KERYX BIOPHARMACEUTICALS INC
Form 10-K
February 21, 2018
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

ý ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 31, 2017.
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 ý
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 ý
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 ý 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 ý No ¨

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

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

Large accelerated filer ý	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if smaller reporting company)	Smaller reporting company ¨
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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

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 $662,026,612 as of June 30, 2017, based on the closing sale price of such stock as reported on the Nasdaq Capital Market.

There were 119,175,538 shares of the registrant's common stock outstanding as of February 9, 2018.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2018 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

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KERYX BIOPHARMACEUTICALS, INC.
ANNUAL REPORT ON FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2017
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This Annual Report on Form 10-K contains trademarks and trade names of Keryx Biopharmaceuticals, Inc., including our name and logo. All other trademarks, service marks, and trade names referenced in this Annual Report on Form 10-K are the property of their respective owners.

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption "Management's Discussion and Analysis of Financial Condition and Results of Operations," may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect," "wi "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), market share and product sales guidance;
- expectations regarding the commercialization of Auryxia;
- expectations regarding our ability to successfully launch and then effectively continue to commercialize Auryxia for the treatment of iron deficiency anemia in adults with chronic kidney disease, not on dialysis in the United States;
- expectations regarding our ability to identify a commercial partner(s) to launch Fexeric® (ferric citrate coordination complex) in the European market;
- expectations for generating revenue, producing positive cash flows or becoming profitable on a sustained basis;
- expectations for our mix of business between private commercial payers and government-sponsored insurance plans;
- estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements;
- expected losses;
- expectations for future capital requirements;
- expectations for increases or decreases in expenses;
- expectations for clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of ferric citrate or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our development and manufacturing capabilities;
- expectations regarding our ability to successfully market Riona® through our Japanese partner, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd.;
- expectations of the scope of patent protection with respect to Auryxia, Fexeric and Riona;
- expectations or ability to enter into marketing and other partnership agreements; and
- expectations or ability to enter into product acquisition and in-licensing transactions.

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.

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PART I

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

ITEM 1. BUSINESS

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with kidney disease. Our long-term vision is to build a multi-product kidney care company. Our marketed product, Auryxia (ferric citrate) tablets, is an orally available, absorbable, iron-based medicine. Auryxia is approved by the U.S. Food and Drug Administration, or FDA, for two indications. Auryxia was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Additionally, in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. With two FDA-approved indications, we will leverage our U.S. clinical and commercial infrastructure to make Auryxia available to millions of people with CKD and either iron deficiency anemia or elevated levels of serum phosphorus, which is referred to as hyperphosphatemia. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco, Inc., or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, and approved in Europe as Fexeric. We use the brand name Auryxia when we refer to ferric citrate for use in the approved indications in the United States. We refer to the product as ferric citrate when referring to its investigational use. Our vision of building a multi-product kidney care company includes expansion of our product portfolio with other medicines that can help patients with kidney disease.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines to the market for the treatment of people with kidney disease that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

Auryxia is approved for two indications in the United States. We developed and subsequently launched Auryxia in the United States in late December 2014 following the FDA's approval of Auryxia for the control of serum phosphorus levels in adult patients with CKD on dialysis. In November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adult patients with CKD, not on dialysis. Auryxia is a non-calcium, non-chewable, orally-administered phosphate binder. Auryxia is the first FDA-approved oral iron medication that was specifically developed to treat iron deficiency anemia in CKD patients, not on dialysis. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist for CKD have iron deficiency anemia, not on dialysis, including approximately 650,000 adults currently being treated by nephrologists for iron deficiency anemia. Iron deficiency anemia is common in the non-dialysis population and the prevalence and severity increases as CKD advances. Iron deficiency anemia is symptomatic and can significantly impact quality of life. Auryxia is being marketed in the United States to nephrologists and renal care teams through our specialty salesforce and commercial infrastructure. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. These target nephrologists treat CKD patients on dialysis and those not on dialysis. We believe strong fundamentals are in place to drive commercial adoption of Auryxia in the dialysis setting and maximize the potential of Auryxia as a treatment of iron deficiency anemia in adults with CKD, not on dialysis.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that can help patients with kidney disease. Our business development activities include evaluating clinical-stage drug candidates, as well as commercially available medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a workforce of high-quality and talented people to support our potential growth.

