KERYX BIOPHARMACEUTICALS INC
Form 10-K
February 26, 2016
Table of Contents

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, 2015.

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.)**

One Marina Park Drive, 12th Floor

Boston, Massachusetts	**02210**
(Address of principal executive offices)	**(Zip Code)**

Registrant s telephone number, including area code: (617) 466-3500

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. x

Indicate by check mark whether the registrant is a large accelerated filer, 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 x	Accelerated filer ¨
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 $1,036,302,000 as of June 30, 2015, based on the closing sale price of such stock as reported on the Nasdaq Capital Market.

There were 105,875,863 shares of the registrant s common stock outstanding as of February 22, 2016.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant s Proxy Statement for the 2016 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

Table of Contents

KERYX BIOPHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K

FOR THE YEAR ENDED DECEMBER 31, 2015

TABLE OF CONTENTS

Table of Contents

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, project and 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 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:

- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Auryxia™ (ferric citrate);
- expectations for increases or decreases in expenses;
- expectations for pre-clinical and clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of Fexeric® (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;
- expectations regarding our ability to successfully market Riona® through our Japanese partners, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd.;
- expectations regarding our ability to successfully develop Auryxia for the treatment of iron deficiency anemia in non-dialysis chronic kidney disease patients;
- expectations regarding our ability to identify a commercial partner to launch Fexeric in the European market;
- expectations for generating revenue, positive cash flow or becoming profitable on a sustained basis;

expectations of the scope of patent protection with respect to Auryxia and Fexeric;

expectations or ability to enter into marketing and other partnership agreements;

expectations or ability to enter into product acquisition and in-licensing transactions;

estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements, including expectations regarding the value and liquidity of our investments;

expected losses; and

expectations for future capital requirements.

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.

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.

Table of Contents

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 bringing innovative therapies to market for patients with renal disease. Our product, Auryxia (ferric citrate), also known as Riona in Japan and Fexeric in Europe, is an oral, absorbable iron-based compound, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our compound, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on approximately 5,000 target nephrologists and their associated dialysis centers. In 2015, we reported net U.S. Auryxia product sales of $10.1 million and achieved a 1% market share by the end of the year.

Our Japanese partner, Japan Tobacco Inc. or JT, together with its subsidiary Torii Pharmaceutical Co. Ltd., or Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD, or NDD-CKD, in January 2014. Torii began to market the product under the brand name Riona in May 2014. Under the license agreement with JT and Torii, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We received royalty revenues of $0.8 million and $3.5 million from the sales of Riona in Japan in 2014 and 2015, respectively. We in turn owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union. We are currently seeking potential partners to commercialize Fexeric in the European Union.

In September 2014, we initiated a pivotal Phase 3 clinical trial of ferric citrate for the treatment of iron deficiency anemia, or IDA, in patients with Stage 3-5 NDD-CKD. This study s primary endpoint is the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period. Secondary endpoints in the Phase 3 study include the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The last patient in this Phase 3 trial completed treatment in January 2016 and we expect to report top line data in the second quarter of 2016, and if successful file for FDA approval of this indication in the third quarter of 2016.

Currently, our only product is Auryxia. In January 2015, we began to recognize product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, revenue from the sublicensing of rights to Auryxia in Japan to our Japanese partners, JT and Torii. We may engage in business development activities that include seeking strategic relationships for Auryxia outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on assets that are complementary to Auryxia.

Table of Contents

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 the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Even though we are commercializing Auryxia, 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 additional regulatory approvals for Auryxia or any other product candidate in which we obtain rights, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize Auryxia alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of Auryxia. In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C., or Baupost. In order to accommodate the full conversion of the Notes, we will seek stockholder approval of an amendment to our certificate of incorporation at the 2016 Annual Meeting of Stockholders to increase the number of shares of authorized common stock. If any necessary share increases are not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. As of December 31, 2015, Baupost beneficially owns approximately 25% of our issued and outstanding common stock. If all of the Notes were converted prior to the approval of the necessary increase in shares, Baupost would beneficially own approximately 28% of our issued and outstanding common stock and Baupost s beneficial ownership of our issued and outstanding common stock would increase to approximately 43% if the remaining Notes were converted into our common stock. In addition, in January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses, in an underwritten public offering of our common stock.

OUR STRATEGY

Our mission is to create long-term stockholder value by bringing differentiated products to market that provide meaningful benefits to patients and their healthcare providers. Our strategy to achieve this mission is to:

- continue to drive commercial adoption of Auryxia in the dialysis setting;
- maximize the potential of ferric citrate through potential label expansion for the treatment of iron deficiency anemia in NDD-CKD patients;
- identify and explore licensing, partnership and other business development opportunities for ferric citrate;
- seek to acquire or in-license medically important drug candidates in clinical development; and
- utilize our clinical development capabilities to manage and progress any future drug candidates we may in-license or acquire through the clinical development and regulatory processes to approval.

CORPORATE INFORMATION

We were incorporated in Delaware in October 1998 and commenced operations in November 1999. In January 2016, we moved our executive offices to One Marina Park Drive, 12th Floor, Boston, Massachusetts 02210. Our telephone number is 617-466-3500, 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, 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

Table of Contents

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.\

AURYXIA (FERRIC CITRATE)

Auryxia, is an oral, absorbable iron-based compound approved for the control of serum phosphorus levels in patients with CKD on dialysis. Auryxia has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes to reduce intestinal absorption and aid in the management of hyperphosphatemia in patients with CKD. The U.S. approval of Auryxia was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Auryxia effectively reduced serum phosphorus levels to within the Kidney Disease Outcomes Quality Initiative, or KDOQI, guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Auryxia s pharmacodynamic properties resulted in increased ferritin, iron and transferrin saturation, or TSAT; whereas these parameters remained relatively constant in patients treated in the active control arm (Renvela® and/or Phoslo®) in our Phase 3 registration program. The most common adverse events for Auryxia treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on approximately 5,000 target nephrologists and their associated dialysis centers. In addition, we have a small team of national account managers who are primarily responsible for working with insurance plans, health maintenance organizations and other payers to secure reimbursement and formulary access for Auryxia. In December 2014, we created the Keryx Patient Plus program to assist with patient accessibility to Auryxia. The Keryx Patient Plus program offers benefit verification, co-pay assistance for eligible commercial patients, a no-cost drug program for those who qualify, and a short-term prescription bridge program that may assist those already on Auryxia who are in danger of suffering a lapse in coverage. We had net U.S. Auryxia product sales in 2015 of $10.1 million and 1% market share by the end of the year.

Foreign Operations

We have no foreign operations. Revenues from customers outside of the United States amounted to approximately 26% of our total revenues for 2015. Our only revenues in 2014 and 2013 were related to license revenues recognized in connection with our license agreement with JT and its subsidiary Torii, which are both headquartered in Japan. Sales of ferric citrate outside of the United States do not and are not expected to materially contribute to our revenues.

Market Opportunity

In the United States, there are approximately 450,000 adult patients with chronic kidney disease requiring dialysis (referred to as End Stage renal disease, or ESRD). Managing ESRD is complex as many metabolic factors, such as iron and phosphorus, are out of balance. Phosphate retention and the resulting hyperphosphatemia in dialysis patients are typically associated with increased risk for heart and bone disease and death. There are approximately 2.9 million prescriptions written in the United States for phosphate binders annually. The majority of ESRD patients require chronic treatment with phosphate-binding agents to lower and maintain serum phosphorus at acceptable levels. In addition, iron can be severely depleted in dialysis patients and they are therefore often treated with intravenous iron, or IV iron, erythropoiesis-stimulating agents, or ESAs, and other medications.

In addition, it is estimated that more than 10% of the U.S. adult population is affected by chronic kidney disease. As kidney function declines levels of serum phosphorus become more prevalent especially in Stages 3-5 of CKD, the

more progressive stages of CKD. 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.

Table of Contents

Iron deficiency anemia, or IDA, 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 United States alone are also afflicted with IDA. 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. No oral iron agents are currently FDA approved to treat IDA 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. Consequently, we believe the NDD-CKD patient population remains underserved.

CKD on Dialysis: Auryxia Approval and Phase 3 Registration Clinical Program

In September 2014, we received approval from the FDA to market Auryxia for the control of elevated serum phosphorus levels in patients with CKD on dialysis. In January 2014, our Japanese partner received approval from the Japanese Ministry of Health, Labour and Welfare to market Riona in Japan as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and NDD-CKD. In September 2015, the EC approved Fexeric for the control of serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. These approvals to treat patients with CKD on dialysis in the United States were based on our Phase 3 clinical registration program in which we conducted a Phase 3 short-term trial, a Phase 3 long-term trial and a long-term open label extension, or OLE, trial. The two Phase 3 trials showed that treatment with Auryxia resulted changes in serum phosphorus levels during and at the end of treatment as compared to baseline that were statistically significant and increases in certain iron parameters, including ferritin, TSAT and hemoglobin levels, as compared to baseline.

The side-effect profile of Auryxia in these Phase 3 trials appeared similar to the profile of the control groups, which received Renvela (sevelamer carbonate) and/or Phoslo (calcium acetate). No serious adverse events deemed to be drug related were reported in the short-term Phase 3 trial. In the long-term Phase 3 trial, the most common adverse events were gastrointestinal-related, including: diarrhea, including soft stools (26% Auryxia vs. 14% control), nausea (15% Auryxia vs. 14% control), feces discoloration (17% Auryxia vs. 0% control), vomiting (9% Auryxia vs. 15% control) and constipation (8% Auryxia vs. 5% control). Adverse events were generally characterized as mild to moderate in nature in this trial. The overall serious adverse event rates in the long-term Phase 3 trial were 41.9% Auryxia vs. 49.7% control and there were no clinically meaningful or statistically significant differences between Auryxia and the control group in serum calcium levels, aluminum levels and liver enzymes, as measured by alanine transaminase, or ALT, and aspartate transaminase, or AST. The safety profile observed in the OLE trial was consistent with that seen in the long-term Phase 3 trial.

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

In November 2010, we completed a Phase 3 short-term, dose-ranging and efficacy trial of Auryxia for the treatment of hyperphosphatemia. This short-term trial 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 Auryxia of either 1 gram, 6 grams or 8 grams per day for a treatment period of 28 days. Auryxia 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-four hemodialysis patients were enrolled into the study. The intent-to-treat, or ITT, group included 146 patients, representing all patients who took at least one dose of Auryxia 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 for four weeks.

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 of treatment in the ITT group, using a regression analysis to evaluate

Table of Contents

this objective. The study met the primary endpoint, with the regression analysis indicating a highly statistically significant dose response (p<0.0001) where mean serum phosphorus levels changed from baseline to end of the trial by 0.1 mg/dL (n=50) with 1 g/day, -2.0 mg/dL (n=51) with 6 g/day and -2.2 mg/dL (n=45) with the 8 g/day dosing. Certain iron parameters, including serum 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 g/day and 8 g/day dose groups. No serious adverse events were deemed to be drug-related by the Data Safety Monitoring Committee in this clinical study.

CKD on Dialysis: Auryxia 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 Auryxia for the treatment of hyperphosphatemia in patients with CKD on dialysis. In this study, conducted pursuant to a SPA agreement with the FDA, Auryxia met the study s primary endpoint, described below, demonstrating a statistically significant change in serum phosphorus levels as compared to placebo over the four-week efficacy assessment period of the study. In addition, Auryxia met the key pre-defined secondary endpoints of increasing ferritin and TSAT and reducing the use of IV iron and ESAs as compared to 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.

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 patients were randomized 2:1 to receive either Auryxia 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 patients randomized to treatment with Auryxia during the safety assessment period and completed the safety assessment period were randomized in a 1:1 ratio to either continue treatment with Auryxia or switch to placebo for a 4-week treatment period. Patients were titrated during the study to achieve serum phosphorus levels that ranged between 3.5 to 5.5 mg/dL. Patients were included in the trial if ferritin was less than 1000 ng/mL and TSAT < 50%.

The primary objectives of this study were to determine the long-term safety of Auryxia in patients with CKD undergoing either hemodialysis or peritoneal dialysis, and the efficacy of Auryxia following 52 weeks of treatment in a four-week, randomized, open-label, placebo-controlled efficacy assessment period. Auryxia 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 at the physician s discretion, though 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.

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 ITT group. The ITT group included 182 patients, representing all patients who took at least one dose of Auryxia or placebo in the efficacy assessment period and provided at least one post-baseline efficacy assessment. Auryxia met the primary efficacy endpoint with a highly statistically significant result (p<0.0001, in an analysis of covariance, or ANCOVA, model with treatment as the fixed effect and baseline as the covariate) where patients on placebo had a change in serum phosphorus form 5.4 mg/dL to 7.2 mg/dL and those on Auryxia changed from 5.1 mg/dL to 4.9 mg/dL demonstrating a 2.2 mg/dL least squares mean difference between groups.

During the 52-week safety assessment period, Auryxia 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, p<0.0001). In addition, as agreed to with the EC, the treatment difference between Auryxia 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. Auryxia successfully achieved the non-inferiority endpoint versus Renvela®.

Table of Contents

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 Auryxia may increase iron storage parameters and reduce the need for IV iron and/or ESAs as compared to the active control group. Auryxia met all the key pre-defined secondary efficacy endpoints related to iron storage parameters with statistically significant treatment differences as compared to the active control group (Renvela® (sevelamer carbonate) and/or Phoslo® (calcium acetate)), as follows:

Auryxia demonstrated a statistically significant treatment difference as compared to the active control group in mean change in serum ferritin from baseline (Day 0) to Week 52 from 593 ng/mL (n=253) at baseline to 895 ng/mL at the end of 52 weeks for Auryxia compared to those on active control where the serum ferritin level at baseline was 610 ng/mL (n=137) and at the end of the 52 week period was 632 ng/mL. Auryxia also demonstrated a statistically significant treatment difference as compared to the active control group in mean change in TSAT from baseline (Day 0) to Week 52 where the TSAT at baseline for Auryxia was 31% (n=252) and at the end of the 52 week period was 39% compared to the active control group where baseline TSAT was 31% (n=137) and at the end of the 52 week period was 30%.

Each subject s average cumulative IV iron intake was calculated over the 52-week safety assessment period. The ITT group consisted of 271 patients and 138 patients for the Auryxia and active control groups, respectively. Auryxia demonstrated a 51% decrease in median IV iron intake as compared to the active control group (median 1.87 mg/day for Auryxia versus 3.83 mg/day for active control, $p<0.0001$). Each patient s average cumulative ESA intake was calculated over the 52-week safety assessment period. The ITT group consisted of 273 patients and 141 patients for the Auryxia and active control groups, respectively. Auryxia demonstrated a 24% decrease in median ESA intake as compared to the active control group (median 756 units/day for Auryxia versus 993 units/day for active control, $p<0.05$).

Auryxia demonstrated a statistically significant treatment difference as compared to the active control group in mean change in hemoglobin from baseline (Day 0) to Week 52 ($p<0.05$) with a mean change in hemoglobin in the Active control group of -0.6 g/dL and a mean change of -0.2 g/dL for those on Auryxia.

Safety and Tolerability Profile

For reference, patients previously intolerant to Renvela® (sevelamer carbonate) and/or Phoslo® (calcium acetate) were ineligible to participate in this study. Based on an analysis of safety data, the side-effect profile of Auryxia and the active control group, or Active Control, appeared similar, with the most common adverse events gastrointestinal-related. The most common gastrointestinal adverse events were: diarrhea, including soft stools (26% Auryxia vs. 14% Active Control), nausea (15% Auryxia vs. 14% Active Control), feces discoloration (17% Auryxia vs. 0% Active Control), vomiting (9% Auryxia vs. 15% Active Control) and constipation (8% Auryxia 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 41.9% Auryxia vs. 49.7% Active Control. Importantly, there were no clinically meaningful or statistically significant differences between Auryxia and the active control group in serum calcium levels, aluminum levels and liver enzymes, as measured by alanine transaminase, or ALT, and aspartate transaminase, or AST.

CKD on Dialysis: Auryxia Open-Label Safety Extension Study

In July 2014, we completed the long-term, OLE study for Auryxia in dialysis-dependent CKD patients. Patients who had participated in and successfully completed the long-term pivotal Phase 3 study were eligible for enrollment in the 48-week OLE study, providing for cumulative exposure to Auryxia of up to two years (n=17). Patients in the OLE study (n=168) were titrated to achieve and maintain serum phosphorus levels within a range

Table of Contents

of 3.5 to 5.5 mg/dL, with a maximum daily dose of 12 grams per day of Auryxia. The safety profile observed in the OLE study was consistent with that seen in the long-term pivotal Phase 3 study and there were no clinically meaningful changes in liver enzymes or aluminum levels over the course of the study.

NDD-CKD: Clinical Program Evaluating Ferric Citrate for the Treatment of Iron Deficiency Anemia

In addition to studying Auryxia to treat patients with CKD on dialysis, we are conducting a clinical program to study the use of ferric citrate for the treatment of iron-deficiency anemia in the non-dialysis setting. We have completed a Phase 2 clinical trial and have initiated a Phase 3 clinical trial of ferric citrate to potentially gain FDA approval to use ferric citrate in patients with NDD-CKD.

Phase 3 Clinical Trial

In September 2014, we initiated a pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia in patients with Stage 3-5 NDD-CKD. This is a 24-week Phase 3, multi-center clinical trial, comprised of a 16-week, randomized, double-blind, placebo-controlled period, or the Randomized Period, followed by an 8-week open label safety extension period, where all patients received ferric citrate, or the Extension Period. Patients with CKD Stage 3-5 who were intolerant of or had an inadequate therapeutic response to oral iron supplements (with a limit of up to 20% of the target randomization in CKD Stage 5) and had a hemoglobin between 9.0 g/dL and £11.5 g/dL at screening for enrollment in the trial. In addition, patients with serum phosphorus <3.5 mg/dL were excluded from the trial. Unlike the Phase 2 NDD-CKD trial where dosing was based on serum phosphorus levels, ferric citrate was dosed, with meals, to obtain an increase in Hgb of >1.0 g/dL from baseline. Increase of study drug dose occurred only if the subject s serum phosphate is ³3.0 mg/dL. The use of oral or IV iron, erythropoiesis-stimulating agents (ESAs), receipt of blood transfusions and phosphate binders were not be permitted at any time during the study.

The study s primary endpoint is a between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week Randomized Period. The primary endpoint in the Phase 3 NDD-CKD study is supported by a post-hoc analysis of this endpoint in the Phase 2 NDD-CKD study that demonstrated that the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any time point during the study was 40% in the ferric citrate arm as compared to 15% in the placebo arm ($p < 0.001$). Secondary endpoints in this Phase 3 study include change from baseline to end of Randomized Period for hemoglobin, ferritin, TSAT and serum phosphorus.

