 349	$ 56

Depreciation expense for the years ended December 31, 2013, 2012 and 2011 was approximately $54,000, $35,000 and $47,000, respectively. The following table summarizes depreciation expense for the years ended December 31, 2013, 2012 and 2011.

(in thousands)	For the year ended December 31 2013	2012	2011
Depreciation expense:			
Research and development	32	21	28
General and administrative	22	14	19
Total	$ 54	$ 35	$ 47

NOTE 6 - GOODWILL

On April 6, 2006, ADI, our wholly-owned subsidiary, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. The purchase price of Accumin was $3,996,000. We accounted for the ADI transaction as a purchase. The excess of the purchase price over the net assets acquired in the ADI transaction represented goodwill of approximately $3,208,000, which was allocated to our Products segment based on the proposed synergies with our then existing drug pipeline activities. In September 2008, we terminated our license agreement related to the ADI product.

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NOTE 7 - OTHER ASSETS

(in thousands)	December 31, 2013	December 31, 2012
Patents and other indefinite-lived intangible assets	$ 352	$ 352
Deposits	163	163
Deferred registration fees	118	35
	633	550
Accumulated amortization	(352)	(352)
	$ 281	$ 198

There were no amortization expenses for the years ended December 31, 2013, 2012 and 2011. We do not expect to record amortization expenses going forward, as all intangible assets are fully amortized.

NOTE 8 - DISCONTINUED OPERATIONS

In December 2011, we ceased the operations of Online Collaborative Oncology Group, which was providing clinical trial management and site recruitment services and ceased all operations related to the Services segment. The results of our Services segment and the related financial positions have been reflected as discontinued operations in the consolidated financial statements. The consolidated financial statements have been reclassified to conform to a discontinued operations presentation for all historical periods presented.

For the year ended December 31, 2011, we recorded a reversal of previously recorded estimated liabilities associated with our discontinued operations of $246,000. Summarized selected financial information for discontinued operations are as follows:

	For the year ended December 31		
(in thousands)	2013	2012	2011
Service revenue	$	$	$ 156
Operating expenses:			
Cost of services			(90)
Total operating income			246
Gain from discontinued operations	$	$	$ 246

NOTE 9 - LICENSE AGREEMENTS

In September 2007, we entered into a Sublicense Agreement with JT and Torii, JT s pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive sublicense rights for the development and

commercialization of ferric citrate in Japan, which is being developed in the U.S. under the trade name Zerenex. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective as of June 8, 2009, we entered into an Amended and Restated Sublicense Agreement (the Revised Agreement) with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the sublicense agreement.

In April 2011, JT and Torii commenced a Phase 3 clinical program of ferric citrate in Japan. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of $5.0 million in April 2011 for the achievement of the Phase 3 commencement milestone. As a result, we recorded license revenue of $5.0 million in accordance with our revenue recognition policy, which is included in the year ended December 31, 2011.

In January 2013, JT and Torii filed 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 CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of $7.0 million in January 2013 for the achievement of the NDA filing milestone. As a result, we recorded license revenue of $7.0 million in accordance with our revenue recognition policy, which is included in the year ended December 31, 2013.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, to be marketed in Japan by JT s subsidiary, Torii

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Pharmaceutical Co., Ltd., under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, Keryx received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. Keryx will also receive double-digit tiered royalties on net sales of Riona® in Japan, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

On April 2, 2012, we reported that the Phase 3 X-PECT (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) clinical trial evaluating perifosine (KRX-0401) + capecitabine (Xeloda) in patients with refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine + placebo. On May 4, 2012, we executed a License Termination and Technology Transfer Agreement with Aeterna Zentaris GmbH (Zentaris), whereby the license agreement for KRX-0401 (perifosine) was terminated, and in exchange for the transfer of the U.S. Investigational New Drug Application, development data, intellectual property and contracts to Zentaris, we will receive a royalty on future net sales, if any, of perifosine in the U.S., Canada and Mexico. Zentaris has assumed all costs related to the Perifosine program going forward.