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CORPORATE INFORMATION

We were incorporated in Delaware in October 1998 and commenced operations in November 1999. Our corporate offices are located at 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 http://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, 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 Securities and Exchange Commission, or 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 with the SEC 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.

AURYXIA (FERRIC CITRATE)

Commercial Program

Auryxia is approved as a treatment for two common complications of CKD. Auryxia is a non-calcium, non-chewable, orally-administered phosphate binder approved in the United States for the control of serum phosphorus levels in patients with CKD on dialysis as well as for treatment of iron deficiency anemia in adults with CKD, not on dialysis. It is also marketed in Japan under the brand name Riona by our Japanese partner, JT and Torii, as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent, or NDD, CKD. We receive royalties from JT and Torii based on their sales in Japan. Our efforts and associated expenses are focused on commercializing Auryxia in the United States.

Auryxia's supplemental new drug application, or sNDA, approval for the treatment of iron deficiency anemia in CKD patients not on dialysis was based on results from a 24-week placebo controlled Phase 3 clinical trial in 234 adults with stage 3-5 NDD-CKD. Patients enrolled in the trial had hemoglobin levels between 9.0 g/dL and 11.5 g/dL and were intolerant to or had an inadequate response to prior treatment with oral iron supplements. The starting dose in the trial was three tablets per day taken with meals; the mean dose was five tablets per day. Importantly, during the trial, patients were not allowed to receive any intravenous, or IV, or oral iron, or erythropoiesis-stimulating agents, or ESAs. In the trial, treatment with Auryxia demonstrated significant increases in hemoglobin levels of >1 g/dL at any point during the 16-week efficacy period for the majority of patients (52.1 percent, n=61/117, compared to 19.1 percent, n=22/115, in the placebo group), a clinically meaningful result. In the trial, ferric citrate was generally well tolerated and adverse events were consistent with its known safety profile. The most commonly reported adverse events in the Phase 3 trial were discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%), and hyperkalemia (5%). Results were published January 2017 in the online issue of the Journal of the American Society of Nephrology.

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 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.

Currently, our only product is Auryxia. From January 2015 through September 2016, we recognized product sales based on prescription sales of Auryxia in the United States. Since October 2016, we recognize product sales based on product sales to our customers. We have also generated, and expect to continue to generate, revenue from the sublicensing of rights to Auryxia in Japan to our Japanese partner. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

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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 Fexeric as a New Active Substance, or NAS, which provides 10 years of data and marketing exclusivity in the European Union, or EU. We do not plan to launch Fexeric on our own in the EU.

Foreign Operations

We have no foreign operations. Revenues from outside of the United States amounted to approximately 8%, 15% and 26% of our total revenues for 2017, 2016 and 2015, respectively, representing the license revenue recognized on net sales of Riona 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

Hyperphosphatemia Market

In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as 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. The majority of ESRD patients require chronic treatment with phosphate-binding agents to lower and maintain serum phosphorus at acceptable levels. There are approximately 2.9 million prescriptions written in the United States for phosphate binders annually. Although the majority of dialysis patients are treated with phosphate binders, according to the Dialysis Outcomes and Practice Patterns Study, or DOPPS, program, 30-40 percent of these patients still have serum phosphorus levels above the KDOQI guidelines recommended range. DOPPS is one of the largest prospective studies of ESRD patients worldwide and includes samples from dialysis patients and units in multiple countries, including the United States to identify clinical practices that benefit patients. As we continue to increase utilization of Auryxia in the dialysis setting, our sales force is focused on asking renal care teams to try Auryxia on patients with serum phosphorus levels outside of the target range. At the American Society of Nephrology's 2016 Kidney Week in November, case study data from 92 patient charts for Auryxia were presented that showed treatment with this medicine lowered and maintained serum phosphorus levels in CKD patients on dialysis. Specifically, the majority of patients when started on Auryxia achieved target serum phosphorus levels within the KDOQI guideline target range at six months of treatment -- 48 percent and 65 percent of patients at one and six months, respectively.

In addition, it is estimated that more than 10 percent of the U.S. adult population is affected by CKD. As kidney function declines, levels of serum phosphorus become more prevalent, especially in non-dialysis stages 3-5 of CKD, which are 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.