The trial enrolled 234 patients and the last patient completed treatment in January 2016. We expect to report top line data in the second quarter of 2016.

NDD-CKD: Phase 2 Clinical Study

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

This Phase 2 study was a multicenter, randomized, double-blind, placebo-controlled clinical trial in patients with Stage 3-5 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 patients were randomized 1:1 to receive either ferric citrate or placebo. Dosing was based upon change serum

phosphorus. One hundred forty-nine (149) patients were randomized into the study

Table of Contents

from 20 sites in the United States. The use of IV or oral 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.

Co-Primary and Key Secondary Endpoints

Ferric citrate demonstrated statistically significant improvements in both co-primary (serum phosphorus and TSAT) and all key secondary endpoints. The ITT group included 141 patients, representing all patients who took at least one dose of ferric citrate or placebo and provided at least one post-baseline efficacy assessment. In the group receiving ferric citrate, the mean serum phosphorus at baseline was 4.5 mg/dL (n=72) and at the end of the 12-week treatment period was 3.9 mg/dL. In the group receiving placebo, the mean serum phosphorus at baseline was 4.7 mg/dL (n=69) and at the end of the 12-week treatment period was 4.4 mg/dL. In the group receiving ferric citrate, the mean TSAT at baseline was 22% (n=72) and at the end of the 12-week treatment period was 32%. In the group receiving placebo, the mean TSAT at baseline was 21% (n=69) and at the end of the 12-week treatment period was 20%.

The key secondary endpoints of the study measuring iron parameters were the mean changes in ferritin and hemoglobin from baseline to the end of the 12-week treatment period as compared to placebo in the ITT group. Ferric citrate significantly increased serum ferritin from 116 ng/mL at baseline to 189 ng/mL at the end of the treatment period, which was significantly higher than that of placebo (baseline 110 ng/mL; week 12 106 ng/mL). Mean hemoglobin change from baseline to the end of the 12-week treatment period was significantly higher in those that received ferric citrate than those that received placebo (p<0.001).

Mean Hemoglobin (g/dL)	**Placebo (n=69)**	**Auryxia (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.

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. There were 12% treatment failures in the placebo group associated with low hemoglobin versus 1% on ferric citrate. In addition, there was a 3% serum phosphorus associated treatment failure in the placebo group compared to none on ferric citrate.

Safety and Tolerability Profile

For reference, patients previously intolerant to Renvela® (sevelamer carbonate) and/or Phoslo® (calcium acetate) were ineligible to participate in this study. Based on an analysis of safety data, the side-effect profile of Auryxia and the active control group, or Active Control, appeared similar, with the most common adverse events gastrointestinal-related. The most common gastrointestinal adverse events were: diarrhea, including soft stools (26% Auryxia vs. 14% Active Control), nausea (15% Auryxia vs. 14% Active Control), feces discoloration (17% Auryxia vs. 0% Active Control), vomiting (9% Auryxia vs. 15% Active Control) and constipation (8% Auryxia 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 41.9% Auryxia vs. 49.7% Active Control. Importantly, there were no clinically meaningful or statistically significant differences between Auryxia and the active control group in serum calcium levels, aluminum levels and liver enzymes, as measured by alanine transaminase, or ALT, and aspartate transaminase, or AST.

Table of Contents

COMMERCIAL ORGANIZATION

We have established a commercial organization to support the sales of Auryxia in the United States. Our sales force and managed markets organizations are responsible for promoting our products to health care professionals, providers, and payors.

Our U.S. sales force and managed markets organizations include approximately 120 employees. We market our products and educate physicians by calling on individual physicians, dieticians, and advertising, public relation efforts, and other activities.

We also have established programs in the United States that provide our products to qualified uninsured or underinsured patients at no charge or at a reduced charge, based on specific eligibility criteria.

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 Auryxia and our proprietary technologies. As part of our business strategy, our policy is to actively file patent applications in the United States 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 United States 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 United States 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

Table of Contents

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 with Panion & BF Biotech, Inc., or Panion, we have the exclusive rights under a series of patent and patent applications to commercialize Auryxia 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 Auryxia.

Our patent rights include: (1) U.S. Patent No. 8,846,976, which expires in 2024 and claims directed to the FDA approved dosing and daily administration of Auryxia, and a method of treating hyperphosphatemia comprising administering a therapeutically effective amount of an orally administrable form of Auryxia to a subject, wherein the orally administrable form is prepared from an active pharmaceutical ingredient (API) having an intrinsic dissolution rate of at least 1.88/mg/cm2/min; (2) U.S. Patent Nos. 7,767,851, 8,299,298, 8,338,642, 8,609,896, 8,754,257, 8,754,258 and 9,050,316, which expire in 2024 and include composition and methods of use claims covering Auryxia; and (3) U.S. Patent No. 8,093,423, which expires in 2026 and includes methods of use claims covering Auryxia. The expiration dates referenced above are without regard to potential patent term extension. In addition, our patent portfolio includes U.S. patent applications directed to formulations of certain ferric citrate product candidates, methods of improving at least one iron storage parameter (e.g., hemoglobin) in chronic kidney disease patients comprising orally administering ferric citrate, and methods of reducing serum phosphorous in chronic kidney disease patients comprising orally administering ferric citrate.

The patent rights that we own or have licensed relating to Auryxia are limited in ways that may affect our ability to exclude third parties from competing against us. 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 Auryxia in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We licensed additional composition of matter and method of use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient, or API, of Auryxia), 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 method of use patents, including U.S. Patent Nos. 7,767,851, 8,299,298 and 8,338,642 and (which expire in 2024), and U.S. Patent No. 8,093,423 (which expires in 2026) 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.

We have filed applications under the Patent Term Extension provisions of 35 U.S.C. § 156 on the above mentioned patents for delays caused by FDA regulatory review. If granted, we can utilize the patent term extension on one of these patents, however, we cannot assure you that we can obtain any extension of the term of these patents. If obtained, the maximum term of extension available under 35 U.S.C. § 156 would

extend the term of the chosen patent by no more than five years. Upon expiration of these patents, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition and/or method of use as our product, so long as the competitors do not infringe any other patents that we may hold.

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.

In October 2014, following the regulatory approval of Riona in Japan, the Japan Patent office granted patent term extensions for patents #4964585 and #4173553, which extended the terms of these patents in Japan to November 2025 and November 2022, respectively.

Table of Contents

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors induce or contribute others in engaging in direct infringement. Proving that a competitor contributes to, or induces, infringement of a patented method by another has additional proof requirements. For example, 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 Auryxia, increase the risk that a generic version of Auryxia could enter the market to compete with Auryxia, limit our development and commercialization of Auryxia, 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 Auryxia. 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.

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 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 United States, or, diseases that affect more than 200,000 individuals in the United States 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 may provide 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 European Union. We cannot assure that our drug candidate, Auryxia, 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 United States, European Union 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.

Table of Contents

LICENSING AGREEMENTS AND COLLABORATIONS

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

Panion & BF Biotech, Inc.

In November 2005, we entered into a license agreement with Panion & BF Biotech, Inc., or Panion. Under the license agreement, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. To date, we have expensed an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia. For the year ended December 31, 2015, we recorded approximately $0.6 million in cost of goods sold related to royalty payments due Panion relating to sales of Auryxia (ferric citrate) in the United States.

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, 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 marketed in the United States under the trade name Auryxia. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, or the Revised Agreement.

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, launched in May 2014 and being marketed in Japan by Torii under the brand name Riona, is indicated as an oral medicine for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

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

Table of Contents

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.

Auryxia is competing in the United States 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), or Genzyme, 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 Auryxia is differentiated in the marketplace versus these FDA approved phosphate binders

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 United States. 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.

Auryxia, currently our only drug product, which we launched in December 2014, is competing 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 Auryxia, including the treatment of hyperphosphatemia and iron deficiency anemia. Other companies have products or 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 Auryxia and other potential drug candidates we may acquire or in-license, and may be commercialized earlier. Additional information can be found in this report in Item 1A under the heading Risk Factors Other Risks Related to Our Business.

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, Auryxia, for use in clinical trials

and for sales.

We believe that we have established contract manufacturing relationships for the supply of Auryxia to ensure that we will have sufficient material for clinical trials and ongoing commercial sales. In addition, we are

Table of Contents

establishing the basis for long-term commercial production capabilities to supply the potential expanded demand for Auryxia in future years. 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.

As we continue to build inventory for the expanded commercialization of Auryxia, we intend to engage additional suppliers to produce Auryxia under current Good Manufacturing Practice, or cGMP, requirements. Our third-party manufacturers have a limited number of facilities in which Auryxia can be produced and will have limited experience in manufacturing Auryxia 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 requirements 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 applicable requirements 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

FDA Approval Process

In the United States, pharmaceutical products are subject to extensive regulation by the FDA. The Federal Food, Drug, and Cosmetic Act, or the FDC Act, and other federal and state statutes and regulations, govern, among other things, the research, development, testing, manufacture, storage, recordkeeping, approval, labeling, promotion and marketing, distribution, post-approval monitoring and reporting, sampling, and import and export of pharmaceutical products. Failure to comply with applicable U.S. requirements may subject a company to a variety of administrative or judicial sanctions, such as FDA refusal to approve pending NDAs, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties and criminal prosecution.

Pharmaceutical product development in the United States typically involves the performance of nonclinical laboratory and animal tests, the submission to the FDA of an investigational new drug application, or IND, which must become effective before clinical testing may commence, and adequate, well-controlled clinical trials to establish the safety and effectiveness of the drug for each indication for which FDA approval is sought. Satisfaction of FDA pre-market approval requirements typically takes many years and the actual time required may vary substantially based upon the

type, complexity, and novelty of the product or disease.

Preclinical tests include laboratory evaluation of product chemistry, formulation, and toxicity, as well as animal studies to assess the characteristics and potential safety and efficacy of the product. The conduct of the

Table of Contents

preclinical and other nonclinical tests must comply with certain federal regulations and requirements, including good laboratory practices. The results of preclinical testing are submitted to the FDA as part of an IND along with other information, including information about product chemistry, manufacturing and controls, and a proposed clinical trial protocol. Long term nonclinical tests, such as animal tests of reproductive toxicity and carcinogenicity, may continue after the IND is submitted.

A 30-day waiting period after the submission of each IND is required prior to the commencement of clinical testing in humans. If the FDA has neither commented on nor questioned the IND within this 30-day period, the clinical trial proposed in the IND may begin.

Clinical trials involve the administration of the investigational new drug to healthy volunteers or patients under the supervision of a qualified investigator. Clinical trials must be conducted: (i) in compliance with federal regulations, (ii) in compliance with good clinical practice, or GCP, an international standard meant to protect the rights and health of patients and to define the roles of clinical trial sponsors, administrators, and monitors, and (iii) under protocols detailing the objectives of the clinical trial, the parameters to be used in monitoring safety and the effectiveness criteria to be evaluated. Each protocol involving testing on U.S. patients and subsequent protocol amendments must be submitted to the FDA as part of the IND.

The FDA may order the temporary, or permanent, discontinuation of a clinical trial at any time or impose other sanctions if it believes that the clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable risk to the clinical trial patients. The clinical trial protocol and informed consent information for patients in clinical trials must also be submitted to an institutional review board, or IRB, at each site where a clinical trial will be performed for approval. An IRB may also require the clinical trial at the site to be halted, either temporarily or permanently, for failure to comply with the IRB s requirements or it may impose other conditions.

Clinical trials to support NDAs for marketing approval are typically conducted in three sequential phases, but the phases may overlap. In Phase 1, the initial introduction of the drug into healthy human subjects or patients, the drug is tested to assess metabolism, pharmacokinetics, pharmacological actions, side effects associated with increasing doses, and, if possible, early evidence on effectiveness. Phase 2 usually involves clinical trials in a limited patient population to determine the effectiveness of the drug for a particular indication, dosage tolerance, and optimum dosage, and to identify common adverse effects and safety risks. If a compound demonstrates evidence of effectiveness and an acceptable safety profile in Phase 2 evaluations, Phase 3 clinical trials are undertaken to obtain the additional information about clinical efficacy and safety in a larger number of patients, typically at geographically dispersed clinical trial sites, to permit the FDA to evaluate the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug. In most cases, the FDA requires two adequate and well-controlled Phase 3 clinical trials to demonstrate the efficacy of the drug. A single Phase 3 clinical trial with other confirmatory evidence may be sufficient in instances where the clinical trial is a large multicenter trial demonstrating internal consistency and a statistically very persuasive finding of a clinically meaningful effect on mortality, irreversible morbidity, or prevention of a disease with potentially serious outcome, and confirmation of the result in a second clinical trial would be practically or ethically impossible.

After completion of the required clinical testing, a new drug application, or NDA, is prepared and submitted to the FDA. FDA approval of the NDA is required before marketing of the product may begin in the United States. The NDA must include the results of all nonclinical, clinical, and other testing and a compilation of data relating to the product s pharmacology, chemistry, manufacture, and controls. The cost of preparing and submitting an NDA is substantial. Under federal law, the submission of most NDAs is additionally subject to a substantial application user fee, and the manufacturer and/or sponsor under an approved NDA is also subject to annual product and establishment user fees which typically increase annually.

The FDA has 60 days from its receipt of an NDA to determine whether the application will be accepted for filing based on the agency s threshold determination that it is sufficiently complete to permit substantive review.

Table of Contents

Once the submission is accepted for filing, the FDA begins an in-depth review. The FDA has agreed to certain performance goals in the review of NDAs. Most such applications for standard review drug products are reviewed within ten to twelve months, while most applications for priority review drugs are reviewed in six to eight months. Priority review can be applied to drugs that the FDA determines offer major advances in treatment, or provide a treatment where no adequate therapy exists. For biologics, priority review is further limited only for drugs intended to treat a serious or life-threatening disease relative to the currently approved products. The review process for both standard and priority review may be extended by FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

The FDA may also refer applications for novel drug products, or drug products that present difficult questions of safety or efficacy, to an advisory committee, which is typically a panel that includes clinicians and other experts, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendation of an advisory committee, but it generally follows such recommendations. Before approving an NDA, the FDA will typically inspect one or more clinical sites to assure compliance with GCP. Additionally, the FDA will inspect the facility or the facilities at which the drug is manufactured. The FDA will not approve the product unless compliance with current good manufacturing practice requirements, or cGMP is satisfactory and the NDA contains data that provide substantial evidence that the drug is safe and effective in the indication studied.

After the FDA evaluates the NDA and the manufacturing facilities, it issues either an approval letter or a complete response letter. A complete response letter generally outlines the deficiencies in the submission and may require substantial additional testing, or information, in order for the FDA to reconsider the application. If, or when, those deficiencies have been addressed to the FDA s satisfaction in a resubmission of the NDA, the FDA will issue an approval letter. The FDA has committed to reviewing such resubmissions in two or six months depending on the type of information included.

An approval letter authorizes commercial marketing of the drug with specific prescribing information for specific indications. As a condition of NDA approval, the FDA may require a risk evaluation and mitigation strategy, or REMS, to help ensure that the benefits of the drug outweigh the potential risks. REMS can include medication guides, communication plans for health care professionals, and elements to assure safe and effective use, or ETASU. ETASU can include, but are not limited to, special training or certification for prescribing or dispensing, dispensing only under certain circumstances, special monitoring, and the use of patient registries. The requirement for a REMS can materially affect the potential market and profitability of the drug. Moreover, product approval may require substantial post-approval testing and surveillance to monitor the drug s safety or efficacy. Once granted, product approvals may be withdrawn if compliance with regulatory standards is not maintained or problems are identified following initial marketing.

Disclosure of Clinical Trial Information

Sponsors of clinical trials of certain FDA-regulated products, including prescription drugs, are required to register and disclose certain clinical trial information on a public website maintained by the U.S. National Institutes of Health. Information related to the product, patient population, phase of investigation, clinical trial sites and investigator, and other aspects of the clinical trial is made public as part of the registration. Sponsors are also obligated to disclose the results of these clinical trials after completion. Disclosure of the results of these clinical trials can be delayed until the product or new indication being studied has been approved. Competitors may use this publicly-available information to gain knowledge regarding the design and progress of our development programs.

17

Table of Contents

The Hatch-Waxman Act

Orange Book Listing

In seeking approval for a drug through an NDA, applicants are required to list with the FDA each patent whose claims cover the applicant s product. Upon approval of a drug, each of the patents listed in the application for the drug is then published in the FDA s Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Drugs listed in the Orange Book can, in turn, be cited by potential generic competitors in support of approval of an abbreviated new drug application, or ANDA. An ANDA provides for marketing of a drug product that has the same active ingredients in the same strengths and dosage form as the listed drug and has been shown through bioequivalence testing to be therapeutically equivalent to the listed drug. Other than the requirement for bioequivalence testing, ANDA applicants are not required to conduct, or submit results of, nonclinical or clinical tests to prove the safety or effectiveness of their drug product. Drugs approved in this way are commonly referred to as generic equivalents to the listed drug, and can often be substituted by pharmacists under prescriptions written for the original listed drug.

The ANDA applicant is required to certify to the FDA concerning any patents listed for the approved product in the FDA s Orange Book. Specifically, the applicant must certify that: (i) the required patent information has not been filed; (ii) the listed patent has expired; (iii) the listed patent has not expired, but will expire on a particular date and approval is sought after patent expiration; or (iv) the listed patent is invalid or will not be infringed by the new product. The ANDA applicant may also elect to submit a section viii statement, certifying that its proposed ANDA label does not contain or carve out any language regarding the patented method-of-use, rather than certify to a listed method-of-use patent.

If the applicant does not challenge the listed patents, the ANDA application will not be approved until all the listed patents claiming the referenced product have expired. A certification that the new product will not infringe the already approved product s listed patents, or that such patents are invalid, is called a Paragraph IV certification. If the ANDA applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders once the ANDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a patent infringement lawsuit in response to the notice of the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of the receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA until the earlier of 30 months, expiration of the patent, settlement of the lawsuit, or a decision in the infringement case that is favorable to the ANDA applicant.

The ANDA application also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

Exclusivity

Upon NDA approval of a new chemical entity or NCE, which is a drug that contains no active moiety that has been approved by the FDA in any other NDA, that drug receives five years of marketing exclusivity during which time the FDA cannot receive any ANDA seeking approval of a generic version of that drug. Certain changes to a drug, such as the addition of a new indication to the package insert, are associated with a three-year period of exclusivity during which the FDA cannot approval an ANDA for a generic drug that includes the change.