NOTE 10 - CONTINGENT EQUITY RIGHTS

On February 5, 2004, we acquired ACCESS Oncology, a related party, for a purchase price of approximately $19,502,000. The purchase price included our assumption of certain liabilities of ACCESS Oncology equal to approximately $8,723,000, the issuance of shares of our common stock valued at approximately $6,325,000, contingent equity rights valued at approximately $4,004,000 and transaction costs of approximately $450,000.

At the effective date of the merger, each share of ACCESS Oncology common stock, including shares issuable upon the exercise of options exercised before March 1, 2004, and upon the exercise of outstanding warrants, was converted into the right to share in the contingent equity rights pro rata with the other holders of ACCESS Oncology common stock. Pursuant to the merger agreement, 623,145 shares of our common stock valued at approximately $6,325,000 have been issued to the former preferred stockholders of ACCESS Oncology. An additional 4,433 shares of our common stock are issuable to those preferred stockholders of ACCESS Oncology who have yet to provide the necessary documentation to receive shares of our common stock.

On December 16, 2009, we announced the initiation of a Phase 3 registration trial of KRX-0401 (perifosine) for the treatment of patients with relapsed / refractory multiple myeloma. The achievement of this event triggered contingent milestone stock consideration payable to the former stockholders of ACCESS Oncology in the amount of an aggregate of 500,000 shares of our common stock valued at $1,365,000.

Due to the termination of the license for KRX-0401 in May 2012, we were no longer committed to pay to the former stockholders of ACCESS Oncology, Inc. certain contingent equity rights (up to 2,872,422 shares of our common stock). For the year ended December 31, 2012, we recognized a non-cash extraordinary gain of $2.6 million relating to the write-off of the contingent equity rights liability.

NOTE 11 - STOCKHOLDERS EQUITY

Preferred Stock

Our amended and restated certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, $0.001 par value, with rights senior to those of our common stock.

Common Stock

On June 18, 2013, at the 2013 Annual Meeting of Stockholders, the Company s stockholders approved an amendment to the Company s amended and restated certificate of incorporation increasing the shares of authorized common stock from 95,000,000 shares to 130,000,000 shares $0.001 par value common stock. The number of authorized shares of preferred stock remains unchanged at 5,000,000 shares.

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On January 22, 2014, we announced the pricing of an underwritten public offering, whereby we sold 7,935,000 shares of our common stock at a price of $14.50 per share for gross proceeds of approximately $115.1 million. Net proceeds from this offering were approximately $107.6 million, net of underwriting discounts and offering expenses of approximately $7.5 million. The shares were sold under a Registration Statement (No. 333-190353) on Form S-3, filed by us with the Securities and Exchange Commission. This shelf registration statement on Form S-3, filed and declared effective by the SEC in August 2013, provides for the offering of up to $150 million of common stock and warrants in the aggregate. Subsequent to this underwritten public offering, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement. We may offer the securities under our shelf registration statement from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in our best interests and the best interests of our stockholders.

On January 30, 2013, we announced the pricing of an underwritten public offering, whereby we sold 9,469,100 shares of our common stock at a price of $8.49 per share for gross proceeds of approximately $80.4 million. Net proceeds from this offering were approximately $74.8 million, net of underwriting discounts and offering expenses of approximately $5.6 million. The shares were sold under Registration Statements (Nos. 333-171517 and 333-186332) on Form S-3 and Form S-3MEF, respectively, and filed by us with the Securities and Exchange Commission.

On May 4, 2011, we announced the pricing of an underwritten registered offering of 7,021,277 shares of our common stock at a price of $4.70 per share for gross proceeds of approximately $33.0 million. Net proceeds from this offering were approximately $30.7 million, net of underwriting discounts and offering expenses of approximately $2.3 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-171517) that was previously filed and declared effective by the SEC on January 28, 2011.

Treasury Stock

As of December 31, 2013 and 2012, we held a total of 79,948 shares of our common stock in treasury, at a total cost of $357,000.