Iron Deficiency Anemia Market

Iron deficiency anemia 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. Given our field force interacts primarily with nephrologists, we have conducted market research to assess how many patients under the care of a nephrologist have iron deficiency anemia and how many of those are treated. Our research shows that approximately 650,000 patients in the United States under the care of a nephrologist are treated for their iron deficiency anemia, and another 250,000 to 400,000 have iron deficiency anemia, but are not currently being treated. To treat this type of anemia, iron replacement therapy is essential to increase iron stores, which is reflected in ferritin and TSAT levels, and to raise hemoglobin levels. Market insights from proprietary and primary market research show that a need exists for an effective, well-tolerated, convenient iron deficiency anemia treatment. Nephrologists report low satisfaction with existing oral iron therapies due to tolerability. Auryxia is the first oral iron medication approved by the FDA that was developed specifically as a treatment for iron deficiency anemia in patients with CKD, not on dialysis. Treatment guidelines recommend treating anemia in CKD patients with oral iron before trying more invasive therapies such as ESAs, and IV iron. ESAs and IV iron are both injectable treatments that are viewed as effective treatment but are not frequently administered in the NDD-CKD setting; complications with IV iron include potential hypersensitivity reactions, including anaphylaxis. Both of these treatment options also have logistical complications associated with administering IV medicines in office settings.

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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 registration clinical program in which we conducted a Phase 3 short-term trial (completed in November 2010), a Phase 3 long-term trial (completed in January 2013) and a long-term open label extension, or OLE, trial (completed in July 2014). The two Phase 3 trials showed that treatment with Auryxia resulted in 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 using a 1 gram oral tablet formulation. 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 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 Trial

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 special protocol assessment, or 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.

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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.

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.

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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 ALT and 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 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: Auryxia Approval and Phase 3 Clinical Program

In November 2017, we received approval from the FDA to market Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. The approval to treat patients with iron deficiency anemia and CKD, not on dialysis was based on our Phase 3 clinical trial which completed in March 2016.

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 was 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, in the Phase 3 study, 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 ≥3.0 mg/dL. The use of oral or IV iron, ESAs, receipt of blood transfusions and phosphate binders were not 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. Secondary endpoints in this Phase 3 study include change from baseline to end of Randomized Period for hemoglobin, ferritin, TSAT and serum phosphorus.

In March 2016, we announced positive top-line results from the U.S.-based Phase 3 study of ferric citrate in treating iron deficiency anemia in patients with Stage 3-5 NDD-CKD. The study met its primary endpoint and all pre-specified secondary endpoints with statistical significance.

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The pivotal Phase 3 study enrolled 234 patients who previously had not adequately responded to or tolerated oral iron therapies at 32 clinical sites in the United States. Patients were randomized 1:1 (ferric citrate versus placebo). Patients enrolled in this study were not allowed to receive any IV or oral iron, or ESAs during this study. The study had a 16-week, randomized, double-blind, placebo-controlled, efficacy period followed by an 8-week open-label safety extension period in which all patients remaining in the study, including the placebo group, received ferric citrate. During the 16-week efficacy period, ferric citrate was administered at a starting dose of three tablets per day with food and could be titrated every four weeks by an additional three tablets for up to a maximum of 12 tablets per day; the mean dose received in ferric citrate treated patients was 5 tablets per day. The primary endpoint was the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week efficacy period.

Baseline laboratory values were similar between the treatment arms.

Baseline laboratory values:	Ferric Citrate (FC) (n=117)	Placebo (P) (n=115)
Hemoglobin (g/dL)	10.4	10.4
TSAT (%)	20.2	19.6
Ferritin (ng/mL)	85.9	81.7
Serum phosphate (mg/dL)	4.2	4.1

Efficacy analyses were performed on an intent-to-treat population and included all enrolled patients who received at least one dose of ferric citrate or placebo and one post-treatment laboratory assessment. The analysis also used a sequential gatekeeping strategy for statistical testing of the secondary endpoints.

Primary and Secondary Endpoint Results

	Ferric Citrate (FC) (n=117)	Placebo (P) (n=115)	P-Value
Primary Endpoint:			
Proportion of patients achieving an increase in hemoglobin of > 1.0 g/dL at any time point during efficacy period* (%)	52.1	19.1	<0.001
Secondary Endpoints:			
Mean change in hemoglobin (g/dL)	0.75	(0.08)	<0.001
Mean change in TSAT (%)	17.8	(0.60)	<0.001
Mean change in ferritin (ng/mL)	162.5	(7.70)	<0.001
Proportion of patients with a durable response during the efficacy period (%)**	48.7	14.80	<0.001
Mean change in serum phosphate (mg/dL)	(0.43)	(0.22)	0.02

* Efficacy period defined as the 16-week randomized, double-blind, placebo controlled period.