An ANDA may be submitted one year before NCE exclusivity expires if a Paragraph IV certification is filed. If there is no listed patent in the Orange Book, there may not be a Paragraph IV certification, and, thus, no ANDA may be filed before the expiration of the exclusivity period.

18

Table of Contents

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent extension. The allowable patent term extension is calculated as half of the drug s testing phase the time between IND submission and NDA submission and all of the review phase the time between NDA submission and approval up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the PTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Advertising and Promotion

Once an NDA is approved, a product will be subject to certain post-approval requirements. For instance, FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, off-label promotion, industry-sponsored scientific and educational activities and promotional activities involving the internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved labeling. Changes to some of the conditions established in an approved application, including changes in indications, labeling, or manufacturing processes or facilities, require submission and FDA approval of a new NDA or NDA supplement before the change can be implemented. An NDA supplement for a new indication typically requires clinical data similar to that in the original application, and the FDA uses the same procedures and actions in reviewing NDA supplements as it does in reviewing NDAs.

Adverse Event Reporting and GMP Compliance

Adverse event reporting and submission of periodic reports is required following FDA approval of an NDA. The FDA also may require post-marketing testing, known as Phase 4 testing, REMS, and surveillance to monitor the effects of an approved product, or the FDA may place conditions on an approval that could restrict the distribution or use of the product. In addition, quality-control, drug manufacture, packaging, and labeling procedures must continue to conform to current good manufacturing practices, or cGMPs, after approval. Drug manufacturers and certain of their subcontractors are required to register their establishments with FDA and certain state agencies. Registration with the FDA subjects entities to periodic unannounced inspections by the FDA, during which the agency inspects manufacturing facilities to assess compliance with cGMPs. Accordingly, manufacturers must continue to expend time, money and effort in the areas of production and quality-control to maintain compliance with cGMPs. Regulatory authorities may withdraw product approvals or request product recalls if a company fails to comply with regulatory standards, if it encounters problems following initial marketing, or if previously unrecognized problems are subsequently discovered.

Pediatric Information

Under the Pediatric Research Equity Act, or PREA, NDAs or supplements to NDAs must contain data to assess the safety and effectiveness of the drug for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the drug is safe and effective. The FDA may grant full or partial waivers, or deferrals, for submission of data. Unless otherwise required by regulation, PREA does not apply to any drug for an indication where orphan designation has been granted.

19

Table of Contents

The Best Pharmaceuticals for Children Act, or BPCA, provides NDA holders a six-month extension of any exclusivity patent or non-patent for a drug if certain conditions are met. Conditions for exclusivity include the FDA s determination that information relating to the use of a new drug in the pediatric population may produce health benefits in that population, the FDA making a written request for pediatric clinical trials, and the applicant agreeing to perform, and reporting on, the requested clinical trials within the statutory timeframe. Applications under the BPCA are treated as priority applications, with all of the benefits that designation confers.

Special Protocol Assessment

A company may reach an agreement with FDA under the Special Protocol Assessment, or SPA, process as to the required design and size of clinical trials intended to form the primary basis of an efficacy claim. Under the FDC Act and FDA guidance implementing the statutory requirement, an SPA is generally binding upon the FDA except in limited circumstances, such as if the FDA identifies a substantial scientific issue essential to determining safety or efficacy after the clinical trial begins, public health concerns emerge that were unrecognized at the time of the protocol assessment, the sponsor and FDA agree to the change in writing, or if the clinical trial sponsor fails to follow the protocol that was agreed upon with the FDA.

Expedited Review and Approval

The FDA has various programs, including Fast Track, priority review, and accelerated approval, which are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Even if a drug qualifies for one or more of these programs, the FDA may later decide that the drug no longer meets the conditions for qualification or that the time period for FDA review or approval will not be shortened. Generally, drugs that may be eligible for these programs are those for serious or life threatening conditions, those with the potential to address unmet medical needs, and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development, and expedite the review, of drugs to treat serious diseases and fill an unmet medical need. The request may be made at the time of IND submission and generally no later than the pre NDA meeting. The FDA will respond within 60 calendar days of receipt of the request. Priority review, which is requested at the time of NDA submission, is designed to give drugs that offer major advances in treatment or provide a treatment where no adequate therapy exists an initial review within six months as compared to a standard review time of ten months. Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated drug and expedite review of the application for a drug designated for priority review. Accelerated approval provides an earlier approval of drugs to treat serious diseases, and that fill an unmet medical need based on a surrogate endpoint, which is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. Discussions with the FDA about the feasibility of an accelerated approval typically begin early in the development of the drug in order to identify, among other things, an appropriate endpoint. As a condition of approval, the FDA may require that a sponsor of a drug receiving accelerated approval perform post marketing clinical trials to confirm the appropriateness of the surrogate marker clinical trial.

In FDASIA, Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of products under accelerated approval. The law required the FDA to issue related draft guidance within a year after the law s enactment and also promulgate confirming regulatory changes. The FDA published a final guidance on May 30, 2014, entitled Expedited Programs for Serious Conditions Drugs and Biologics. One of the expedited programs added by FDASIA is that for Breakthrough Therapy. A Breakthrough Therapy designation is designed to expedite the development and review of drugs that are intended to treat a serious condition where preliminary clinical evidence indicates that the drug may demonstrate substantial improvement over available therapy on a clinically significant endpoint(s). A sponsor may request Breakthrough Therapy designation at the time that the IND is submitted, or no

later than at the end of Phase 2 meeting. The FDA will respond to a Breakthrough Therapy designation request within sixty days of receipt of the request. A drug that

Table of Contents

receives Breakthrough Therapy designation is eligible for all fast track designation features, intensive guidance on an efficient drug development program, beginning as early as Phase 1 and commitment from the FDA involving senior managers.

Foreign Approval

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.

Pharmaceutical coverage, pricing and reimbursement

Sales of our products will depend, in part, on the extent to which our products will be covered by third party payors, such as government health programs, commercial insurance and managed healthcare organizations. In the United States, no uniform policy of coverage and reimbursement for drug products exists. Accordingly, decisions regarding the extent of coverage and amount of reimbursement to be provided for any of our products will be made on a payor-by-payor basis. As a result, the coverage determination process is often a time consuming and costly process that will require us to provide scientific and clinical support for the use of our product candidates to each payor separately, with no assurance that coverage and adequate reimbursement will be obtained.

Third party payors are increasingly challenging the price and examining the medical necessity and cost effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved, we may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost effectiveness of any products, in addition to the costs required to obtain regulatory approvals. Our product candidates may not be considered medically necessary or cost effective. If third party payors do not consider a product to be cost effective compared to other available therapies, they may not cover the product after approval as a benefit under their plans or, if they do, the level of payment may not be sufficient to allow a company to sell its products at a profit.

The U.S. government and state legislatures have shown significant interest in implementing cost containment programs to limit the growth of government paid health care costs, including price controls, restrictions on reimbursement and requirements for substitution of generic products for brand named prescription drugs. For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, contains provisions that may reduce the profitability of drug products, including, for example, increased rebates for drugs reimbursed by Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain Medicare Part D beneficiaries and

annual fees based on pharmaceutical companies share of sales to federal health care programs. Adoption of government controls and measures, and tightening of restrictive policies in jurisdictions with existing controls and measures, could limit payments for pharmaceuticals.

Table of Contents

As noted above, even if we are able to secure regulatory approval, sales of any of our products may suffer if the government and third party payors fail to provide adequate coverage and reimbursement. An increasing emphasis on cost containment measures in the United States has increased, and we expect this sentiment will continue to increase the pressure on drug pricing. Coverage policies and third party reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which we receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Other healthcare laws and compliance requirements

Manufacturing, sales, promotion and other activities following product approval are also subject to regulation by numerous regulatory authorities in addition to the FDA, including the Centers for Medicare & Medicaid Services, other divisions of the Department of Health and Human Services, the U.S. Department of Justice, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments.

We also are subject to various federal and state laws targeting fraud and abuse in the healthcare industry. These laws may impact, among other things, our proposed sales, marketing and educational programs. In addition, we may be subject to patient privacy regulation by both the federal government and the states in which we conduct our business. The laws that may affect our ability to operate include:

The federal Anti-Kickback Statute, which prohibits, among other things, persons from knowingly and willfully soliciting, receiving, offering or paying remuneration, directly or indirectly, in cash or in kind, to induce or reward, or in return for, either (1) the referral of an individual to a person for furnishing any item or service for which payment is available under a federal health care program, or (2) the purchase, lease, order or recommendation thereof of any good, facility, service or item for which payment is available under a federal health care program;

The False Claims Act and civil monetary penalty laws, which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false or fraudulent claims for payment from the federal government or making or using, or causing to be made or used, a false record or statement material to a false or fraudulent claim;

The federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created new federal criminal statutes that prohibit executing a scheme to defraud any healthcare benefit program, obtaining money or property of the health care benefit program through false representations or knowingly and willingly falsifying, concealing or covering up a material fact, making false statements or using or making any false or fraudulent document in connection with the delivery of, or payment for, health care benefits or services;

HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

The provision under the ACA commonly referred to as the Sunshine Act, which requires applicable manufacturers of covered drugs, devices, biologics and medical supplies to track and annually report to CMS payments and other transfers of value provided to physicians and teaching hospitals and certain ownership and investment interests held by physicians or their immediate family members in applicable manufacturers and group purchasing organizations; and

State law equivalents of each of the above federal laws, such as the Anti Kickback Statute and False Claims Act, and state laws concerning security and privacy of health care information, which may differ in substance and application from state to state thereby complicating compliance efforts.

The ACA broadened the reach of the fraud and abuse laws by, among other things, amending the intent requirement of the federal Anti-Kickback Statute and the applicable criminal healthcare fraud statutes contained

Table of Contents

within 42 U.S.C. Section 1320a 7b. Pursuant to the statutory amendment, a person or entity no longer needs to have actual knowledge of this statute or specific intent to violate it in order to have committed a violation. In addition, the ACA provides that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act or the civil monetary penalties statute. Many states have adopted laws similar to the federal Anti-Kickback Statute, some of which apply to the referral of patients for healthcare items or services reimbursed by any source, not only the Medicare and Medicaid programs.

As noted above, the federal False Claims Act prohibits anyone from, among other things, knowingly presenting, or causing to be presented, false or fraudulent claims for payment from federal programs, including Medicare and Medicaid. Although we would not submit claims directly to payors, manufacturers can be held liable under these laws if they are deemed to cause the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers. In addition, our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information and other information affecting federal, state, and third party reimbursement for our products, and the sale and marketing of our products are subject to scrutiny under this law. For example, pharmaceutical companies have been prosecuted under the federal False Claims Act in connection with their off label promotion of drugs. Penalties for such violations could include three times the actual damages sustained by the government, mandatory civil penalties between $5,500 and $11,000 for each separate false claim, exclusion from participation in federal healthcare programs, and the potential implication of various federal criminal statutes. Private individuals also have the ability to bring actions under the federal False Claims Act, or qui tam actions, and certain states have enacted laws based on the federal False Claims Act.

RESEARCH AND DEVELOPMENT

Company sponsored research and development expenses totaled $34.7 million in 2013, $51.5 million in 2014 and $36.7 million in 2015. Research and development expenses consist primarily of salaries and related personnel costs (including stock-based compensation expense), fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-FDA approval 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 February 12, 2016, we had 184 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.

Table of Contents

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 and industry

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, 2015, we had an accumulated deficit of $674.0 million. As we continue our research and development and initial commercial efforts, we will incur increasing losses. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug, Auryxia. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post approval regulatory obligations and successfully manufacture and commercialize our drug.

We are highly dependent on the commercial success of Auryxia in the United States for the foreseeable future and as a result we may be unable to attain profitability and positive cash flow from operations.

In September 2014, the FDA approved Auryxia for the control of serum phosphorus levels in patients with CKD on dialysis. The commercial success of Auryxia will depend on a number of factors, including:

- the effectiveness of Auryxia as a treatment for adult patients with CKD on dialysis;
- the adoption of Auryxia by physicians, which depends on whether physicians view it as a safe and effective treatment to lower serum phosphorus levels in patients with CKD on dialysis;
- the effectiveness of the sales, managed markets and marketing efforts by us and our competitors;
- the size of the treatable patient population;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, Auryxia by providing third party payers with a strong value proposition based on the existing burden of illness associated with CKD patients on dialysis and the benefits of Auryxia;
- the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with Auryxia;

our ability to obtain and maintain strong intellectual property protection for Auryxia;

the development or commercialization of competing products or therapies for the control of serum phosphorus levels in patients with CKD on dialysis; and

our ability to identify reliable suppliers and successfully manufacture Auryxia.

In addition to these factors, the commercial success of Auryxia is also dependent on gaining approval from the FDA to market Auryxia in the United States for additional indications, including for the treatment of iron deficiency anemia in patients with Stage 3-5 NDD-CKD, which is the indication being studied in our ongoing Phase 3 clinical trial.

Our revenues from the commercialization of Auryxia are subject to these and other factors, and therefore may be unpredictable from quarter-to-quarter. Ultimately, we may never generate sufficient revenues from Auryxia to reach or maintain profitability or sustain our anticipated levels of operations.

Table of Contents

We have limited experience as a company in sales and marketing, and with respect to pricing and obtaining adequate third-party reimbursement and as a result we may be unable to effectively market our product and retain market access.

We currently have limited experience as a company in sales and marketing and with respect to pricing and obtaining adequate third-party reimbursement for drugs. In order to market Auryxia, if it is approved in the United States for the treatment of iron deficiency anemia in patients with Stage 3-5 NDD-CKD, we intend to expand our marketing organization and hire additional sales representatives, which will require substantial effort and significant management and financial resources. We will need to devote significant effort, in particular, to recruiting individuals with experience in the sales and marketing of pharmaceutical products. Competition for personnel with these skills is intense and may be particularly difficult for us as no drug has previously been marketed for the treatment of iron deficiency anemia in patients with Stage 3-5 NDD-CKD. Additionally, our investment in this infrastructure might be lost if Auryxia is not approved for the treatment of iron deficiency anemia in patients with Stage 3-5 NDD-CKD.

Approval of Fexeric (ferric citrate coordination complex) in the European Union does not ensure successful commercialization and reimbursement.

On September 23, 2015, the EC approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union.

We are not currently marketing Fexeric in the European Union, however we are seeking potential partners to commercialize Fexeric in the European Union. We cannot assure you that we will be able to find a commercialization partner in the European Union or that we will be able to agree to acceptable terms with any partner to launch and commercialize Fexeric in the European Union.

The commercial success of Fexeric is subject to the same risks we face with commercializing Auryxia in the United States. In addition, in European countries, pricing and payment of prescription pharmaceuticals is subject to more extensive governmental control than in the United States. Pricing negotiations with European governmental authorities can take six to 12 months or longer after the receipt of regulatory approval and product launch. If reimbursement for Fexeric is unavailable in any country in which reimbursement is sought, limited in scope or amount, or if pricing is set at or reduced to unsatisfactory levels, our ability or any potential partner s ability to successfully commercialize Fexeric in such a country would be impacted negatively. Furthermore, if these measures prevent us or any potential partner from selling Fexeric on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of Fexeric in that country.

Our potential revenues from the commercialization of Fexeric in the European Union are subject to these and other factors, and therefore we may never reach or maintain profitability in the European Union.

Auryxia may cause undesirable side effects or have other properties that could limit its commercial potential.

The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia in the United States were diarrhea (21%), nausea (11%), constipation (8%), vomiting (7%) and cough (6%). Gastrointestinal adverse reactions were the most common reason for discontinuing Auryxia (14%) in clinical trials. If we or others identify previously unknown side effects, if known side effects are more frequent or severe than in the past, if we or others detect unexpected safety signals for Auryxia or any products perceived to be similar to Auryxia, or if any of the foregoing are perceived to have occurred, then:

sales of Auryxia may be impaired;

regulatory approvals for Auryxia may be restricted or withdrawn;

Table of Contents

- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals, or we may decide to conduct a product recall;

- reformulation of the product, additional nonclinical or clinical studies, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;

- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of Auryxia within its indicated populations, as well as be precluded from studying Auryxia in additional indications and populations or in new formulations; and

- government investigations or lawsuits, including class action suits, may be brought against us.

Any of the above occurrences would harm or prevent sales of Auryxia, likely increase our expenses and impair our ability to successfully commercialize Auryxia.

Furthermore, as we explore development opportunities to enhance the clinical profile of Auryxia, any clinical trials conducted, if successful, may expand the patient populations treated with Auryxia within or outside of its current indications or patient populations, which could result in the identification of previously unknown side effects, increased frequency or severity of known side effects, or detection of unexpected safety signals. In addition, now that Auryxia is commercially available, it will be used in a wider population and in less rigorously controlled environments than in clinical studies. As a result, regulatory authorities, healthcare practitioners, third party payers or patients may perceive or conclude that the use of Auryxia is associated with serious adverse effects, undermining our commercialization efforts.

We rely on third parties to manufacture and analytically test our drug. If these third parties do not successfully manufacture and test our drug, 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 for commercial distribution and use in clinical trials. 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 will depend on the ability of such third parties to manufacture our drug on a large scale at a competitive cost and in accordance with current cGMPs and other regulatory requirements, including requirements from federal, state and local environmental and safety regulatory agencies and foreign regulatory requirements, if applicable. Significant scale-up of manufacturing may result in unanticipated technical challenges and will require validation studies that are subject to FDA inspection. Scale-up and technology transfer activities can be complex, and insufficient process knowledge can result in a poorly scaled up process with inadequate process control. A lack of process control can lead to increased deviations during the manufacturing process, out of specification test results, batch rejection and the possible distribution of drug products that do not conform to predetermined specifications. In addition, a variety of factors can affect a contract manufacturer s qualifications to produce acceptable product, including deficiencies in the contractor s quality unit, lack of training, a shortage of qualified personnel, capacity constraints and changes in the contractor s commercial or quality related priorities. 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, particularly given that some of the third parties we intend to employ in the manufacturing process are

single source providers. These risks become more acute as we scale up for commercial quantities, where a reliable source of active pharmaceutical ingredient, or API, and a qualified contract manufacturer become critical to commercial success. For example, given the large quantity of materials required for Auryxia production and the large quantities of Auryxia that will be required for commercial success, the commercial viability of Auryxia 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 the API and finished drug product on a commercial scale. Failure to achieve this level

Table of Contents

of supply can jeopardize and prevent the successful commercialization of the product. Moreover, issues that may arise in our scale-up and technology transfer of Auryxia may lead to significant delays in our development and commercial timelines.