Equity Incentive Plans

We have in effect the following stock option and incentive plans.

a. The 1999 Stock Option Plan was adopted in November 1999. Under the 1999 Stock Option Plan, our board of directors could grant stock-based awards to directors, consultants and employees. The plan authorizes grants to purchase up to 4,230,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 25 years from the date of the grant, unless otherwise authorized by the board. The plan permits the board of directors or a committee appointed by the board to administer the plan. The administrator has the authority, in its discretion, to determine the terms and conditions of any option granted to a service provider, including the vesting schedule. As of December 31, 2013, no additional shares of our common stock may be issued under the 1999 Stock Option Plan.

b. The 2004 Long-Term Incentive Plan was adopted in June 2004 by our stockholders. Under the 2004 Long-Term Incentive Plan, the compensation committee of our board of directors is authorized to grant stock-based awards to directors, consultants and employees. The 2004 plan authorizes grants to purchase up to 4,000,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2013, up to an additional 244,165 shares may be issued under the 2004 Long-Term Incentive Plan.

c. The 2007 Incentive Plan was adopted in June 2007 by our stockholders. Under the 2007 Incentive Plan, the compensation committee of our board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2007 Incentive Plan authorizes grants to purchase up to 6,000,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2013, up to an additional 9,837 shares may be issued under the 2007 Incentive Plan.

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d. The 2009 CEO Incentive Plan was adopted in May 2009. Under the 2009 CEO Incentive Plan, our board of directors granted an option to Ron Bentsur, our Chief Executive Officer, to purchase up to 600,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of grant. As of December 31, 2013, the option is fully vested and exercisable.

e. The 2013 Incentive Plan was adopted in June 2013 by our stockholders at our 2013 Annual Meeting of Stockholders. Under the 2013 Incentive Plan, the compensation committee of the Company s board of directors is authorized to grant stock-based awards to directors, officers, employees and consultants. The 2013 Incentive Plan authorizes grants to purchase up to 3,500,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of their grant. As of December 31, 2013, up to an additional 2,871,000 shares may be issued under the 2013 Incentive Plan.

Total shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 3,125,002 shares at December 31, 2013.

Stock Options

The following table summarizes stock option activity for all plans for the years ended December 31, 2013, 2012 and 2011:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term	Aggregate Intrinsic Value
Outstanding at January 1, 2011	7,638,403	$ 7.05		
Granted	692,350	4.53		
Exercised	(2,382,027)	1.30		$ 6,604,300
Forfeited	(98,600)	4.32		
Expired	(2,333,126)	13.26		
Outstanding at December 31, 2011	3,517,000	6.40		$ 2,139,130
Granted	521,500	2.36		
Exercised				$
Forfeited	(266,621)	7.77		
Expired	(370,208)	11.02		
Outstanding at December 31, 2012	3,401,671	5.17		$ 2,373,509
Granted	932,366	6.29		
Exercised	(443,813)	2.10		$ 4,614,741
Forfeited	(44,854)	8.70		
Expired				

Outstanding at December 31, 2013	3,845,370	$ 5.75	6.2	$ 28,361,438
Vested and expected to vest at December 31, 2013	3,804,543	$ 5.76	6.2	$ 28,045,772
Exercisable at December 31, 2013	2,519,162	$ 5.74	5.0	$ 18,719,371

The following table summarizes information about stock options outstanding at December 31, 2013:

	Options outstanding			Options exercisable	
Range of exercise prices	**Number outstanding**	**Weighted-average remaining contractual life (years)**	**Weighted-average exercise price**	**Number exercisable**	**Weighted-average exercise price**
$ 0.10 - $ 3.00	1,698,612	7.0	$ 1.64	1,078,621	$ 1.11
3.70 - 8.56	1,106,208	7.5	5.74	656,991	4.94
9.34 - 14.64	1,040,550	3.5	12.48	783,550	12.78
$ 0.10 - $ 14.64	3,845,370	6.2	$ 5.75	2,519,162	$ 5.74

Upon the exercise of stock options, we issue new shares of our common stock. As of December 31, 2013, 77,500 options issued to employees and 50,000 options issued to consultants are unvested, milestone-based options.