** Sustained treatment effect on hemoglobin was defined as a mean change from baseline ≥0.75 g/dL over any 4-week time period during the efficacy period, provided that an increase of at least 1.0 g/dL had occurred during that 4-week period.

Safety and Tolerability Profile

The safety population in the study included all randomized patients who took at least one dose of study drug. The safety analysis demonstrated that ferric citrate was generally well tolerated in adults with Stage 3-5 NDD-CKD. Specifically, the results showed:

- During the efficacy period, the majority of adverse events reported were mild to moderate, with the most common being diarrhea (20.5% FC; 16.4% P), constipation (18.8% FC; 12.9% P), discolored feces (14.5% FC; 0% P), and nausea (11.1% FC; 2.6%P). During the efficacy period, hypophosphatemia was reported as an adverse event in four patients, one patient in the ferric citrate arm and three patients in the placebo arm.

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- During the efficacy period, 26 percent (31/117) of ferric citrate-treated patients and 30 percent (35/116) of those receiving placebo discontinued treatment. Of the patients who discontinued, 12 patients treated with ferric citrate discontinued due to an adverse event, compared to 10 patients who received placebo.
- During the efficacy period, the rate of serious adverse events was balanced between the ferric citrate and placebo treatment groups, at 12% and 11%, respectively. None of the serious adverse events were deemed drug related.

During the course of the study, there were two deaths reported, both in patients receiving ferric citrate; neither of which were related to study drug.

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 and CKD support staff, including dietitians, registered nurses, nurse practitioners and physician assistants, as well as through 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. Our ability to protect our proprietary technologies from unauthorized use by third parties is limited by the extent to which 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 lags 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, or USPTO, 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.

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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 (if a license is available on commercially reasonable terms) under such patent or to develop or obtain alternative technology. In the event of a litigation involving a third-party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third-party, require us to seek a license for the disputed rights from such third-party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

Pursuant to our license 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 includes claims covering a method of treating hyperphosphatemia using Auryxia and encompasses the dosing regimen approved by the FDA for Auryxia; (2) U.S. Patent Nos. 7,767,851, 8,299,298, 8,338,642, 8,609,896, 8,754,257, 8,754,258, 8,901,349, 9,050,316, 9,328,133 and 9,757,416, which expire in 2024 and include either composition of matter claims, methods of use claims or both 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 a U.S. patent with claims directed to formulations of ferric citrate and U.S. patent applications directed to methods for the prophylaxis or treatment of hyperphosphatemia comprising administering a ferric citrate tablet , methods of improving at least one iron storage parameter (e.g., hemoglobin) in certain CKD patients comprising orally administering ferric citrate, and methods for treating iron deficiency anemia in certain CKD patients comprising orally administering a certain tablet formulation of ferric citrate.

Pursuant to our sublicense with our Japanese partner, Japan Tobacco Inc., or JT, and its subsidiary, Torii Pharmaceutical Co. Ltd., or Torii, we have also exclusively sublicensed certain Japanese patent rights to JT and Torii. These sublicensed rights include: (1) Japanese Patent No. 4173553, which expires in 2022; (2) Japanese Patent No. 4964585, which expires in 2025; (3) Japanese Patent No. 5667343, which expires in 2026; and (4) five pending Japanese patent applications. Each of the foregoing patents and patent applications include either composition of matter claims, methods of use claims, or both, covering Riona, the trade name under which JT and Torii market ferric citrate in Japan. The terms of the Japanese patents referred to in (1) and (2) above have been extended based on the Japanese regulatory review process for Riona under the Japanese patent term extension program. To date, to our knowledge, no contested proceedings or third-party claims have been lodged against any of these three Japanese patents.

The term of a patent will vary depending upon the legal term for a patent in the country in which the patent is obtained. Generally, the term for a patent is 20 years from the earliest filing date of a non-provisional patent application in the United States. In the United States, the term of a patent may be lengthened by patent term adjustment, which compensates a patentee for administrative delays by the USPTO in examining and granting a patent or may be shortened if a patent is terminally disclaimed over an earlier filed patent. In addition, the term of a U.S. patent that covers a drug, biological product or medical device approved by the FDA for commercial marketing may be eligible for patent term extension, provided statutory and regulatory requirements are met.