Our third-party manufacturers may not perform as required under the terms of our supply agreement or quality agreement, or may not remain in the contract manufacturing business for the time required by us to successfully manufacture and distribute our drug. 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 cGMPs, 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. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract, supplier qualification and periodic audits, 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 Auryxia 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 approvals for our drug. 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 approvals for our drug or our commercial efforts. 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 Auryxia, 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 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 drug;
- assist us in developing, testing and obtaining regulatory approval for and commercializing our compound and technologies; and

market and distribute our drug.

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

Table of Contents

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 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 drug and any future drug candidate.

We will incur significant liability if it is determined that we are promoting any off-label use of Auryxia.

Physicians are permitted to prescribe drug products for uses that are not described in the product s labeling and that differ from those approved by the FDA or other applicable regulatory agencies. Such off-label uses are common across medical specialties. Although the FDA and other regulatory agencies do not regulate a physician s choice of treatments, the FDA and other regulatory agencies do restrict communications on the subject of off-label use. Companies are not permitted to promote drugs for off-label uses or promote drugs using marketing claims that are not otherwise consistent with the FDA-approved labeling, including comparative or superiority claims that are not consistent with the FDA-approved labeling or supported by substantial evidence. Accordingly, we may not promote Auryxia in the United States for use in any indications other than for the control of serum phosphorus levels in patients with CKD on dialysis and all promotional claims must be consistent with the FDA-approved labeling for Auryxia. The FDA and other regulatory and enforcement authorities actively enforce laws and regulations prohibiting promotion of off-label uses and the promotion of products for which marketing approval has not been obtained as well as the false advertising or misleading promotion of drugs. A company that is found to have improperly promoted off-label uses or to have otherwise engaged in false or misleading promotion of drugs will be subject to significant liability, including civil and administrative remedies as well as criminal sanctions.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional scientific exchange concerning their products in certain circumstances. We intend to engage in medical education activities and communicate with healthcare providers in compliance with all applicable laws, regulatory guidance and industry best practices. Although we believe we have put in place a robust compliance program designed to ensure that all such activities are performed in a legal and compliant manner, Auryxia is our first commercial product, so our implementation of our compliance program in connection with commercialization activities is still relatively new.

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, as well as the timing of coverage and reimbursement decisions by third-party payors. Third-party

Table of Contents

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. Likewise, current and future legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs, such as the Patient Protection Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, could result in lower prices or rejection of coverage and reimbursement for our drug. In addition, third-party insurance coverage may not be available to patients for our product. 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.

If we fail to comply with healthcare regulations, we could face substantial penalties and our business, operations and financial condition could be adversely affected.

As a manufacturer of pharmaceuticals, even though we do not (and do not expect in the future to) control referrals of healthcare services or bill directly to Medicare, Medicaid or other third-party payers, certain federal and state healthcare laws and regulations pertaining to fraud and abuse and patients rights are and will be applicable to our business. We are subject to healthcare fraud and abuse and patient privacy regulation by both the federal government and the states in which we conduct our business. These regulations include:

- federal healthcare program anti-kickback laws, which prohibit, among other things, persons from soliciting, receiving or providing remuneration, directly or indirectly, to induce either the referral of an individual, for an item or service or the purchasing or ordering of a good or service, for which payment may be made under federal healthcare programs such as Medicare and Medicaid;

- federal false claims laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, claims for payment from Medicare, Medicaid, or other third-party payers that are false or fraudulent, and which may apply to entities like us which provide coding and billing advice to customers;

- the federal Health Insurance Portability and Accountability Act of 1996, which prohibits executing a scheme to defraud any healthcare benefit program or making false statements relating to healthcare matters and which also imposes certain requirements relating to the privacy, security and transmission of individually identifiable health information;

- the Federal Food, Drug, and Cosmetic Act, which among other things, strictly regulates drug product marketing, prohibits manufacturers from marketing drug products for off-label use and regulates the distribution of drug samples;

state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts;

the federal Foreign Corrupt Practices Act which prohibits corporations and individuals from paying, offering to pay, or authorizing the payment of anything of value to any foreign government official, government staff member, political party, or political candidate in an attempt to obtain or retain business or to otherwise influence a person working in an official capacity; and

the federal Physician Payments Sunshine Act, which was passed as part of the Patient Protection and Affordable Care Act of 2010, and similar state laws in certain states, that require pharmaceutical and medical device companies to monitor and report certain payments and transfers of value made to physicians and teaching hospitals.

Table of Contents

If our operations are found to be in violation of any of the laws described above or any other laws, rules or regulations that apply to us, we will be subject to penalties, including civil and criminal penalties, damages, fines and the curtailment or restructuring of our operations. Any penalties, damages, fines, curtailment or restructuring of our operations could adversely affect our ability to operate our business and our financial results.

In preparation for the commercial launch of Auryxia, we assembled an experienced compliance team who compiled a program based on industry best practices designed to ensure our commercialization of Auryxia complies with all applicable laws, regulations and industry standards. We also hire, manage and incentivize our employees around a culture of compliance, trust, respect and ownership. Because our program is relatively new and the requirements in this area are constantly evolving, we cannot be certain that our program will eliminate all areas of potential exposure. Although compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, the risks cannot be entirely eliminated. Any action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management s attention from the operation of our business, as well as damage our business or reputation. Moreover, achieving and sustaining compliance with applicable federal and state privacy, security, fraud and reporting laws may prove costly.

If our competitors develop and market products that are less expensive, have a reduced pill burden, 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.

Auryxia is competing in the United States 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), or Genzyme, 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 Auryxia 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. There are several parties pursuing approval of pending Abbreviated New Drug Applications, or ANDAs, for generic Renvela® with the FDA. In addition, a generic formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the United States in October 2008. In addition, upon the expiration of its core patents, generic formulations of Fosrenol® may be launched. These generic formulations could have a further material effect on the pricing of phosphate binders.

Furthermore, 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. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors.

Table of Contents

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 February 12, 2016, we had 184 full and part-time employees. To successfully develop and commercialize our drug and any drug candidates we may in-license or acquire, 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 our ability to continue to execute on our business plan could be materially impaired.

In July 2015, we appointed Scott Holmes to serve as our Senior Vice President and Chief Financial Officer. James F. Oliviero left the Company after serving in various finance capacities for twelve years, including as our Chief Financial Officer since 2009.

Greg Madison assumed the Chief Executive Officer role following the resignation of Mr. Bentsur on April 30, 2015. Previously, Mr. Madison was appointed to our Board of Directors in March 2015. Mr. Madison joined Keryx in February 2014 as Executive Vice President and Chief Operating Officer to transition Keryx from a development stage organization into a fully integrated commercial entity, and bring to Keryx a wealth of relevant expertise in both the phosphate binder and iron deficiency anemia markets.

Brian Adams joined Keryx in April 2014 as General Counsel and was additionally appointed as our Corporate Secretary in March 2015.

In April 2015, we appointed John F. Neylan, M.D., as our Senior Vice President and Chief Medical Officer.

Although we have employment agreements with Greg Madison, Brian Adams, Scott Holmes and John Neylan, M.D., these agreements do not prevent them from terminating their employment with us.

Risks associated with our product development efforts

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 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 United States.

Negative or inconclusive results from the clinical trials we conduct, such as the ongoing Phase 3 study of Auryxia for the treatment of iron deficiency anemia in patients with NDD-CKD, 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 for

KRX-0401. We may also opt to change the delivery method, formulation or dosage which could affect efficacy results for the drug. Accordingly, we may not be able to complete our current or future clinical trials within an acceptable time frame, if at all.

Table of Contents

Pre-clinical testing and clinical development are long, expensive and uncertain processes. If our Phase 3 study of ferric citrate for the treatment of IDA in patients with Stage 3-5 NDD-CKD raises safety signals or fails to demonstrate efficacy despite positive results in earlier clinical testing, we may be unable to submit or receive regulatory approval for an expanded indication for Auryxia.

In September 2014, we initiated a pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia in patients with Stage 3-5 NDD-CKD, and expect to submit this data to the FDA for approval in the third quarter of 2016. However, we may need to conduct significant additional research and human testing before we may submit an application for regulatory approval. 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 may pose additional questions or request further toxicological, drug-drug interaction, pre-clinical or clinical data or substantiation. 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. The last patient in this Phase 3 trial completed treatment in January 2016 and top line data is expected to be reported in the second quarter of 2016.

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. While both the FDA and EC have previously reviewed the data from our Phase 3 clinical program for CKD patients on dialysis and Phase 2 study in NDD 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. 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 may be viewed as flawed by the FDA. 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.

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) trial results in April 2012, and we can provide no assurance that we will not experience such setbacks with ferric citrate or any other drug candidate we develop. If we experience delays in the testing or approval process for our existing drug or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval. 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 further commercializing Auryxia.

We do not own our drug, Auryxia. We have licensed and sublicensed the rights, patent or otherwise, to Auryxia from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under

Table of Contents

the agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Auryxia) 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 Auryxia. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia. 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 drug 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 or drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drugs. Finally, our rights to develop and commercialize Auryxia, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Auryxia and the licenses and sublicenses we grant to others.

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

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.

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.

Table of Contents

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 United States 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 United States or internationally, the reimportation of drugs into the United States 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 United States, 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.

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, delayed 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. In April 2014, the United States Congress passed legislation known as Protecting Access to Medicare Act of 2014, which, among other things, delays by eight years the implementation of oral-only ESRD related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2025. If phosphate binders are included in the bundle beginning in 2025, or earlier, 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 Auryxia.

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. On July 9, 2012, the Food and Drug Administration Safety and Innovation Act was enacted to, among other

Table of Contents

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. On November 27, 2013, the Drug Quality and Security Act, which includes the Drug Supply Chain Security Act, was signed into law to, among other things, build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Requirements for the tracing of products through the pharmaceutical distribution supply chain took effect on January 1, 2015 for manufacturers and building internal systems to ensure compliance with this law will require dedication of resources. In addition, this law requires engaging in transactions only with authorized trading partners and could limit our pool of available trading partners.

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

The use of our drug or future drug candidates in clinical trials, and the future sale of any approved drug 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 product or limit commercialization of any approved product.

We have expanded our insurance coverage to include the commercial sale of Auryxia; 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 to our business.

Security breaches and other disruptions could compromise our information and expose us to liability, which would cause our business and reputation to suffer.

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of Auryxia patients, clinical trial participants and employees. We also have outsourced elements of our information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third party

providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors and other third party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups. Any such breach could compromise our, and their, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Table of Contents

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, including the October 2015 private placement of $125 million in Notes, combined with future anticipated cash flows will be sufficient to execute 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 commercial activities related to Auryxia and the magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of, and results from, clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire.

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 commercial activities related to Auryxia and the magnitude of cash received from product sales;
- the timing and expenditures associated with the build-up of inventory and capacity expansion;
- the timing, design and conduct of, and results from, clinical trials for Auryxia;
- the timing of expenses associated with manufacturing and product development of Auryxia 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 timing and expenditures associated with commercial activities related to launching Fexeric in Europe, either by us or through a commercialization partner;
- 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 and those that may be in-licensed, partnered or acquired; and

- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights or defending against claims of infringement initiated by third parties in respect of their intellectual property rights.

If our cash is insufficient to meet our 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.

Table of Contents

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 United States 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 any related patent may expire prior to, or remain in existence for only a short period following, commercialization, thus 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 United States. In addition, in jurisdictions outside the United States where we own or license 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, Auryxia, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia.

The patent rights that we own or have licensed relating to Auryxia are limited in ways that may affect our ability to exclude third parties from competing against us. 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 Auryxia in the United States (U.S. Patent

No. 5,753,706) expires in February 2017. We licensed additional composition of matter and method of use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient, or API, of Auryxia), 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 method of use patents, including U.S. Patent Nos. 7,767,851, 8,299,298 and 8,338,642 and (which expire in 2024), and U.S. Patent No. 8,093,423 (which expires in 2026) only protect the product when

Table of Contents

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.

We have filed applications under the Patent Term Extension provisions of 35 U.S.C. § 156 on the above mentioned patents for delays caused by FDA regulatory review. If granted, we can utilize the patent term extension on one of these patents, however, we cannot assure you that we can obtain any extension of the term of these patents. If obtained, the maximum term of extension available under 35 U.S.C. § 156 would extend the term of the chosen patent by no more than five years. Upon expiration of these patents, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition and/or method of use as our product, so long as the competitors do not infringe any other patents that we may hold.

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.

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors induce or contribute to others in engaging in direct infringement. Proving that a competitor contributes to, or induces, infringement of a patented method by another has additional proof requirements. For example, 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 Auryxia, increase the risk that a generic version of Auryxia could enter the market to compete with Auryxia, limit our development and commercialization of Auryxia, 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 Auryxia. 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.

In addition, any limitations of our patent protection described above may adversely affect the value of our drug product 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, if granted by the FDA, 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.

In the United States, 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 may provide 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 United States 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)

Table of Contents

or ion(s) responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an 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 Auryxia.

We cannot assure that Auryxia or any drug candidates we may acquire or in-license, will obtain such pediatric exclusivity, NCE exclusivity or any other market exclusivity in the United States, 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. We also cannot assure that Auryxia or any drug candidates we may acquire or in-license will obtain patent term extension.

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 Auryxia 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 Auryxia or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Auryxia or such technologies, and/or require our licensor or us to obtain a license to continue to use Auryxia 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

Baupost, our largest stockholder may have significant influence over our company and may cause us to take actions that may not be, or refrain from taking actions that may be, in our best interest or the best interest of our other stockholders.

As of December 31, 2015, Baupost beneficially owns approximately 25% of our issued and outstanding common stock. If all of the Notes were converted prior to the approval of the necessary increase in shares, Baupost would beneficially own approximately 28% of our issued and outstanding common stock and Baupost s beneficial ownership of our issued and outstanding common stock would increase to approximately 43% if the remaining Notes were converted into our common stock. Baupost, through its equity interests, may have significant influence over matters submitted to our stockholders for approval and other corporate actions, such as:

election of directors;

timing and manner of dividend distributions;

approval of contracts between us and Baupost or its respective affiliates, which could involve conflicts of interest;

open market purchase programs or other purchases of our common shares;

Table of Contents

delay, defer or prevent a change in who controls us;

discourage bids for our shares at a premium over the market price; and

adversely affect the market price of our common shares.

Moreover, because large stockholders have potential power to direct or influence our corporate actions, we may be required to engage in transactions that may not be agreeable to our other stockholders or that may not be in the best interest of our other stockholders. In conjunction with the financing, we increased the number of directors on our Board to eight, as Baupost has the right to appoint a director to our Board. Baupost also has the right to appoint an observer to our board.

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 make it more difficult for us to raise funds through the sale of equity in the future.

In October 2015, we raised $125 million through the private placement of Convertible Senior Notes, due 2020, with funds managed by The Baupost Group, L.L.C. The zero-coupon notes will mature in October 2020 unless converted into shares of our common stock in accordance with their terms prior to such date. Keryx does not have the right to redeem the notes prior to maturity. The conversion price of the notes shall be equal to the closing price of Keryx s common stock on the day prior to closing, October 14, 2015, or $3.74 per share, subject to certain adjustments under the terms of the notes.

On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under registration statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the Securities and Exchange Commission.

We may need to seek additional financings to provide cash necessary to execute our current operations, including, but not limited to, beyond the continued commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire. 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:

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;

Table of Contents

changes in financial estimates by securities analysts;

actual or anticipated variations in quarterly or annual operating results;

developments relating to the marketing, safety and efficacy of our drug product, and regulatory filings and approvals for us or our competitors;

expectations regarding our financial condition;

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

expectations or investor speculation regarding the strength of our intellectual property position, or the availability of other forms 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. For example, in the past, we have been the subject of a putative stockholders securities class action alleging misstatements or omissions in relation to our clinical trials for KRX-0401 (perifosine), which we abandoned in May 2012 following negative Phase 3 trial results. Any litigation 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.

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 office is located in Boston, Massachusetts. In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94 month term that commenced on May 1, 2015 for new office space to serve as our corporate headquarters.

Table of Contents

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.

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.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

Table of Contents

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, 2015		
Fourth Quarter	$ 5.81	$ 3.19
Third Quarter	$ 10.31	$ 3.38
Second Quarter	$ 12.51	$ 9.32
First Quarter	$ 14.68	$ 10.87

	High	Low
Fiscal Year Ended December 31, 2014		
Fourth Quarter	$ 17.20	$ 13.57
Third Quarter	$ 18.19	$ 12.71
Second Quarter	$ 17.03	$ 12.11
First Quarter	$ 17.04	$ 12.16

Holders

The number of record holders of our common stock as of February 10, 2016 was 53.

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. Further, in accordance with the Indenture (as defined in Note 10 to the Consolidated Financial Statements included in this annual report on Form 10-K), we are restricted from making payments of cash dividends.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2015, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1999 Stock Option Plan, as amended, 2004 Long-Term Incentive Plan, 2007 Incentive Plan, 2009 CEO Incentive Plan and 2013 Incentive Plan, as amended.

Plan Category	Equity Compensation Plan Information

	Number of securities to be issued upon exercise of outstanding options	Weighted-average exercise price of outstanding options	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans	5,411,557	$ 10.96	3,099,139

Table of Contents

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

COMMON STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2009 through December 31, 2015, 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, 2010, 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.

Table of Contents

ITEM 6. SELECTED FINANCIAL DATA.

The following Statement of Operations Data for the years ended December 31, 2015, 2014, 2013, 2012 and 2011, and Balance Sheet Data as of December 31, 2015, 2014, 2013, 2012 and 2011, 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 contained elsewhere in this annual report on Form 10-K.

	Years ended December 31,				
	2015	**2014**	**2013**	**2012**	**2011**
	(in thousands, except per share data)				
Statement of Operations Data:					
Net U.S. Auryxia product sales	$ 10,141	$	$	$	$
License revenue	3,539	10,825	7,000		5,000
Total Revenues	13,680	10,825	7,000		5,000
Operating expenses:					
Cost of goods sold	4,520				
License expenses	2,124	495			
Research and development	36,694	51,502	34,734	20,031	27,012
Selling, general and administrative	81,410	70,057	19,349	7,048	6,737
Total operating expenses	124,748	122,054	54,083	27,079	33,749
Operating loss	(111,068)	(111,229)	(47,083)	(27,079)	(28,749)
Other income (expense):					
Other income (expense), net	(11,987)	411	351	1,719	380
Loss from continuing operations before income taxes	(123,055)	(110,818)	(46,732)	(25,360)	(28,369)
Income taxes	(90)	(700)			
Loss from continuing operations	(123,145)	(111,518)	(46,732)	(25,360)	(28,369)
Gain from discontinued operations					246
Loss before extraordinary gain	(123,145)	(111,518)	(46,732)	(25,360)	(28,123)
Extraordinary gain				2,639	
Net loss	$ (123,145)	$ (111,518)	$ (46,732)	$ (22,721)	$ (28,123)
Basic and diluted loss per common share:					
Continuing operations	$ (1.19)	$ (1.23)	$ (0.58)	$ (0.36)	$ (0.42)
Discontinued operations					*
Extraordinary gain				0.04	

Basic and diluted loss per common share	$ (1.19)	$ (1.23)	$ (0.58)	$ (0.32)	$ (0.42)

* Amount less than one cent per share.