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Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under the 2004 Long-Term Incentive Plan and 2007 Incentive Plan. The time-vesting restricted stock grants vest primarily over a period of three to four years. The following table summarizes restricted share activity for the years ended December 31, 2013, 2012 and 2011:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at January 1, 2011	1,400,694	$ 1.63	$ 6,415,179
Granted	206,450	4.49	
Vested	(957,225)	1.20	$ 4,650,171
Forfeited	(28,338)	3.35	
Outstanding at December 31, 2011	621,581	3.16	$ 1,572,600
Granted	997,300	1.94	
Vested	(339,954)	2.91	$ 965,496
Forfeited	(97,250)	2.33	
Outstanding at December 31, 2012	1,181,677	2.27	$ 3,095,994
Granted	831,020	7.68	
Vested	(568,030)	2.43	$ 4,612,275
Forfeited	(23,737)	8.52	
Outstanding at December 31, 2013	1,420,930	$ 5.27	$ 18,401,044

As of December 31, 2013, 390,000 and 100,000 shares of restricted stock issued to employees and consultants, respectively, are unvested, milestone-based shares.

On September 14, 2009, we entered in an employment agreement with Ron Bentsur, our Chief Executive Officer, which was amended on January 13, 2012, and further amended on June 11, 2013. The agreement, as amended, terminates on May 20, 2015, subject to certain early termination events. As of December 31, 2013, Mr. Bentsur has been granted a total of 750,000 shares of restricted stock based on the achievement of certain milestone awards described in his employment agreement. In addition, as of December 31, 2013, Mr. Bentsur has the opportunity to earn certain milestone awards as follows:

(1) 500,000 shares of fully vested common stock will be granted to Mr. Bentsur, upon the first to occur of (a) our first commercial sale of Zerenex in the U.S. off an approved NDA, (b) our receipt of the first royalty upon the commercial sale of Zerenex in the U.S. by a partner to whom we have sold exclusive or non-exclusive commercial rights, or (c) our complete outlicensing of the entire product rights of Zerenex in the U.S.

(2) 100,000 shares of restricted stock will be granted to Mr. Bentsur upon each event of our outlicensing Zerenex in a foreign market, other than Japan, resulting in a greater than $10 million non-refundable cash payment to us with a gross deal value to us of at least $50 million. Such restricted stock will vest in equal installments over each of the first three anniversaries of the date of grant, provided that Mr. Bentsur remains an employee during such vesting period.

Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future.

Black-Scholes Option Valuation Assumptions	**2013**	**2012**	**2011**
Risk-free interest rates	0.7%	0.6%	1.4%
Dividend yield			
Volatility	102.0%	106.3%	115.0%
Weighted-average expected term	3.8 years	4.0 years	4.0 years

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The weighted average grant date fair value of options granted was $4.28, $1.73 and $3.43 per option for the years ended December 31, 2013, 2012 and 2011, respectively. We used historical information to estimate forfeitures within the valuation model. As of December 31, 2013, there was $3.3 million and $5.7 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.2 years and 2.6 years, respectively. These amounts do not include, as of December 31, 2013, 127,500 options outstanding and 490,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones, such as FDA approval of our drug candidate and change in control. Stock-based compensation will be measured and recorded if and when it is probable that the milestone will occur.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the years ended December 31, 2013, 2012 and 2011:

	For the year ended December 31,		
(in thousands)	2013	2012	2011
Stock-based compensation expense associated with restricted stock	$ 3,859	$ 967	$ 1,044
Stock-based compensation expense associated with option grants	2,094	1,200	1,048
	$ 5,953	$ 2,167	$ 2,092

NOTE 12 - INCOME TAXES

We account for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of our business. Based upon management s assessment of all available evidence, we believe that it is more-likely-than-not that the deferred tax assets will not be realizable; and therefore, a full valuation allowance is established. The valuation allowance for deferred tax assets was $162.8 million and $143.2 million as of December 31, 2013 and 2012, respectively.

As of December 31, 2013, we have U.S. net operating loss carryforwards (NOL s) of approximately $401.3 million, of which approximately $58.3 million were derived from certain stock option exercises and any such benefit realized will be credited to additional paid in capital. For income tax purposes, these NOL s will expire in the years 2019 through 2032. Due to our various equity transactions, the utilization of certain NOL s could be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision and/or the separate return limitation year losses limitation.