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 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, such defense or protection 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.

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

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 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. We may also seek to utilize market exclusivities in other territories, such as in the EU. 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, EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

LICENSING AGREEMENTS AND COLLABORATIONS

We have formed strategic alliances with a number of companies for the development, manufacture and commercialization of 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 ferric citrate in the licensed territory, and through September 2017, was eligible to receive a manufacturing fee for product manufactured for us in the licensed territory. For the years ended December 31, 2017 and 2016, we recorded approximately $3.3 million and $1.6 million, respectively, 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.

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

In September 2007, we entered into a Sublicense Agreement with JT and Torii, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, which was amended in June 2013, or 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, or 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 Revised Agreement, we received a non-refundable milestone payment of $7.0 million in January 2013 for the achievement of the NDA filing milestone.

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 and may also receive 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. We recorded $5.1 million and $4.8 million in license revenue related to royalties earned on net sales of Riona in Japan in 2017 and 2016, respectively. We record the associated mid-single digit percentage of net sales royalty expense due to Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii is recorded. We recorded $3.0 million and $2.9 million in license expense in 2017 and 2016, respectively, related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

The sublicense terminates upon the expiration of all underlying patent rights. Also, JT and Torii may terminate the sublicense agreement with or without cause upon at least six months prior written notice to us. Additionally, either party may terminate the sublicense agreement for cause upon 60 days' prior written notice after the breach of any material provision of the sublicense agreement, or after certain insolvency events.

COMPETITION

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

Hyperphosphatemia Competition

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. The majority of the phosphate binders listed above are now available in generic forms. 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.

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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 a dynamic bone disease. Calcification of the cardiovascular system is believed to represent a significant risk factor for morbidity and mortality in patients with CKD. Due to this, in 2017, Kidney Disease Improving Global Outcomes Mineral and Bone Disease Practice Guidelines strengthened the language restricting use of calcium-based binders.

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.

Iron Deficiency Anemia Competition

Auryxia is competing in the United States for the treatment of iron deficiency anemia in CKD patients, not on dialysis, with over-the-counter oral iron, other prescription oral iron formulations and IV iron. Auryxia is the only branded oral iron medicine that was developed and specifically approved for the treatment of iron deficiency anemia in this patient population. Nephrologists have reported limited success with traditional oral iron formulations (both over-the-counter and prescription products). IV iron is an effective treatment but is not frequently administered in the NDD-CKD setting due to potential hypersensitivity reactions, including anaphylaxis and logistical complications associated with administering IV medicines in office settings. Auryxia is the only oral iron medicine being actively promoted in the nephrology setting.

Auryxia, currently our only product, which we launched in its first approved indication 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 product candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop products. 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 Auryxia, for use in clinical trials and for commercial sale.

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. We currently have multiple suppliers of Auryxia's active pharmaceutical ingredient, or API, and one supplier with two approved sites for the supply of Auryxia drug product. We are currently working with our drug product supplier to have a third site approved. In addition, we are continuing to establish 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 and finished drug product 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 expand capacity to produce Auryxia under current Good Manufacturing Practice, or cGMP, requirements. Our third-party manufacturers have a limited number of approved facilities in which Auryxia can be produced and have limited experience in manufacturing Auryxia in quantities sufficient for higher levels of demand. Our third-party manufacturers 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.

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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 EU 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 or add additional manufacturing sites 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 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.

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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, an 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. 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.

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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.

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 make certain certifications 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 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 also will not be approved until any applicable non-patent exclusivity listed in the Orange Book for the referenced product has expired.

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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 approve an ANDA for a generic drug that includes such changes.

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.

Patent Term Extension

After NDA approval, owners of relevant drug patents or their agents may apply for up to a five-year patent extension for delays caused by FDA regulatory review. 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 the FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years.

We have filed applications under the patent term extension provisions of 35 U.S.C. § 156 for U.S. Patent Nos. 8,299,298, 8,093,423, 7,767,851, 5,753,706, and 8,338,642 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. 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 own or license.

For patents that might expire before a determination regarding patent term extension, the patent owner or its agent may request an interim patent term 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 USPTO must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely.