	As of December 31,				
(in thousands)	**2015**	**2014**	**2013**	**2012**	**2011**
Balance Sheet Data:					
Cash, cash equivalents, interest receivable and short-term investment securities	$ 200,290	$ 85,840	$ 55,696	$ 14,677	$ 39,470
Working capital	171,688	69,285	41,600	7,068	30,237
Total assets	258,685	103,628	60,766	18,569	43,488
Convertible senior notes	90,773				
Total liabilities	171,751	30,144	15,366	8,075	12,441
Total stockholders equity	86,934	73,484	45,400	10,494	31,047

Table of Contents

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 this report under the heading 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 bringing innovative therapies to market for patients with renal disease. Our product, Auryxia (ferric citrate), also known as Riona in Japan and Fexeric in Europe, is an oral, absorbable iron-based compound, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our compound, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

Auryxia has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes to reduce intestinal absorption and aid in the management of hyperphosphatemia in patients with CKD. The U.S. approval of Auryxia was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Auryxia effectively reduced serum phosphorus levels to within the Kidney Disease Outcomes Quality Initiative, or KDOQI, guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Auryxia s pharmacodynamic properties resulted in increased ferritin, iron and transferrin saturation, or TSAT; whereas these parameters remained relatively constant in patients treated in the active control arm (Renvela® and/or Phoslo®) in our Phase 3 registration program. The most common adverse events for Auryxia treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on approximately 5,000 target nephrologists and their associated dialysis centers. In addition, we have a small team of national account managers who are primarily responsible for working with insurance plans, health maintenance organizations and other payers to secure reimbursement and formulary access for Auryxia. In December 2014, we created the Keryx Patient Plus program to assist with patient accessibility to Auryxia. The Keryx Patient Plus program offers benefit verification, co-pay assistance for eligible commercial patients, a no-cost drug program for those who qualify, and a short-term prescription bridge program that may assist those already on Auryxia who are in danger of suffering a lapse in coverage. In the United States there are approximately 450,000 patients on dialysis and approximately 2.9 million prescriptions written annually for phosphate binders. We had net U.S. Auryxia product sales in 2015 of $10.1 million and 1% market share by the end of the year.

Our Japanese partner, Japan Tobacco Inc. or JT, together with its subsidiary Torii Pharmaceutical Co. Ltd., or Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health,

Table of Contents

Labour and Welfare as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD, or NDD-CKD, in January 2014. Torii began to market the product under the brand name Riona in May 2014. Under the license agreement with JT and Torii, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We received royalty revenues of $0.8 million and $3.5 million from the sales of Riona in Japan in 2014 and 2015, respectively. We in turn owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union. We are currently seeking potential partners to commercialize Fexeric in the European Union.

In September 2014, we initiated a pivotal Phase 3 clinical trial of ferric citrate for the treatment of iron deficiency anemia, or IDA, in patients with Stage 3-5 NDD-CKD. This study s primary endpoint is the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period. Secondary endpoints in the Phase 3 study include the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The last patient in this Phase 3 trial completed treatment in January 2016 and we expect to report top line data in the second quarter of 2016, and if successful file for FDA approval of this indication in the third quarter of 2016.

Currently, our only product is Auryxia. In January 2015, we began to recognize product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, revenue from the sublicensing of rights to Auryxia in Japan to our Japanese partners, JT and Torii. We may engage in business development activities that include seeking strategic relationships for Auryxia outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on assets that are complementary to Auryxia.

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 the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Even though we are commercializing Auryxia, 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 additional regulatory approvals for ferric citrate or any other product candidate in which we obtain rights, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize Auryxia alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of ferric citrate. In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C., or Baupost. As of December 31, 2015, Baupost beneficially owns approximately 25% of our issued and outstanding common stock. If all of the Notes were converted prior to the approval of the necessary increase in shares, Baupost would beneficially own approximately 28% of our issued and outstanding common stock and Baupost s beneficial ownership of our issued and outstanding common stock would increase to approximately 43% if the remaining Notes were converted into our common stock. In addition, in January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses, in an underwritten public offering of our common stock.

We have devoted substantially all of our efforts to the identification, in-licensing, development and partnering of drug candidates, as well as pre-commercial/commercial activities related to Auryxia, and have

Table of Contents

incurred negative cash flow from operations each year since our inception. 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, commercial, partnership and licensing activities. Prior to the U.S. launch of Auryxia in late December 2014, we had not commercialized any drug. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug.

Financial Performance Overview

Net U.S. Auryxia product sales represents the gross product sales of Auryxia in the United Sates less provisions for product sales allowances and accruals. These provisions include trade allowances, rebates, chargebacks and discounts, product returns and other incentives. See Critical Accounting Policies below for more information on the components of net U.S. Auryxia product sales.

Our license revenues consist of license fees and milestone payments arising from our agreement with JT and Torii. See Critical Accounting Policies below for more information on our recognition of license revenues from our agreement with JT and Torii.

Royalty revenue consists of royalties received from our Japanese partner on net sales of Riona in Japan. Based on our agreement with JT and Torii, and in accordance with our revenue recognition policy described below, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred.

Cost of goods sold includes the cost of API for Auryxia on which product sales were recognized during the period, as well as the associated costs for tableting, packaging, shipment, insurance and quality assurance. Cost of goods sold also includes expenses due the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

Our license expenses consist of royalty and other expenses due to the licensor of Auryxia related to our license agreement with JT and Torii. With regard to license expense, such expense is directly related to the royalty revenue received from JT and Torii and is recognized in the same period as the revenue is recorded. Other expenses are recognized in the period they are incurred.

Our research and development expenses consist primarily of salaries and related personnel costs, including stock-based compensation, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-approval inventory build-up, 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. Research and development expenses for the years ended December 31, 2015, 2014 and 2013 were $36.7 million, $51.5 million and $34.7 million, respectively.

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

(in thousands)	Years ended December 31, 2015	2014	2013
Auryxia (ferric citrate)	$ 32,911	$ 44,735	$ 32,001
Other	264	388	386
Stock-based compensation expense	3,519	6,379	2,347
Total	$ 36,694	$ 51,502	$ 34,734

Table of Contents

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

Our results of operations include stock-based 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. See Critical Accounting Policies below for a discussion of our recognition of stock-based compensation expenses. The expense is included in the respective categories of expense in the consolidated statements of operations. We expect to continue to incur significant stock-based compensation expenses.

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis, there is no guarantee that we will be able to record meaningful commercial sales of Auryxia in the future or become profitable. In addition, we expect losses to continue as we continue to fund the development and commercialization of Auryxia, including, but not limited to, supplemental new drug application submissions building of inventory, 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. 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.

RESULTS OF OPERATIONS

Years Ended December 31, 2015 and 2014

Net U.S. Auryxia Product Sales. For the year ended December 31, 2015, we recognized $10.1 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks. Our commercial launch of Auryxia occurred in late December 2014. There were no product sales for the year ended December 31, 2014.

(in thousands)	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 16,295	
Less provision for product sales allowances and accruals		
Trade allowances	1,897	12%
Rebates, chargebacks and discounts	2,418	15%
Product returns	0	0%
Other incentives (1)	1,839	11%
Total	6,154	38%
Net U.S. Auryxia product sales	$ 10,141	

(1) Includes co-pay mitigation and voucher rebates.

We sell product to a limited number of major wholesalers, which we refer to as our Distributors, as well as certain pharmacies, which we refer to collectively as our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with our revenue recognition policy, until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue recognition is deferred until the earlier of the product being resold for purposes of filling patient prescriptions

Table of Contents

and the expiration of the right of return (twelve months after the expiration date of the product), and not based on sales from us to our Customers. At December 31, 2015, we have deferred revenue of $3.5 million, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable discounts and rebates. We expect Auryxia product sales and patient prescriptions to increase in 2016 as we continue the commercialization of Auryxia.

Other incentives include costs associated with patient services programs, including a voucher program that provides a free month of drug to patients as we work to build formulary access for Auryxia. We expect that voucher redemptions will represent a continuously decreasing percentage of our gross sales. We expect that this decrease in our voucher program, however, will be offset by increases in rebates as more of our business will be contracted with third-party payors.

License Revenue. For the year ended December 31, 2015, we recognized $3.5 million in license revenue on royalty payments from sales of Riona in Japan as compared to $10.8 million for the year ended December 31, 2014. This decrease was due to the one-time recognition of a $10.0 million non-refundable milestone payment in January 2014 related to JT and Torii s achievement of marketing approval of Riona in Japan.

Cost of Goods Sold. For the year ended December 31, 2015, we recognized $4.5 million in cost of goods sold related to product sales of Auryxia. Our commercial launch of Auryxia occurred in late December 2014. There was no cost of goods sold expense recorded for the year ended December 31, 2014. The cost of goods sold for the year ended December 31, 2015 includes $2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production capacity at certain of our third-party manufacturers.

License Expenses. For the year ended December 31, 2015, we recognized $2.1 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.5 million for the year ended December 31, 2014. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $14.8 million, or 29%, to $36.7 million for the year ended December 31, 2015, as compared to $51.5 million for the year ended December 31, 2014. The decrease in research and development expenses was due to an $11.1 million decrease in expenses related to the manufacturing of Auryxia, which were expensed through approval of Auryxia in September 2014 and are now capitalized as inventory following approval, as well as a $6.6 million decrease in regulatory and clinical study expenses related to Auryxia. Stock-based compensation also decreased $2.9 million for the year ended December 31, 2015 as compared to the prior year period, primarily as a result of the vesting of milestone-based stock options and restricted shares upon the FDA approval and first commercial sale of Auryxia to wholesalers in 2014. These decreases were partially offset by $7.9 million of expenses for medical affairs activities in the year ended December 31, 2015, as the medical affairs group will increasingly be supporting additional research and development of Auryxia in the post-approval setting and, therefore, the associated costs are included in research and development expenses as of January 2015. We expect our research and development expenses to decrease slightly in 2016 following the completion in the second quarter of 2016 of our pivotal Phase 3 study of Auryxia for the treatment of iron deficiency anemia, or IDA, in patients with Stage 3-5 NDD-CKD.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $11.3 million, or 16%, to $81.4 million for the year ended December 31, 2015, as compared to $70.1 million for the year ended December 31, 2014. The increase was primarily due to a $12.2 million increase in sales expense related to the commercialization of Auryxia, including an increase in sales force. We expect our selling, general and administrative costs to remain relatively consistent in 2016 as compared to 2015.

Other income (expense), net. Other income (expense), net for the year ended December 31, 2015 was $12.0 million (expense) compared to $0.4 million (income) for the year ended December 31, 2014. This increase in expense was primarily the result of $11.4 million of expense recorded related to the amortization of the debt discount recognized in connection with the issuance of the Notes in October 2015. Additionally, we recorded

Table of Contents

$1.1 million of expense in 2015 related to the increase in fair value of the derivative liability from October 15, 2015 to December 31, 2015. This derivative liability was recorded in connection with the issuance of the Notes in October 2015 and represents the portion of the Notes that is required to be accounted for separately. See Note 10 Debt for additional details.

Income Taxes. For the year ended December 31, 2015, we recognized $0.1 million in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes, as compared to $0.7 million in income tax expense for the year ended December 31, 2014. Indefinite-lived intangibles are non-monetary assets which are not amortized under generally accepted accounting principles in the United States, or GAAP, since there is no foreseeable limit to the cash flows provided by them. 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 liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. We continue to maintain a full valuation allowance against our net deferred tax assets.

Years Ended December 31, 2014 and 2013

License Revenue. License revenue for the year ended December 31, 2014 was $10.8 million due to the recognition of a $10.0 million non-refundable milestone payment in January 2014 related to JT and Torii s achievement of marketing approval in Japan and $0.8 million of royalty payments from sales of Riona in Japan. 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 Auryxia in Japan.

License Expenses. For the year ended December 31, 2014, we recognized $0.5 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan. There were no license expenses for the year ended December 31, 2013.

Research and Development Expenses. Research and development expenses increased by $16.8 million to $51.5 million for the year ended December 31, 2014, as compared to $34.7 million for the year ended December 31, 2013. The increase in research and development expenses was due primarily to a $12.7 million increase in research and development expenses related to our Auryxia program, including costs associated with the manufacturing of pre-approval inventory and the submission of our marketing authorization application in Europe. The year ended December 31, 2014, includes a $2.0 million one-time milestone payment to Panion, the licensor of Auryxia, for JT and Torii s achievement of the Japanese marketing approval milestone in January 2014 and a $3.0 million one-time milestone payment to Panion for our achievement of U.S. FDA approval of Auryxia in September 2014. Stock-based compensation expense increased by $4.0 million to $6.4 million for the year ended December 31, 2014, as compared to $2.3 million for the year ended December 31, 2013, primarily related to $4.6 million of expense due to the vesting of milestone-based stock options and restricted shares upon the FDA approval.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $50.7 million to $70.1 million for the year ended December 31, 2014, as compared to $19.3 million for the year ended December 31, 2013. The increase was primarily related to a $24.3 million increase in pre-commercial/commercial activities, including associated personnel costs, in preparation for the commercialization of Auryxia and increased stock-based compensation expense. Stock-based compensation expense increased by $17.0 million to $20.6 million for the year ended December 31, 2014, as compared to $3.6 million for the year ended December 31, 2013, primarily related to $11.0 million of expense due to the vesting of milestone-based stock options and restricted shares upon the FDA approval and first commercial sale of Auryxia to wholesalers, as well as to increased selling, general and

administrative personnel and the recording of the fair value of equity awards granted, which are expensed over the vesting periods of the individual awards.

Table of Contents

Interest and Other Income, Net. Interest and other income, net, increased by $60,000 to $411,000 for the year ended December 31, 2014, as compared to $351,000 for the year ended December 31, 2013. The increase was due to a higher level of invested funds in our investment portfolio following our January 2014 public offering.

Income Taxes. For the year ended December 31, 2014, we recognized $0.7 million in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP since there is no foreseeable limit to the cash flows provided by them. 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 liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. There was no income tax expense for the year ended December 31, 2013. We continue to maintain a full valuation allowance against our net deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible notes, option and warrant exercises, interest income, and from the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. The commercial launch of our product, Auryxia, occurred in late December 2014 and we began to recognize revenue from the sales of Auryxia in 2015. Even though we are commercializing Auryxia, 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 additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C, or Baupost. The Notes may be converted into shares of our common stock at the discretion of Baupost at a conversion price of $3.74, subject to adjustment based on the occurrence of certain events. In order to accommodate the full conversion of the Notes, we will seek stockholder approval of an amendment to our certificate of incorporation at the 2016 Annual Meeting of Stockholders to increase the number of shares of authorized common stock. If any necessary share increases are not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. We also entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement with the SEC covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare such resale registration statement effective. Further, the Registration Rights Agreement permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns may be conducted upon written request from Baupost. In addition, the Registration Rights Agreement provides Baupost certain piggyback registration rights.

On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under registration statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the Securities and Exchange Commission.

In January 2014, our Japanese partner, JT and Torii, received manufacturing and marketing approval of Riona from the Japanese Ministry of Health, Labour and Welfare. We receive royalty payments based on a tiered

Table of Contents

double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We owe royalties at a mid-single digit percentage of net sales to the licensor of Auryxia associated with net sales of Riona in Japan.

As of December 31, 2015, we had $200.3 million in cash and cash equivalents, as compared to $85.8 million in cash, cash equivalents, short-term investments and interest receivable at December 31, 2014, representing an increase of $114.5 million.

We currently expect that our existing capital resources and future anticipated cash flows will be sufficient to execute our current business objectives. 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 commercial activities related to Auryxia and the magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the continued commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factor, Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

Net cash used in operating activities for the year ended December 31, 2015 was $127.5 million, primarily attributable to our net loss of $123.1 million, adjusted for non-cash stock-based compensation expense and amortization of the debt discount recognized in connection with the issuance of the Notes, as well as changes in operating assets and liabilities, principally the increase of inventory and decrease in accrued expenses from December 31, 2014. Net cash used in operating activities for the year ended December 31, 2014 was $81.0 million, primarily attributable to our net loss of $111.5 million, adjusted for non-cash stock-based compensation expense and changes in operating assets and liabilities, principally the increase in inventory and increase in accrued expenses from December 31, 2013. The increase in net cash used in operating activities in 2015 was primarily related to Auryxia commercial expenditures to support the launch of Auryxia in the United States, including the manufacturing inventory and the continued Phase 3 clinical development of ferric citrate for NDD-CKD indications.

Net cash provided by investing activities for the year ended December 31, 2015 was $8.7 million, attributable to $11.5 million provided by maturities of short-term investments, partially offset by capital expenditures. Net cash used in investing activities for the year ended December 31, 2014 was $13.0 million, primarily attributable to purchases of short-term investments, partially offset by proceeds from maturities of short-term investments.

Net cash provided by financing activities for the year ended December 31, 2015 was $244.7 million, primarily attributable to net proceeds from the issuance of the Notes in October 2015 and from the public offering of common stock in January 2015. Net cash provided by financing activities for the year ended December 31, 2014 was $112.6 million, primarily attributable to net proceeds from the public offering of common stock in January 2014. The increase in cash provided by financing activities from 2014 to 2015 was a result of the net proceeds from the Notes issued in October 2015, as well as an incremental $10.8 million of net proceeds received from our public offering of common stock in January 2015 as compared to our public offering of common stock in January 2014.

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

53

Table of Contents

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, 2015, we have known contractual obligations, commitments and contingencies of $173.8 million. Of this amount, $7.6 million relates to selling, general and administrative agreements primarily associated with the commercialization of Auryxia, of which $7.2 million is due within the next year, $2.1 million relates to research and development agreements (relating to our Auryxia clinical and regulatory programs), and $26.7 million relates to various third-party contract manufacturing agreements for the production and packaging of Auryxia drug substance and drug product. The debt obligation in the table below reflects our obligations under the Notes to make a principal payment for the par value of the Notes at maturity. Any future conversion or settlement of the Notes could impact the timing and amount of our potential cash payments under the Notes (see Note 10 Debt). The remaining $12.5 million relates to our operating lease obligations.