Income tax expense differed from amounts computed by applying the US federal income tax rate of 34% to pretax loss as follows:

(in thousands)	For the year ended December 31, 2013	2012	2011
Loss from continuing operations before income taxes, as reported in the consolidated statements of operations	$ (46,732)	$ (25,360)	$ (28,369)
Computed expected tax (benefit) expense	(15,889)	(8,622)	(9,645)
Increase (decrease) in income taxes resulting from:			
Expected (benefit) expense from state & local taxes	(1,523)	(827)	(925)
Stock compensation	(1,842)	905	5,872
Deferred impact rate change			19,072
Permanent differences	66	(196)	(147)
Other			(2)
Prior year true-up	(409)	(6,450)	(829)
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	19,597	15,190	(13,396)
	$	$	$

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The significant components of deferred income tax expense (benefit) attributable to loss from operations are as follows:

(in thousands)	For the year ended December 31, 2013	2012	2011
Deferred tax (benefit) expense	$ (19,597)	$ (15,190)	$ 13,396
Federal deferred tax benefit relating to the exercise of stock options	( )	( )	( )
Increase (decrease) in the valuation allowance for deferred tax asset	19,597	15,190	(13,396)
	$	$	$

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2013 and 2012 are presented below.

(in thousands)	December 31, 2013	December 31, 2012
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 149,510	$ 133,677
Non-cash compensation	7,022	6,478
Unrealized / realized loss on securities	1,164	1,164
Capitalized Inventory	3,061	
Research and development	2,088	1,684
Intangible assets due to different amortization methods	(135)	63
Accrued expenses	53	100
Other temporary differences	11	10
Deferred tax asset, excluding valuation allowance	162,774	143,176
Less valuation allowance	(162,774)	(143,176)
Net deferred tax assets	$	$

We file income tax returns in the U.S federal and various state and local jurisdictions. For federal and state income tax purposes, the 2010, 2011 and 2012 tax years remain open for examination under the normal three year statute of limitations. The statute of limitations for income tax audits in the U.S. will commence upon utilization of net operating losses and will expire three years from the filing of the tax return.

There was no accrual for uncertain tax positions or for interest and penalties related to uncertain tax positions for 2013, 2012 and 2011. We do not believe that there will be a material change in our unrecognized tax positions over the next twelve months. All of the unrecognized tax benefits, if recognized, would be offset by the valuation allowance.

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NOTE 13 - INTEREST AND OTHER INCOME, NET

The components of interest and other income, net are as follows:

	For the year ended December 31,		
(in thousands)	2013	2012	2011
Interest income	$ 190	$ 52	$ 159
Other income	161	166	221
Compensatory damage award, net		1,501	
	$ 351	$ 1,719	$ 380

In 2012, we recorded other income due to the award of $1.5 million in compensatory damages, net of fees and legal expenses, relating to the statement of claim we filed with the Financial Institution Regulatory Authority against an SEC registered broker-dealer for damages arising from that broker-dealer s recommendations and purchases of auction rate securities for our cash management account.

NOTE 14 - COMMITMENTS AND CONTINGENCIES

Research and Development Agreements

We have entered into various research and development agreements (relating to our development of Zerenex) under which we are obligated to make payments of approximately $19,921,000 through 2016. The following table shows future research and development payment obligations by period as of December 31, 2013.

(in thousands)	2014	2015	2016	2017	2018
Research and development agreements	$ 19,629	$ 254	$ 38		

The above table includes a $14,817,000 commitment for inventory build in 2014. The capitalization of inventory for our product candidate will commence when it is probable that our product will be approved for commercial marketing.

Most of the commitments in the table above are contingent upon our continuing development of Zerenex.

Leases

In March and September 2013, we extended our lease on our corporate and executive office located in New York City, adding approximately 6,800 square feet of additional leased space and extending its term through September 30, 2016. We also executed an amendment to our office sharing agreement with a third party for a portion of our leased space through September 29, 2014.

Total rental expense was approximately $667,000, $537,000 and $538,000 for the years ended December 31, 2013, 2012, and 2011, respectively. We recognized sublet income of $161,000, $166,000 and $221,000 for the years ended December 31, 2013, 2012, and 2011, respectively, related to the office sharing agreement.

Future minimum lease commitments as of December 31, 2013, in the aggregate total approximately $2,848,000 through September 2016. The following table shows future minimum lease commitments by period as of December 31, 2013.

(in thousands)	2014	2015	2016	2017	2018
Operating leases	$ 949	$ 1,045	$ 854		

The remaining sublet income of $120,600 is not included as an offset to our operating lease obligations in the table above.

Royalty and Contingent Milestone Payments

We have licensed the patent rights to Zerenex from a third party. The license agreement requires us to make contingent milestone payments to the licensor of up to $7.0 million over the life of the license, which will be due upon the regulatory approvals of Zerenex in the U.S., EU and Japan. The uncertainty relating to the timing of regulatory approvals prevents us from including the entire commitment in the Research and Development table above. Subsequent to December 31, 2013, we paid a $2.0 million milestone payment to the licensor of Zerenex relating to the marketing approval of ferric citrate in Japan in January 2014, which is not included in the above table. In addition, under the license agreement, we must pay royalties on net sales of Zerenex.

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NOTE 15 - LITIGATION

In October 2009, we filed a statement of claim with the Financial Institution Regulatory Authority, or FINRA, to commence an arbitration proceeding against an SEC registered broker-dealer. In this arbitration proceeding, we sought damages arising from that broker-dealer s recommendations and purchases of auction rate securities for our cash management account. On May 7, 2012, we received the arbitrators award, which required the broker-dealer to pay us compensatory damages in the amount of approximately $1.8 million. In June 2012, we received the award, which amounted to, after fees and legal expenses, approximately $1.5 million.

On February 1, 2013, a lawsuit was filed against us and our chief executive officer on behalf of a putative class of all of our shareholders (other than the defendants) who acquired our shares between June 1, 2009 and April 1, 2012. Smith v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-0755-TPG (S.D.N.Y.). On February 26, 2013, a substantially similar lawsuit was filed against us and our chief executive officer as well as our chief financial officer. Park v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-1307-TPG (S.D.N.Y.). On June 10, 2013, the Court entered an Order consolidating the two lawsuits and appointing a lead plaintiff. The case is now styled In re Keryx Biopharmaceuticals, Inc. Securities Litigation, Case No. 1:13-CV-0755-KBF (S.D.N.Y.). On July 10, 2013, the lead plaintiff filed a Consolidated Amended Complaint that, in substance, repeated the claims alleged in the consolidated lawsuits. The Consolidated Amended Complaint asserts claims against (i) us for alleged violations of Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act) and Rule 10b-5 promulgated thereunder and (ii) our chief executive officer for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. The claims in the Consolidated Amended Complaint are premised on general allegations that we and the individual defendant participated directly or indirectly in the preparation and/or issuance of purportedly false and misleading earnings reports, SEC filings, press releases, and other public statements, which allegedly caused our stock to trade at artificially inflated prices. The lead plaintiff seeks an unspecified amount of damages. On August 26, 2013, we filed a motion to dismiss the Consolidated Amended Complaint. On October 10, 2013, lead plaintiff filed an opposition to our motion to dismiss. Our reply in further support of our motion to dismiss was filed on November 12, 2013. On February 14, 2014, the Court entered an Opinion and Order granting the motion to dismiss. The Court entered Judgment for the Defendants on February 24, 2014. We believe the claims made in this action are without merit, and intend to defend the consolidated action vigorously. We cannot, however, predict the outcome or effect, if any, of the lawsuit on our business.