(in thousands)	Payment due by period				
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Selling, general and administrative agreements	$ 7,590	$ 7,230	$ 360	$	$
Research and development agreements	2,102	2,102			
Manufacturing agreements	26,677	26,677			
Convertible senior notes	125,000			125,000	
Operating leases	12,473	2,168	3,229	3,338	3,738
Total	$ 173,842	$ 38,177	$ 3,589	$ 128,338	$ 3,738

In April 2015, we signed a lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94 month term that commenced on May 1, 2015 and will expire in February 2022, for office space to serve as our corporate headquarters.

COSTS AND TIME TO COMPLETE PRODUCT DEVELOPMENT

The information below provides an estimate regarding the cost associated with the completion of the development phase for ferric citrate, which is currently our only product candidate in development. 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**	**Estimated cost to complete phase**
Ferric citrate	Iron deficiency anemia in NDD-CKD	$2 - $3 million

The cost in the above table is an estimate and is 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.

Table of Contents

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 consolidated 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 consolidated 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:

Revenue Recognition and Related Sales Allowances and Accruals

Our commercial launch of Auryxia occurred in late December 2014. We sell product to a limited number of major wholesalers, which we refer to as our Distributors, as well as certain pharmacies, which we refer to collectively as our Customers. Our Distributors resell the product to retail pharmacies for purposes of the pharmacies reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable. Until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue will be recognized based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Customers, we anticipate that our revenues will be recognized based on sales to our Customers. We currently defer Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue is recorded net of discounts, rebates, and chargebacks. We also defer the related cost of product sales and record such amounts as finished goods inventory held by others, which is included in inventory on our consolidated balance sheet, until revenue related to such product sales is recognized.

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product sales from the sales to Customers and (ii) reasonably estimate our net product sales. We calculate gross product sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services, such as fees for certain data that Distributors provide to us. The payment terms for sales to Distributors generally include a prompt-pay discount for payment made by check within 30 days. Based on our judgment and industry experience, we expect our Distributors to earn these discounts and fees, and deduct the full

amount of these discounts and fees from our gross product sales and accounts receivable at the time such revenues are recognized.

Table of Contents

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various commercial and Medicare Part D private insurance providers, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We also contract with certain specialty pharmacies directly so that Auryxia will be eligible for purchase by these specialty pharmacies. We estimate the rebates, chargebacks and discounts we will provide to Third-party Payors and specialty pharmacies, and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We estimate the rebates, chargebacks and discounts that we will provide to third-party payors and specialty pharmacies based upon (i) our contracts with these third-party payors and specialty pharmacies, (ii) the government-mandated discounts applicable to government-funded programs, and (iii) information obtained from our Customers and other third parties regarding the payor mix for Auryxia.

Product Returns: For the year ended December 31, 2015, the first full period in which we began selling Auryxia, we were not able to reasonably estimate product returns for all product sold to Customers. Once sufficient data exists or we are able to reasonably estimate the amount of Auryxia that will be returned, we will deduct these estimated amounts from our gross revenues at the time that revenues are recognized. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of December 31, 2015, we have experienced an immaterial number of product returns.

Other Incentives: Other incentives that we offer to indirect customers include co-pay mitigation rebates provided by us to commercially insured patients who have coverage for Auryxia and who reside in states that permit co-pay mitigation programs, and vouchers for a month supply of Auryxia at no patient cost. Our co-pay mitigation program is intended to reduce each participating patient s portion of the financial responsibility for Auryxia s purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, we estimate the average co-pay mitigation amounts and the percentage of patients that we expect to participate in the program in order to establish our accruals for co-pay mitigation rebates and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We adjust our accruals for co-pay mitigation and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

The following table summarizes product sales recognized and deferred during the years ended December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
Net U.S. Auryxia product sales recognized	$ 10,141	$
Deferred product sales	3,526	414
	$ 13,667	$ 414

In conjunction with our recognition and deferral of product sales, we expensed and capitalized the associated cost of goods, as follows, during the years ended December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
Cost of goods sold expensed	$ 4,520	$
Finished goods inventory held by others	231	47
	$ 4,751	$ 47

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 or ASC. We

Table of Contents

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.

For arrangements for which royalty revenue information becomes available and collectability is reasonably assured, we recognize revenue during the applicable period earned. When collectability is reasonably assured but a reasonable estimate of royalty revenue cannot be made, the royalty revenue is recognized in the quarter that the licensee provides the written report and related information to us.

Stock-Based 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.

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.

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

Table of Contents

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.

Inventory

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of our inventories, which include amounts related to materials, third-party contract manufacturing and packaging services, and manufacturing overhead, on a first-in, first-out basis. We capitalize inventory costs at our suppliers when, based on management s judgment, the realization of future economic benefit is probable at each given supplier. We received FDA approval for Auryxia on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers were included as a component of research and development expense.

Accounts Receivable, Allowances for Doubtful Accounts and Cash Discounts

We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at December 31, 2015 and 2014.

Accounting Related to Goodwill

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.

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

Table of Contents

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.

For the years ended December 31, 2015 and 2014, we recognized $90,000 and $700,000, respectively, in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes. Indefinite-lived intangibles are non-monetary assets which are not amortized for book purposes since there is no foreseeable limit to the cash flows provided by them. 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 liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets.

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2014, the FASB issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard will have on our financial position and results of operations.

In August 2014, the FASB issued a new standard, Accounting Standards Update (ASU) No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. This new standard will explicitly require management to assess an entity s ability to continue as a going concern and to provide footnote disclosures in certain cases. Currently there is no guidance in GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern. The new standard applies to all entities and provides an explicit requirement that management assesses and discloses going concern uncertainties. Previous guidance in auditing standards required auditors to evaluate going concern. The new standard will be effective for all entities in the first annual period ending after December 15, 2016, which is December 31, 2016 for calendar year-end entities. Earlier application is permitted.

In April 2015, the FASB issued a new standard, ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs. The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The standard is effective for interim and annual periods beginning after December 15, 2015. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

In July 2015, the FASB issued a new standard, ASU No. 2015-11, Simplifying the Measurement of Inventory. Under this standard, the measurement principle for inventory will change from lower of cost or market value to lower of cost

and net realizable value. The standard defines net realizable value as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and

Table of Contents

transportation. The standard is applicable to inventory that is accounted for under the first-in, first-out or average cost method and is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

In November 2015, the FASB issued a new standard, ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax liabilities and assets be classified as noncurrent in a classified balance sheet. The standard is effective for interim and annual periods beginning after December 15, 2016. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

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

Interest Rate Risk

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of December 31, 2015, our portfolio of financial instruments consists of cash equivalents, 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.

Equity Price Risk

Our Convertible Notes include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the notes. The amount of cash we may be required to pay is determined by the price of our common stock. The fair values of our Convertible Notes are dependent on the price and volatility of our common stock and will generally increase or decrease as the market price of our common stock changes.

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, 2015, 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, 2015, 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

Table of Contents

Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2014. 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 (2013). Our management has concluded that, as of December 31, 2015, 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, 2015 and 2014, 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, 2015, 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, 2015, 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, 2015, 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.

Table of Contents

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, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* 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 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, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* 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 February 26, 2016, expressed an unqualified opinion thereon.

/s/ UHY LLP
New York, New York

February 26, 2016

ITEM 9B. OTHER INFORMATION.

None.

Table of Contents

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 2016 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 2016 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 2016 Annual Meeting of Stockholders.

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 2016 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 2016 Annual Meeting of Stockholders.

Table of Contents

PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES.

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

See the Exhibit Index immediately following the signature page of this Annual Report on Form 10-K.

Table of Contents

Keryx Biopharmaceuticals, Inc.

Consolidated Financial Statements as of December 31, 2015

Contents Page

Table of Contents

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, 2015 and 2014, 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, 2015. 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, 2015 and 2014, and the consolidated results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015 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, 2015, based on criteria established in *Internal Control Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 26, 2016, expressed an unqualified opinion thereon.

/s/ UHY LLP
New York, New York
February 26, 2016

Table of Contents

Keryx Biopharmaceuticals, Inc.

Consolidated Balance Sheets as of December 31,

(in thousands, except share and per share amounts)

	2015	2014
Assets		
Current assets:		
Cash and cash equivalents	$ 200,290	$ 74,284
Short-term investment securities		11,508
Interest receivable		48
Inventory	41,881	7,830
Accounts receivable, net	3,656	834
Receivable from landlord	637	
Other current assets	2,830	4,092
Total current assets	249,294	98,596
Property, plant and equipment, net	5,083	1,532
Goodwill	3,208	3,208
Other assets, net	1,100	292
Total assets	$ 258,685	$ 103,628
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 21,322	$ 24,146
Accrued compensation and related liabilities	5,473	4,751
Deferred revenue	3,526	414
Derivative liability	46,686	
Deferred lease incentive, current portion	244	
Other current liabilities	355	
Total current liabilities	77,606	29,311
Convertible senior notes	90,773	
Deferred lease incentive, net of current portion	1,506	
Deferred tax liability	790	700
Other liabilities	1,076	133
Total liabilities	171,751	30,144

Commitments and contingencies		
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 shares authorized, 105,221,555 and 92,758,789 shares issued, 105,141,607 and 92,678,841 shares outstanding at December 31, 2015 and 2014, respectively)	105	93
Additional paid-in capital	761,189	624,606
Treasury stock, at cost, 79,948 shares at December 31, 2015 and 2014	(357)	(357)
Accumulated deficit	(674,003)	(550,858)
Total stockholders equity	86,934	73,484
Total liabilities and stockholders equity	$ 258,685	$ 103,628

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

Table of Contents

Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Operations for the Years Ended December 31,

(in thousands, except share and per share amounts)

	2015	2014	2013
Revenues:			
Net U.S. Auryxia product sales	$ 10,141	$	$
License revenue	3,539	10,825	7,000
Total revenues	13,680	10,825	7,000
Operating expenses:			
Cost of goods sold	4,520		
License expenses	2,124	495	
Research and development	36,694	51,502	34,734
Selling, general and administrative	81,410	70,057	19,349
Total operating expenses	124,748	122,054	54,083
Operating loss	(111,068)	(111,229)	(47,083)
Other income (expense), net	(11,987)	411	351
Loss before income taxes	(123,055)	(110,818)	(46,732)
Income taxes	90	700	
Net loss	$ (123,145)	$ (111,518)	$ (46,732)
Basic and diluted net loss per common share	$ (1.19)	$ (1.23)	$ (0.58)
Weighted average shares used in computing basic and diluted net loss per common share	103,898,399	91,000,902	81,009,561

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

Table of Contents

Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Stockholders Equity

for the Years Ended December 31, 2015, 2014 and 2013

(in thousands, except share amounts)

	Common stock		Additional paid-in	Treasury stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	deficit	Total
Balance at January 1, 2013	72,002,949	$ 72	$ 403,387	79,948	$ (357)	$ (392,608)	$ 10,494
Issuance of common stock in public offering (net of offering costs of $5,640)	9,469,100	10	74,743				74,753
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
Stock-based compensation			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
Issuance of common stock in public offering (net of offering costs of $7,525)	7,935,000	8	107,524				107,532
Issuance of restricted stock	1,451,558	1					1
Forfeiture of restricted stock	(88,859)	( )*					( )*
Issuance of common stock in connection with the exercise of options	737,945	1	5,053				5,054
Stock-based compensation			27,015				27,015
Net loss						(111,518)	(111,518)
Balance at December 31, 2014	92,758,789	$ 93	$ 624,606	79,948	$ (357)	$ (550,858)	$ 73,484

Issuance of common stock in public offering (net of offering costs of $8,216)	10,541,667	10	118,274				118,284
Issuance of restricted stock	1,247,250	1					1
Forfeiture of restricted stock	(330,102)	( )*					( )*
Surrender of common stock for tax withholding	(1,625)	( )*	(15)				(15)
Issuance of common stock in connection with the exercise of options	1,005,576	1	1,462				1,463
Stock-based compensation			16,862				16,862
Net loss						(123,145)	(123,145)
Balance at December 31, 2015	105,221,555	$ 105	$ 761,189	79,948	$ (357)	$ (674,003)	$ 86,934

* *Amount less than one thousand dollars.*

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

Table of Contents

Keryx Biopharmaceuticals, Inc.

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

(in thousands)

	2015	2014	2013
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (123,145)	$ (111,518)	$ (46,732)
Adjustments to reconcile loss to cash flows used in operating activities:			
Stock-based compensation expense	16,500	26,957	5,953
Amortization of debt discount	11,357		
Change in fair value of derivative liability	1,102		
Depreciation and amortization	596	306	54
Loss on disposal of fixed assets	507		
Cash received from landlord	1,276		
Amortization of deferred lease incentive	(163)		
Deferred income taxes	90	700	
Changes in operating assets and liabilities:			
Other current assets	1,262	(2,860)	(802)
Accounts receivable, net	(2,822)	(834)	
Accrued interest receivable	47	(48)	
Inventory	(29,189)	(7,771)	
Security deposits	(807)		
Other assets	355	(11)	(83)
Accounts payable and accrued expenses	(9,201)	10,142	6,792
Accrued compensation and related liabilities	723	3,427	497
Deferred revenue	3,112	414	
Other liabilities	943	95	2
Net cash used in operating activities	(127,457)	(81,001)	(34,319)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(2,777)	(1,489)	(346)
Investment in held-to-maturity short-term securities		(49,771)	(24,403)
Proceeds from maturity of held-to-maturity short-term securities	11,508	38,263	24,403
Net cash provided by (used in) investing activities	8,731	(12,997)	(346)
CASH FLOWS FROM FINANCING ACTIVITIES			

Proceeds from public offerings, net	118,284	107,532	74,753
Proceeds from issuance of convertible senior notes	125,000		
Proceeds from exercise of options	1,463	5,054	931
Surrender of common stock for tax withholding	(15)		
Net cash provided by financing activities	244,732	112,586	75,684
NET INCREASE IN CASH AND CASH EQUIVALENTS	126,006	18,588	41,019
Cash and cash equivalents at beginning of year	74,284	55,696	14,677
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 200,290	$ 74,284	$ 55,696
Supplemental disclosures of non-cash investing and financing activities			
Increase of receivable from landlord and deferred lease incentive	637		

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

Table of Contents

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 bringing innovative therapies to market for patients with renal disease. Our product, Auryxia (ferric citrate), also known as Riona in Japan and Fexeric in Europe, is an oral, absorbable iron-based compound, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our compound, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

Auryxia has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes to reduce intestinal absorption and aid in the management of hyperphosphatemia in patients with CKD. The U.S. approval of Auryxia was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Auryxia effectively reduced serum phosphorus levels to within the Kidney Disease Outcomes Quality Initiative, or KDOQI, guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Auryxia s pharmacodynamic properties resulted in increased ferritin, iron and transferrin saturation, or TSAT; whereas these parameters remained relatively constant in patients treated in the active control arm (Renvela® and/or Phoslo®) in our Phase 3 registration program. The most common adverse events for Auryxia treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on approximately 5,000 target nephrologists and their associated dialysis centers. In addition, we have a small team of national account managers who are primarily responsible for working with insurance plans, health maintenance organizations and other payers to secure reimbursement and formulary access for Auryxia. In December 2014, we created the Keryx Patient Plus program to assist with patient accessibility to Auryxia. The Keryx Patient Plus program offers benefit verification, co-pay assistance for eligible commercial patients, a no-cost drug program for those who qualify, and a short-term prescription bridge program that may assist those already on Auryxia who are in danger of suffering a lapse in coverage. In the United States there are approximately 450,000 patients on dialysis and approximately 2.9 million prescriptions written annually for phosphate binders. We had net U.S. Auryxia product sales in 2015 of $10.1 million and 1% market share by the end of the year.

Our Japanese partner, Japan Tobacco Inc. or JT, together with its subsidiary Torii Pharmaceutical Co. Ltd., or Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD, or NDD-CKD, in January 2014. Torii began to market the product under the brand

name Riona in May 2014. Under the license agreement with JT and Torii, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We in turn owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

Table of Contents

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union. We are currently seeking potential partners to commercialize Fexeric in the European Union.

In September 2014, we initiated a pivotal Phase 3 clinical trial of ferric citrate for the treatment of iron deficiency anemia, or IDA, in patients with Stage 3-5 NDD-CKD. This study s primary endpoint is the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period. Secondary endpoints in the Phase 3 study include the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The last patient in this Phase 3 trial completed treatment in January 2016 and we expect to report top line data in the second quarter of 2016, and if successful file for FDA approval of this indication in the third quarter of 2016.

Currently, our only product is Auryxia. In January 2015, we began recognizing product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, revenue from the sublicensing of rights to Auryxia in Japan to our Japanese partners, JT and Torii. We may engage in business development activities that include seeking strategic relationships for Auryxia outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on assets that are complementary to Auryxia.

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 the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Even though we are commercializing Auryxia, 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 additional regulatory approvals for Auryxia or any other product candidate in which we obtain rights, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize Auryxia alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of Auryxia. In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C, or Baupost. The Notes may be converted into shares of our common stock at the discretion of Baupost at a conversion price of $3.74, subject to adjustment based on the occurrence of certain events. In order to accommodate the full conversion of the Notes, we will seek stockholder approval of an amendment to our certificate of incorporation at the 2016 Annual Meeting of Stockholders to increase the number of shares of authorized common stock. If any necessary share increases are not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. We also entered into a Registration Rights Agreement with the purchasers of the Notes. See Note 10 Debt.

On January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under registration statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the Securities and Exchange Commission.

We currently expect that our existing capital resources combined with the proceeds of $125 million in Notes raised in October 2015 and future anticipated cash flows will be sufficient to execute our current business objectives. The

actual amount of cash that we will need to operate is subject to many factors, including, but not

Table of Contents

limited to, the timing and expenditures associated with commercial activities related to Auryxia and the magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, our ability to identify a commercial partner for and launch Fexeric in Europe, and the timing, design and conduct of clinical trials for Auryxia. Further, if any necessary share increases are not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factor, Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

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

CORPORATE

We were incorporated in Delaware in October 1998 and commenced operations in November 1999. In January 2016, we moved our corporate offices to One Marina Park Drive, 12th Floor, Boston, Massachusetts 02210. Our telephone number is 617-466-3500, 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, 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.

RECENTLY ISSUED ACCOUNTING STANDARDS

In May 2014, the FASB issued a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard will have on our financial position and results of operations.