NOTE 16 - QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	2013			
	Mar. 31	**June 30**	**Sept. 30**	**Dec. 31**
	(in thousands, except per share data)			
Revenue:				
License revenue	$ 7,000	$	$	$
Total revenue	7,000			
Operating expenses:				
Research and development:				
Non-cash compensation	191	243	319	1,594
Other research and development	6,239	6,934	10,351	8,863

Total research and development	6,430	7,177	10,670	10,457
General and administrative:				
Non-cash compensation	390	395	422	2,399
Other general and administrative	2,338	3,882	4,640	4,883
Total general and administrative	2,728	4,277	5,062	7,282
Total operating expenses	9,158	11,454	15,732	17,739
Operating loss	(2,158)	(11,454)	(15,732)	(17,739)
Other income				
Interest and other income, net	103	96	81	71
Loss before income taxes	(2,055)	(11,358)	(15,651)	(17,668)
Income taxes				
Net loss	$ (2,055)	$ (11,358)	$ (15,651)	$ (17,668)
Basic and diluted net loss per common share	$ (0.03)	$ (0.14)	$ (0.19)	$ (0.21)

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	2012			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Operating expenses:				
Research and development:				
Non-cash compensation	$ 278	$ 73	$ 161	$ 150
Other research and development	7,122	3,726	3,768	4,753
Total research and development	7,400	3,799	3,929	4,903
General and administrative:				
Non-cash compensation	368	365	384	388
Other general and administrative	1,408	1,535	1,213	1,387
Total general and administrative	1,776	1,900	1,597	1,775
Total operating expenses	9,176	5,699	5,526	6,678
Operating loss	(9,176)	(5,699)	(5,526)	(6,678)
Other income				
Interest and other income, net	62	1,556	51	50
Loss before income taxes and extraordinary gain	(9,114)	(4,143)	(5,475)	(6,628)
Income taxes				
Loss before extraordinary gain	(9,114)	(4,143)	(5,475)	(6,628)
Extraordinary gain		2,639		
Net loss	$ (9,114)	$ (1,504)	$ (5,475)	$ (6,628)
Basic and diluted net loss per common share				
Before extraordinary gain	(0.13)	(0.06)	(0.08)	(0.09)
Extraordinary gain		0.04		
Basic and diluted net loss per common share	$ (0.13)	$ (0.02)	$ (0.08)	$ (0.09)

NOTE 17 - SUBSEQUENT EVENTS

On January 22, 2014, we announced the pricing of an underwritten public offering, whereby we sold 7,935,000 shares of our common stock at a price of $14.50 per share for gross proceeds of approximately $115.1 million. Net proceeds from this offering were approximately $107.6 million, net of underwriting discounts and offering expenses of approximately $7.5 million. The shares were sold under a Registration Statement (No. 333-190353) on Form S-3, filed by us with the Securities and Exchange Commission.

In January 2014, our Japanese partner, JT and Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, to be marketed in Japan by JT s subsidiary, Torii, under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the license agreement with JT and Torii, Keryx received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. Keryx will also receive double-digit tiered royalties on net sales of Riona® in Japan, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

Date: March 13, 2014

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Ron Bentsur
Ron Bentsur

Chief Executive Officer and Director

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Ron Bentsur and James F. Oliviero, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on March 13, 2014, and in the capacities indicated:

Signatures	Title
/s/ Ron Bentsur Ron Bentsur	Chief Executive Officer and Director (principal executive officer)
/s/ James F. Oliviero James F. Oliviero, CFA	Chief Financial Officer (principal financial and accounting officer)
/s/ Michael P. Tarnok Michael P. Tarnok	Chairman of the Board of Directors
/s/ Kevin Cameron Kevin Cameron	Director

/s/ Joseph Feczko, M.D	Director
Joseph Feczko, M.D	
/s/ Senator Wyche Fowler, Jr.	Director
Senator Wyche Fowler, Jr.	
/s/ Jack Kaye	Director
Jack Kaye	
/s/ Daniel P. Regan	Director
Daniel P. Regan	

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EXHIBIT INDEX

Exhibit Number	Exhibit Description
21.1	List of Subsidiaries.
23.1	Consent of UHY LLP.
24.1	Power of Attorney of Director and Officers of Keryx Biopharmaceuticals, Inc. (included herein).
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 13, 2014.
101	The following financial information from Keryx Biopharmaceuticals, Inc. s Annual Report on Form 10-K for the year ended December 31, 2013, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.