In August 2014, the Financial Accounting Standards Board (FASB) issued a new standard, Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. This new standard will explicitly require management to assess an entity s ability to continue as a going concern and to provide footnote disclosures in certain cases. Currently there is no guidance in GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern. The new standard applies to all entities and provides an explicit requirement that management assesses and discloses going concern uncertainties. Previous guidance in auditing standards required auditors to evaluate going concern. The new standard will be effective for all entities in the first annual period ending after December 15, 2016, which is December 31, 2016

for calendar year-end entities. Earlier application is permitted.

Table of Contents

In April 2015, the FASB issued a new standard, ASU No. 2015-03, Simplifying the Presentation of Debt Issuance Costs. The new standard requires that debt issuance costs related to a recognized debt liability be presented in the balance sheet as a direct deduction from the carrying amount of that debt liability, consistent with debt discounts. The standard is effective for interim and annual periods beginning after December 15, 2015. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

In July 2015, the FASB issued a new standard, Accounting Standards Update No. 2015-11, Simplifying the Measurement of Inventory. Under this standard, the measurement principle for inventory will change from lower of cost or market value to lower of cost and net realizable value. The standard defines net realizable value as the estimated selling price in the ordinary course of business, less reasonably predictable costs of completion, disposal, and transportation. The standard is applicable to inventory that is accounted for under the first-in, first-out or average cost method and is effective for reporting periods beginning after December 15, 2016, with early adoption permitted. We do not expect adoption to have a material impact on our consolidated financial statements.

In November 2015, the FASB issued a new standard, ASU No. 2015-17, Balance Sheet Classification of Deferred Taxes. The new standard requires that deferred tax liabilities and assets be classified as noncurrent in a classified balance sheet. The standard is effective for interim and annual periods beginning after December 15, 2016. We do not expect adoption of this standard to have a material impact on our consolidated financial statements.

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 these consolidated 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 these consolidated financial statements.

CASH AND CASH EQUIVALENTS

We consider liquid investments with original maturities of three months or less when purchased to be cash and cash equivalents. At December 31, 2015, all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

INVESTMENT SECURITIES

We classify our short-term debt securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Available-for-sale investment securities are recorded at fair value. Other-than-temporary impairment charges are included in interest and other income, net, and unrealized gains (losses), if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders equity.

Table of Contents

INVENTORY

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of our inventories, which include amounts related to materials, third-party contract manufacturing and packaging services, and manufacturing overhead, on a first-in, first-out basis. We capitalize inventory costs at our suppliers when, based on management s judgment, the realization of future economic benefit is probable at each given supplier. We received FDA approval for Auryxia on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers was included as a component of research and development expense.

ACCOUNTS RECEIVABLE, NET

We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to certain of our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at December 31, 2015 and 2014.

RECEIVABLE FROM LANDLORD

In April 2015, we signed a new lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94 month term that commenced on May 1, 2015. Our landlord has agreed to pay for up to approximately $1.9 million of improvements to the space, which we account for as a lease incentive under the FASB Accounting Standards Codification (the Codification or ASC).

The following table summarizes our receivable from our landlord associated with the lease incentive at December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
Receivable from landlord	$ 637	$

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 selling, general and administrative.

Table of Contents

REVENUE RECOGNITION

Our commercial launch of Auryxia occurred in late December 2014. We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectability is reasonably assured, and (iv) the price is fixed or determinable. Until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue will be recognized based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on sales from us to such Customers. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Customers, we anticipate that our revenues will be recognized based on sales to our Customers. We currently defer Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue is recorded net of discounts, rebates, and chargebacks. We also defer the related cost of product sales and record such amounts as finished goods inventory held by others, which is included in inventory on our consolidated balance sheet, until revenue related to such product sales is recognized.

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product sales from the sales to Customers and (ii) reasonably estimate our net product sales. We calculate gross product sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns, upon our ultimate transition to a sell-in revenue recognition model and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services, such as fees for certain data that Distributors provide to us. The payment terms for sales to Distributors generally include a prompt-pay discount for payment made by check within 30 days. Based on our judgment and industry experience, we expect our Distributors to earn these discounts and fees, and deduct the full amount of these discounts and fees from our gross product sales and accounts receivable at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various commercial and Medicare Part D private insurance providers, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We also contract with certain specialty pharmacies directly so that Auryxia will be eligible for purchase by these specialty pharmacies. We estimate the rebates, chargebacks and discounts we will provide to Third-party Payors and specialty pharmacies, and deduct these estimated amounts from our gross product sales at the time the sales are recognized. We estimate the rebates, chargebacks and discounts that we will provide to Third-party Payors and specialty pharmacies based upon (i) our contracts with these Third-party Payors and specialty pharmacies, (ii) the government-mandated discounts applicable to government-funded programs and (iii) information obtained from our Customers and other third parties regarding the payor mix for Auryxia.

Product Returns: For the year ended December 31, 2015, the first full period in which we began selling Auryxia, we were not able to reasonably estimate product returns for all product sold to Customers. Once sufficient data exists or

we are able to reasonably estimate the amount of Auryxia that will be returned, we will deduct these estimated amounts from our gross revenues at the time that revenues are recognized. Our Customers

Table of Contents

have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of December 31, 2015, we have experienced an immaterial number of product returns.

Other Incentives: Other incentives that we offer to indirect customers include co-pay mitigation rebates provided by us to commercially insured patients who have coverage for Auryxia and who reside in states that permit co-pay mitigation programs, and vouchers for a month supply of Auryxia at no patient cost. Our co-pay mitigation program is intended to reduce each participating patient s portion of the financial responsibility for Auryxia s purchase price to a specified dollar amount. Based upon the terms of the program and information regarding programs provided for similar specialty pharmaceutical products, we estimate the average co-pay mitigation amounts and the percentage of patients that we expect to participate in the program in order to establish our accruals for co-pay mitigation rebates and deduct these estimated amounts from our gross product sales at the time the sales are recognized. We adjust our accruals for co-pay mitigation and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

Our U.S. Auryxia product sales for the year ended December 31, 2015 were offset by provisions for allowances and accruals as set forth in the tables below. There were no product sales for the year ended December 31, 2014.

(in thousands)	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 16,295	
Less provision for product sales allowances and accruals		
Trade allowances	1,897	12%
Rebates, chargebacks and discounts	2,418	15%
Product returns		0%
Other incentives (1)	1,839	11%
Total	6,154	38%
Net U.S. Auryxia product sales	$ 10,141	

(1) Includes co-pay mitigation and voucher rebates.

The following table summarizes product sales recognized and deferred during the years ended December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
Net U.S. Auryxia sales recognized	$ 10,141	$
Deferred product sales	3,526	414

	$ 13,667	$ 414

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 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

Table of Contents

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.

For arrangements for which royalty revenue information becomes available and collectability is reasonably assured, we recognize revenue during the applicable period earned. When collectability is reasonably assured but a reasonable estimate of royalty revenue cannot be made, the royalty revenue is recognized in the quarter that the licensee provides the written report and related information to us.

COST OF GOODS SOLD

Cost of goods sold includes the cost of active pharmaceutical ingredient (API) for Auryxia on which product sales were recognized during the period, as well as the associated costs for tableting, packaging, shipment, insurance and quality assurance. Cost of goods sold also includes expenses due the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

In conjunction with our recognition and deferral of product sales, we expensed and capitalized the associated cost of goods, as follows, during the years ended December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
Cost of goods sold expensed	$ 4,520	$
Finished goods inventory held by others	231	47
	$ 4,751	$ 47

Finished goods inventory held by others as of December 31, 2015 and 2014 represents the cost of goods sold that has been deferred to align with our deferral of product sales. The cost of goods sold for the year ended December 31, 2015 includes $2.6 million related to manufacturing charges incurred as a result of not fully utilizing planned production capacity at certain of our third-party manufacturers.

LICENSE EXPENSES

License expenses include royalty and other expenses due to the licensor of Auryxia related to our license agreement with JT and Torii. With regard to royalty expense, such expense is directly related to the royalty revenue received from JT and Torii and is recognized in the same period as the revenue is recorded. Other expenses are recognized in the period they are incurred.

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(s) commence when it is probable that the 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

Table of Contents

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 consolidated 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. A valuation allowance is recorded against deferred tax assets if it is more likely than not that some or all of our deferred tax assets will not be realized.

We, and our subsidiaries, file income tax returns in the U.S. federal jurisdiction and in various states. Our subsidiary, Keryx Biopharma UK Ltd., files annual returns and accounts in the United Kingdom. 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.

We recognize interest and penalties related to uncertain income tax positions in income tax expense.

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 liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets.

We are not aware of any unrecorded tax liabilities which would materially impact our financial position or our results of operations.

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.

Table of Contents

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, 2015, 2014 and 2013, which are not included in the computation of net loss per share amounts, were 5,411,557, 5,132,426 and 3,845,370, respectively. No warrants were outstanding during each of these periods.

SEGMENT REPORTING

We operate in only one reportable segment: the Products segment.

ACQUISITIONS

We adopted Accounting Standards Codification (ASC) Topic 805, Business Combinations, as of January 1, 2009. The adoption of ASC Topic 805 was effective on a prospective basis and requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the net assets acquired is recorded as 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 undiscounted 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 undiscounted cash flows, an impairment charge is recognized.

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, 2015, management concluded that there was no impairment of our goodwill. As of December 31, 2013, 2014 and 2015, 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.

Table of Contents

Our accounts receivable, net at December 31, 2015 and 2014 represent amounts due to the Company from customers. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total accounts receivable, net as of December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
AmerisourceBergen Drug Corporation	17%	28%
Cardinal Health, Inc.	24%	31%
McKesson Corporation	23%	30%
Davita Rx	19%	11%
Fresenius Medical Care Rx	15%	<10%

We currently depend on a single supply source for Auryxia drug product. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at levels to meet market demand, we could experience a loss of revenue, which could materially and adversely impact our results of operations.

NOTE 2 CASH AND CASH EQUIVALENTS

(in thousands)	December 31, 2015	December 31, 2014
Money market funds	$ 193,886	$ 69,591
Checking and bank deposits	6,404	4,693
Total	$ 200,290	$ 74,284

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.

NOTE 3 INVESTMENT SECURITIES

We record our investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investment securities are recorded at fair value (see Note 4 Fair Value Measurements). Other-than-temporary impairment charges are included in interest and other income, net, and unrealized gains (losses), if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders equity.

We were not invested in investment securities at December 31, 2015.

The following tables summarize our investment securities at December 31, 2014:

	December 31, 2014
(in thousands)	

	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments (held-to-maturity):				
Obligations of domestic governmental agencies (matured January 2015)	$ 11,508	$	$	$ 11,508
Total short-term investment securities	$ 11,508	$	$	$ 11,508

Table of Contents

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.

The following table provides the fair value measurements of applicable financial assets as of December 31, 2015 and 2014:

	Financial assets at fair value as of December 31, 2015		
(in thousands)	Level 1	Level 2	Level 3
Money market funds (1)	$ 193,886	$	$
Total	$ 193,886	$	$

	Financial assets at fair value as of December 31, 2014		
(in thousands)	Level 1	Level 2	Level 3
Money market funds (1)	$ 69,591	$	$
Obligations of domestic governmental agencies (held-to-maturity) (2)	11,508		
Total	$ 81,099	$	$

(1)

Included in cash and cash equivalents on our consolidated balance sheet. The carrying amount of money market funds approximates fair value.

(2) Amortized cost approximates fair value.

Debt

In October 2015, we issued the Notes. As of December 31, 2015, the fair value of our Notes was $132.9 million, which differs from their carrying value. The fair value of our Notes is influenced by interest rates and our stock price and stock price volatility. See Note 10 Debt for additional information on our debt obligations.

Table of Contents

NOTE 5 INVENTORY

Upon approval of Auryxia on September 5, 2014 by the FDA, we began capitalizing our purchases of saleable inventory of Auryxia from suppliers. Inventories consist of the following at December 31, 2015 and 2014:

(in thousands)	December 31, 2015	December 31, 2014
Raw materials	$ 495	$ 111
Work in process	40,124	7,263
Finished goods	1,031	409
Finished goods inventory held by others	231	47
Total inventory	$ 41,881	$ 7,830

NOTE 6 PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2015	December 31, 2014
Leasehold improvements	$ 3,943	$ 39
Office furniture and equipment	595	853
Computers, software and related equipment	997	1,823
	5,535	2,715
Accumulated depreciation and amortization	(452)	(1,183)
Net book value	$ 5,083	$ 1,532

The following table summarizes depreciation expense for the years ended December 31, 2015, 2014 and 2013.

	For the years ended December 31,		
(in thousands)	2015	2014	2013
Depreciation expense:			
Research and development	$ 52	$ 56	$ 32
Selling, general and administrative	544	250	22
Total	$ 596	$ 306	$ 54

NOTE 7 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 $4.0 million. 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 $3.2 million, 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.

NOTE 8 OTHER ASSETS

(in thousands)	December 31, 2015	December 31, 2014
Deposits	$ 1,087	$ 279
Deferred registration fees	13	13
	$ 1,100	$ 292

Table of Contents

As of December 31, 2015 and 2014, we also have approximately $0.4 million in patents which have been fully amortized. There were no amortization expenses for the years ended December 31, 2015, 2014 and 2013. We do not expect to record amortization expenses going forward, as all definite-lived intangible assets are fully amortized.

NOTE 9 LICENSE AGREEMENTS

In November 2005, we entered into a license agreement with Panion & BF Biotech, Inc. (Panion). Under the license agreement, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of Auryxia. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia.

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 marketed in the United States under the trade name Auryxia. 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 January 2013, JT and Torii filed its new drug application (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, launched in May 2014 and being marketed in Japan by JT s subsidiary, Torii 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, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. As a result, we recorded license revenue of $10.0 million in accordance with our revenue recognition policy, which is included in the year ended December 31, 2014. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred. For the years ended December 31, 2015 and 2014, we recorded $3.5 million and $0.8 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. For the year ended December 31, 2013, we recorded $7.0 million in license revenue related to a milestone earned in January 2013 in connection with the achievement of the NDA filing milestone in Japan. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of Auryxia, in the same period as the royalty revenue from JT and Torii is recorded. For the years ended December 31, 2015 and 2014, we recorded $2.1 million and $0.5 million, respectively, in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan. We did not record any license expenses in the year ended December 31, 2013.

NOTE 10 DEBT

In October 2015, we completed the sale of $125 million of Notes due 2020, in a private placement (the Private Placement) to funds managed by Baupost pursuant to a Notes Purchase Agreement dated October 14,

Table of Contents

2015. The Notes were issued under an Indenture dated as of October 15, 2015, with The Bank of New York Mellon Trust Company, N.A. as trustee (the Indenture). Under the terms of the Indenture, the Notes may be converted into shares of our common stock at the discretion of Baupost. In furtherance thereof, we will seek stockholder approval of an amendment to our certificate of incorporation to increase in the number of authorized shares of our common stock to ensure that we have an adequate share reserve to cover any conversions by Baupost, and if any necessary share increases are not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. Further, the Indenture subjects us to certain financial and business covenants and contains restrictions on the payments of cash dividends.

The Indenture contains customary terms and events of default. If an event of default (other than certain events of bankruptcy, insolvency or reorganization involving us) occurs and is continuing, the Trustee by notice to us, or the holders of at least 25% in aggregate principal amount of the outstanding Notes by written notice to us and the Trustee, may declare 100% of the principal on all of the Notes to be due and payable. Upon such a declaration of acceleration, such principal will be due and payable immediately. Upon the occurrence of certain events of bankruptcy, insolvency or reorganization involving us, 100% of the principal on all of the Notes will become due and payable automatically.

Further, in connection with the Private Placement, we entered into a Registration Rights Agreement with the purchasers of the Notes (the Registration Rights Agreement), pursuant to which we agreed to (i) file a registration statement (the Resale Registration Statement) with the SEC covering the resale of the Notes and the underlying common stock which the Notes are convertible into upon the written request of Baupost, and (ii) use commercially reasonable efforts, subject to receipt of necessary information from all the purchasers of the Notes, to cause the SEC to declare the Resale Registration Statement effective. Further, the Registration Rights Agreement permits Baupost to demand from time to time that we file a shelf Registration Statement pursuant to Rule 415 of the Securities Act from which any number of shelf takedowns may be conducted upon written request from Baupost. Finally, the Registration Rights Agreement affords Baupost certain piggyback registration rights.

The Notes, a portion of which are currently convertible, are convertible at the option of Baupost at an initial conversion rate of 267.3797 shares of our common stock per $1,000 principal amount, equal to a conversion price of $3.74 per share, which represents the last reported sale price of our stock on October 14, 2015. The conversion rate is subject to adjustment from time to time upon the occurrence of certain events. Further, upon the occurrence of certain fundamental changes involving us, Baupost may require us to repurchase for cash all or part of their Notes at a repurchase price equal to 100% of the principal amount of the Notes to be repurchased.

A portion of the Notes, represented by $60,680,000 of the $125,000,000 par value of the Notes, is currently convertible into shares of our common stock at the option of Baupost. The remaining portion of the Notes, represented by $64,320,000 of the total par value, is contingently convertible into shares of our common stock or cash at the option of Baupost. As discussed above, we will seek stockholder approval of an amendment to our certificate of incorporation to increase the number of authorized shares of our common stock to ensure that we have an adequate share reserve to cover any conversions by Baupost. If the necessary share increase is approved by our stockholders by July 1, 2016 (Shareholder Approval Deadline), the portion of the Notes that is contingently convertible will be convertible into shares of our common stock at the option of Baupost. If the share increase is not approved by our stockholders by the Shareholder Approval Deadline, the contingently convertible portion of the Notes, represented by $64,320,000 of the par value, will be convertible to cash at the option of Baupost.

Under the terms of the Indenture, prior to the Shareholder Approval Deadline, any conversion by Baupost shall be deemed a partial share settlement and partial cash settlement, based on a pro-rata portion of the Notes based on the original convertible and contingently convertible par values of the Notes. In such an event, the contingently convertible portion of the Notes would be settled subsequent to July 1, 2016 in a manner dictated by whether

shareholder approval of the amendment to our certificate of incorporation discussed above is obtained

Table of Contents

by the Shareholder Approval Deadline. If we are required to satisfy our obligation partially in cash, we will pay an amount for each $1,000 principal amount of the Notes being converted equal to the sum of the Daily Conversion Values for each of the five consecutive trading days following conversion notice, where the Daily Conversion Value for each day is 20% of the product of (a) the conversion rate on such trading day and (b) the daily volume-weighted average price for such trading day.

In accordance with accounting guidance for debt with a conversion option, we separated the conversion option from the debt instrument and account for it separately as a derivative liability, due to the Notes being partially convertible to cash at the option of Baupost. We allocated the proceeds between the debt component and the embedded conversion option (the derivative) by performing a valuation of the derivative as of the transaction date, which was determined based on the difference between the fair value of the Notes with the conversion option and the fair value of the Notes without the conversion option. The fair value of the derivative liability was recognized as a debt discount and the carrying amount of the convertible notes represents the difference between the proceeds from the issuance of the Notes and the fair value of the derivative liability on the date of issuance. The excess of the principal amount of the debt component over its carrying amount (debt discount) is amortized to interest expense using the effective interest method over the expected life of the debt.

Our outstanding convertible notes and derivative liability balances as of December 31, 2015 consisted of the following:

(in thousands)	December 31, 2015
Debt component:	
Principal	$ 125,000
Less: debt discount originally recorded	(45,584)
Add: amortization of debt discount to interest expense	11,357
Net carrying amount	$ 90,773
Original derivative liability recorded	$ 45,584
Fair value adjustment	1,102
Derivative liability balance	$ 46,686

We determined the expected life of the debt was equal to the period through July 1, 2016, as this represents the point at which a portion of the Notes is contingently convertible into cash. Accordingly, approximately $11.4 million of interest expense was recognized related to the Notes during the year ended December 31, 2015, all of which was attributable to the amortization of the debt discount. As of December 31, 2015, the carrying value of the Notes was $90.8 million and the fair value of the Notes was $132.9 million.

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 January 21, 2015, we announced the pricing of an underwritten public offering in which we sold 10,541,667 shares of our common stock at a price of $12.00 per share for gross proceeds of approximately $126.5 million. Net proceeds from this offering were approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million. The shares were sold under Registration Statements (Nos. 333-201605 and 333-201639) on Form S-3 and Form S-3MEF, respectively, filed by us with the Securities and Exchange Commission.

Table of Contents

On January 22, 2014, we announced the pricing of an underwritten public offering in which 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 $107.5 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.

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 10 years from the date of the grant. 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, 2015, 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, 2015, no additional shares of our common stock 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 expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2015, up to an additional 15,254 shares may be issued under the 2007 Incentive Plan.

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 former 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. During the year ended December 31, 2015, the option was exercised in full.

e. The 2013 Incentive Plan was adopted in June 2013 by our stockholders at our 2013 Annual Meeting of Stockholders. The 2013 Incentive plan was amended by our stockholders at a special meeting of our stockholders in November 2014, which increased the number of authorized shares issuable thereunder from 3,500,000 to 9,500,000. 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 plan expires 10 years from adoption and limits the term of each option to no more than 10 years from the date of grant. As of December 31, 2015, up to an additional 3,083,885 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 3,099,139 shares at December 31, 2015.

Table of Contents

Stock Options

The following table summarizes stock option activity for all plans for the years ended December 31, 2015, 2014 and 2013:

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term	Aggregate Intrinsic Value
Outstanding at January 1, 2013	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		$ 28,361,438
Granted	2,264,550	14.69		
Exercised	(737,945)	6.85		$ 6,252,223
Forfeited	(239,549)	10.38		
Expired				
Outstanding at December 31, 2014	5,132,426	9.32		$ 26,916,823
Granted	2,097,950	11.37		
Exercised	(1,005,576)	1.46		$ 8,564,645
Forfeited	(694,454)	13.54		
Expired	(118,789)			
Outstanding at December 31, 2015	5,411,557	$ 10.96	7.2	$ 2,049,329
Vested and expected to vest at December 31, 2015	5,323,492	$ 10.94	7.2	$ 2,039,828
Exercisable at December 31, 2015	2,663,080	$ 9.74	5.5	$ 1,749,412

Upon the exercise of stock options, we issue new shares of our common stock. As of December 31, 2015, 125,000 options issued to employees are unvested, milestone-based options.

Table of Contents

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under our equity incentive plans. 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, 2015, 2014 and 2013:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at January 1, 2013	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
Granted	1,451,558	14.38	
Vested	(1,856,682)	8.78	$ 28,608,133
Forfeited	(88,859)	8.22	
Outstanding at December 31, 2014	926,947	12.22	$ 13,116,300
Granted	1,247,250	11.28	
Vested	(499,348)	11.74	$ 4,662,429
Forfeited	(330,102)	11.75	
Outstanding at December 31, 2015	1,344,747	$ 11.59	$ 6,790,972

As of December 31, 2015, 560,000 shares of restricted stock issued to employees are unvested, milestone-based shares.

On September 14, 2009, we entered into an employment agreement with Ron Bentsur, our Chief Executive Officer, which was amended on January 13, 2012, and further amended on September 11, 2013. The agreement, as amended, terminated on May 20, 2015. As of December 31, 2014, Mr. Bentsur has been granted a total of 1,250,000 shares of restricted stock based on the achievement of certain milestone awards described in his employment agreement, all of which had vested as of December 31, 2014.

As per his employment agreement, in December 2014, 500,000 shares of fully vested common stock were granted to Mr. Bentsur, upon the first commercial sale of Auryxia to wholesalers in the United States. In addition, upon reaching the same milestone, 266,666 shares of restricted stock previously issued to Mr. Bentsur were vested. We recorded

$10.1 million of stock-based compensation expense associated with the granting and vesting of the 766,666 shares of restricted stock in December 2014, which is included in selling, general and administrative expenses in the year ended December 31, 2014.

Stock-Based Compensation

The following tables summarize stock-based compensation expense information about equity incentive grants for the years ended December 31, 2015, 2014 and 2013:

	For the years ended December 31,		
(in thousands)	**2015**	**2014**	**2013**
Cost of goods sold	$ 14	$	$
Research and development expenses	3,519	6,379	2,347
Selling, general and administrative expenses	12,967	20,578	3,606
	$ 16,500	$ 26,957	$ 5,953

Table of Contents

(in thousands)	For the years ended December 31, 2015	2014	2013
Stock-based compensation expense associated with restricted stock	$ 5,073	$ 20,031	$ 3,859
Stock-based compensation expense associated with stock options	11,427	6,926	2,094
	$ 16,500	$ 26,957	$ 5,953

Stock-based compensation costs capitalized as part of inventory were immaterial for the years ended December 31, 2015 and 2014.

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	2015	2014	2013
Risk-free interest rates	1.7%	1.9%	0.7%
Dividend yield			
Volatility	89.2%	103.0%	102.0%
Weighted-average expected term	6.0 years	6.0 years	3.8 years

The weighted average grant date fair value of options granted was $8.47, $11.81 and $4.28 per option for the years ended December 31, 2015, 2014 and 2013, respectively. We used historical information to estimate forfeitures within the valuation model. As of December 31, 2015, there was $18.0 million and $7.3 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 1.9 years and 1.1 years, respectively. These amounts do not include, as of December 31, 2015, 125,000 options outstanding and 560,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones. Stock-based compensation will be measured and recorded if and when it is probable that the milestone will occur.

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 $232.7 million and $205.0 million as of December 31, 2015 and 2014, respectively, an increase of $27.7 million.

As of December 31, 2015, we have U.S. net operating loss (NOL) carryforwards of approximately $609.4 million, of which approximately $83.8 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 NOLs will expire in the years 2019 through 2035. Due to our various equity transactions, the utilization of certain NOLs 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.

Table of Contents

For the year ended December 31, 2015 and 2014, we recognized $0.1 million and $0.7 million, respectively, in income tax expense related to the recording of a deferred tax liability associated with capitalized goodwill, an indefinite-lived intangible asset that is being amortized for tax purposes. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP since there is no foreseeable limit to the cash flows provided by them. 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 liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. There was no income tax expense for the year ended December 31, 2013.

The income tax provision consists of the following:

(in thousands)	December 31, 2015	December 31, 2014	December 31, 2013
Current:			
Federal	$	$	$
State			
Total current			
Deferred:			
Federal	81	640	
State	9	60	
Total deferred	90	700	
Total income taxes	$ 90	$ 700	$

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

(in thousands)	For the years ended December 31, 2015	2014	2013
Loss before income taxes, as reported in the consolidated statements of operations	$ (123,055)	$ (110,818)	$ (46,732)
Computed expected tax benefit	(41,838)	(37,678)	(15,889)
Increase (decrease) in income taxes resulting from:			
Expected (benefit) expense from state & local taxes	(3,991)	(3,594)	(1,523)
Stock-based compensation expense	(2,328)	(7,178)	(1,842)
Tax impact of derivative liability	16,977		
Permanent differences	1,445	97	66
Impact of state NOL carryforward change		6,726	
Prior year true-up	2,191	70	(409)

Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	27,634	42,257	19,597
	$ 90	$ 700	$

Table of Contents

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

	For the years ended December 31,		
(in thousands)	2015	2014	2013
Deferred tax benefit	$ (44,521)	$ (41,557)	$ (19,597)
Tax impact of derivative liability	16,977	( )	( )
Increase in the valuation allowance for deferred tax asset	27,634	42,257	19,597
	$ 90	$ 700	$

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2015 and 2014 are presented below.

(in thousands)	December 31, 2015	December 31, 2014
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 219,658	$ 182,864
Stock-based compensation expense	13,667	11,379
Unrealized / realized loss on securities	514	1,052
Capitalized Inventory	4,501	7,106
Research and development	2,087	2,087
Intangible assets due to different amortization methods	1,912	(321)
Debt discount	(12,748)	
Deferred revenue	1,313	154
Other temporary differences	970	9
Net deferred tax asset, excluding valuation allowance	231,874	204,330
Less valuation allowance	(232,664)	(205,030)
Net deferred tax liabilities	$ (790)	$ (700)

We file income tax returns in the U.S federal and various state and local jurisdictions. For federal and state income tax purposes, the 2012, 2013 and 2014 tax years remain open for examination under the normal three year statute of limitations. The statute of limitations for income tax audits in the United States 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 2015, 2014 and 2013. 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.

NOTE 13 OTHER INCOME (EXPENSE), NET

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

	For the years ended December 31,		
(in thousands)	2015	2014	2013
Interest income	$ 472	$ 290	$ 190
Interest expense	(11,357)		
Other income (expense)	(1,102)	121	161
	$ (11,987)	$ 411	$ 351

Table of Contents

NOTE 14 COMMITMENTS AND CONTINGENCIES

As of December 31, 2015, we have known contractual obligations, commitments and contingencies of $173.8 million. Of this amount, $7.6 million relates to selling, general and administrative agreements primarily associated with the launch and commercialization of Auryxia, of which $7.2 million is due within the next year, $2.1 million relates to research and development agreements (relating to our Auryxia clinical and regulatory programs), and $26.7 million relates to various third-party contract manufacturing agreements for the production and packaging of Auryxia drug substance and drug product. The debt obligation in the table below reflects our obligations under the Notes to make a principal payment for the par value of the Notes at maturity. Any future conversion or settlement of the Notes could impact the timing and amount of our potential cash payments under the Notes (see Note 10 Debt). The remaining $12.5 million relates to our operating lease obligations.

(in thousands)		Payment due by period			
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Selling, general and administrative agreements	$ 7,590	$ 7,230	$ 360	$	$
Research and development agreements	2,102	2,102			
Manufacturing agreements	26,677	26,677			
Convertible senior notes	125,000			125,000	
Operating leases	12,473	2,168	3,229	3,338	3,738
Total	$ 173,842	$ 38,177	$ 3,589	$ 128,338	$ 3,738

Leases

In April 2015, we signed a new lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94 month term that commenced on May 1, 2015. In order to make the space usable for our operations, substantial improvements were made. Our landlord has agreed to pay for up to approximately $1.9 million of the improvements, and we bear all additional costs that are incurred. As such, we have determined that we are the owner of the improvements and account for tenant improvements paid by our landlord as a lease incentive. On May 1, 2015, in accordance with ASC 840-20, we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets useful lives or the remaining lease term, whichever is shorter.

In March 2014, we entered into a sublease for approximately 10,395 square feet of leased office space in Boston, Massachusetts, with a term through December 31, 2015.

In March and September 2013, we extended our lease on our corporate 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, which term ended on September 29, 2014.

Total rental expense was approximately $2.2 million, $1.6 million and $0.7 million for the years ended December 31, 2015, 2014, and 2013, respectively. We recognized sublet income of $0.1 million and $0.2 million for the years ended

December 31, 2014, and 2013, respectively, related to the office sharing agreement which ended in September 2014.

Royalty and Contingent Milestone Payments

Under the license agreement with Panion, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of Auryxia. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing

Table of Contents

approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia in the United States and of Riona in Japan. We record royalties on net sales of Auryxia in cost of goods sold and royalties on net sales of Riona in license expense.

Litigation

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

NOTE 15 QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	2015			
	Mar. 31	**June 30**	**Sept. 30**	**Dec. 31**
	(in thousands, except per share data)			
Revenues:				
Product revenue, net	$ 422	$ 1,758	$ 3,191	$ 4,770
License revenue	753	756	1,017	$ 1,013
Total revenues	1,175	2,514	4,208	5,783
Operating expenses:				
Cost of goods sold	76	304	3,065	1,075
License expenses:	452	453	611	608
Research and development	9,591	7,963	11,150	7,990
Selling, general and administrative	18,880	20,762	20,205	21,563
Total operating expenses	28,999	29,482	35,031	31,236
Operating loss	(27,824)	(26,968)	(30,823)	(25,453)
Other income				
Other income (expense), net	107	114	100	(12,308)
Loss before income taxes	(27,717)	(26,854)	(30,723)	(37,761)
Income taxes	22	23	22	23
Net loss	$ (27,739)	$ (26,877)	$ (30,745)	$ (37,784)
Basic and diluted net loss per common share*	$ (0.28)	$ (0.26)	$ (0.29)	$ (0.36)

Table of Contents

	2014			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenue:				
License revenue	$ 10,000	$	$ 256	$ 569
Operating expenses:				
License expenses:			154	341
Research and development	16,359	10,275	19,053	5,815
Selling, general and administrative	7,292	12,268	16,447	34,050
Total operating expenses	23,651	22,543	35,654	40,206
Operating loss	(13,651)	(22,543)	(35,398)	(39,637)
Other income				
Interest and other income, net	121	129	109	52
Loss before income taxes	(13,530)	(22,414)	(35,289)	(39,585)
Income taxes				700
Net loss	$ (13,530)	$ (22,414)	$ (35,289)	$ (40,285)
Basic and diluted net loss per common share*	$ (0.15)	$ (0.24)	$ (0.38)	$ (0.44)

* *The aggregate of quarterly computed basic and diluted net loss per common share may not agree with the annual amount due to rounding.*

Table of Contents

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: February 26, 2016

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ Gregory P. Madison
Gregory P. Madison

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 Gregory P. Madison and Brian Adams, 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 February 26, 2016, and in the capacities indicated:

Signatures	Title
/s/ Gregory P. Madison	Chief Executive Officer and Director
Gregory P. Madison	(principal executive officer)
/s/ Scott A. Holmes	Chief Financial Officer
Scott A. Holmes	(principal financial and accounting officer)
/s/ Michael P. Tarnok	Chairman of the Board of Directors
Michael P. Tarnok	
/s/ John P. Butler	Director
John P. Butler	

/s/ Kevin Cameron	Director
Kevin Cameron	
/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	

Table of Contents

EXHIBIT INDEX

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.
4.2	Indenture, dated as of October 15, 2015, between Keryx Biopharmaceuticals, Inc. and The Bank of New York Mellon Trust Company, N.A., filed as Exhibit 10.2 to the Form 8-K filed on October 19, 2015, 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.
10.3	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.
10.4	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.
10.5	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.
10.6	Amendment to Keryx Biopharmaceuticals, Inc. 2013 Incentive Plan, filed with the Registrant s Definitive Proxy Statement for the Special Meeting of Stockholders on November 17, 2014, filed on

October 10, 20072014, and incorporated herein by reference.

10.7! 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.

10.8! 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.

Table of Contents

Exhibit Number	Exhibit Description
10.9!	Amended and Restated Sub-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 12, 2009, and incorporated herein by reference.
10.10!	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.
10.11	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.
10.12	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.
10.13	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.
10.14	Third 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, 2014, filed on August 7, 2014, and incorporated herein by reference.
10.15	Employment Agreement with James F. Oliviero, dated February 26, 2015, filed as Exhibit 10.16 to the Registrant s Form 10-K for the year ended December 31, 2014, filed on February 27, 2015, and incorporated herein by reference.
10.16!	Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Norwich Pharmaceuticals, Inc. dated January 17, 2014, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 6, 2014, and incorporated herein by reference.
10.17!	First Addendum to Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Norwich Pharmaceuticals, Inc. dated October 24, 2014, filed as Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2014, filed on November 6, 2014, and incorporated herein by reference.
10.18	Employment Agreement with Gregory P. Madison dated March 10, 2015, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015, and incorporated herein by reference.
10.19	Employment Agreement with Brian Adams dated April 8, 2014, filed as Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015, and incorporated herein by reference.
10.20	Employment Agreement with John F. Neylan, M.D. dated April 22, 2015, filed as Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015, and incorporated herein by reference
10.21	Third Amendment to Employment Agreement with Ron Bentsur dated April 30, 2015, filed as Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended March 31, 2015, filed on May 4, 2015, and incorporated herein by reference.

10.22 Employment Agreement with Scott Holmes dated June 26, 2015, filed as Exhibit 10.1 to the Form 8-K filed on July 27, 2015, and incorporated herein by reference.

Table of Contents

Exhibit Number	Exhibit Description
10.23	First Amendment to Employment Agreement with Gregory P. Madison dated October 15, 2015, filed as Exhibit 10.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015, and incorporated herein by reference.
10.24	First Amendment to Employment Agreement with Brian Adams dated October 15, 2015, filed as Exhibit 10.2 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015, and incorporated herein by reference.
10.25	First Amendment to Employment Agreement with Scott Holmes dated October 15, 2015, filed as Exhibit 10.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015, and incorporated herein by reference
10.26	First Amendment to Employment Agreement with John F. Neylan, M.D. dated October 15, 2015, filed as Exhibit 10.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended September 30, 2015, filed on October 29, 2015, and incorporated herein by reference.
10.27	Notes Purchase Agreement, dated as of October 14, 2015, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C, filed as Exhibit 10.1 to the Form 8-K filed on October 19, 2015, and incorporated herein by reference.
10.28	Registration Rights Agreement, dated as of October 15, 2015, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C., filed as Exhibit 10.3 to the Form 8-K filed on October 19, 2015, and incorporated herein by reference.
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 on the signature to this Annual Report on Form 10-K).
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 February 26, 2016.
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 February 26, 2016.
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 February 26, 2016.
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 February 26, 2016.
101	The following financial information from Keryx Biopharmaceuticals, Inc. s Annual Report on Form 10-K for the year ended December 31, 2014, 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.