We have filed for an interim patent term extension in accordance with 35 U.S.C. § 156(e)(2) for U.S. Patent No. 5,753,706.

In addition, certain other non-jurisdictions, including Japan, have provisions that provide for patent term extension. In October 2014, following the regulatory approval of Riona in Japan, the Japan Patent office granted the patent term extensions filed by our sublicensee, JT, for Japanese Patents Nos. 4964585 and 4173553. As a result of the extension of patent term, Japanese Patents Nos. 4964585 and 4173553 will expire in November 2025 and November 2022, respectively.

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.

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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 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.

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.

Foreign Approval

Should we wish to market our products outside the United States, 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 EU, registration procedures are available to companies wishing to market a product in more than one EU 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 United States 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.

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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.

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;

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- 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 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 $37.7 million in 2017, $29.5 million in 2016 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 inventory manufactured prior to regulatory approval of the product or the specific contract manufacturer, 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."

SEGMENT REPORTING

We conduct our operations in one business segment as further described in Note 14 – Business Segments to our consolidated financial statements.

EMPLOYEES

As of February 9, 2018, we had 210 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.

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.

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Risks related to our business and industry

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 the current good manufacturing practices, or 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 an interruption in the supply of our drug to the market, particularly given that some of the third parties we intend to employ in the manufacturing process are single source providers. As a result of the large quantity of materials required for Auryxia production and the large quantities of Auryxia that is required for our 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 continually produce the active pharmaceutical ingredient, or API, and finished drug product on a commercial scale. Failure to achieve and maintain these levels 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 and continued commercial scale manufacture of Auryxia may lead to significant delays in our development and commercial timelines and negatively impact our financial performance. For example, a production-related issue resulted in an interruption in the supply of Auryxia in the third and fourth quarters of 2016. This supply interruption negatively impacted our revenues in 2016. Although we have resolved this supply interruption and taken steps designed to prevent future interruptions in the supply of Auryxia, any additional supply interruptions would negatively and materially impact our reputation and financial condition.

We currently have multiple suppliers of Auryxia's API and one supplier with two approved sites for the supply of Auryxia drug product. We are currently working with our drug product supplier to have a third site approved. 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 adequate levels, we could experience losses of revenue, which could materially and adversely impact our results of operations.

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 and maintain 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.

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In addition, 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 and as demonstrated by our recent interruption in the supply of Auryxia, negatively impact our sales of Auryxia.

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 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 decreased sales and/or delays in achieving the business or regulatory milestones required for additional commercialization of our current drug and any future drug candidate.

We have a limited operating history as a commercial-stage company 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 as a commercial-stage company. 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, 2017, we had an accumulated deficit of $998.5 million. As we continue our research and development and commercial efforts, we may 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 any additional regulatory approvals that we may seek 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 U.S. Food and Drug Administration, or FDA, approved Auryxia for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis and in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. The commercial success of Auryxia will depend on a number of factors, including:

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the effectiveness of Auryxia as a treatment for adult patients with CKD on dialysis and for iron deficiency anemia in adults with CKD, not on dialysis;

- the adoption of Auryxia by physicians, which depends on whether physicians view it as a safe and effective treatment for their patients;

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- our ability to successfully launch and then effectively continue to commercialize Auryxia in the newly approved indication of iron deficiency anemia in adults with CKD, not on dialysis;
- the effectiveness of the sales, managed markets and marketing efforts by us and our competitors;
- our ability to continue to supply Auryxia to the market without interruption;
- our ability to identify reliable suppliers and successfully manufacture Auryxia;
- our ability to continue to grow Auryxia product sales following the resupply of Auryxia to the market following the recent interruption in its supply;
- 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 and the benefits of Auryxia to patients;
- our mix of business between private commercial payers and government-sponsored plans;
- 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; and
- the development or commercialization of competing products.

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.

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, including in the newly approved indication of iron deficiency anemia in adults with CKD, not on dialysis, we intend to continue 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 oral drug has previously been specifically marketed for the treatment of iron deficiency anemia in patients with CKD, not on dialysis.

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

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 pre-dialysis and dialysis patients. 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, or EU.

We are not currently marketing Fexeric in the EU, however, we are seeking potential partners to commercialize Fexeric in the EU. We cannot assure you that we will be able to find a commercialization partner in the EU or that we will be able to agree to acceptable terms with any partner to launch and commercialize Fexeric in the EU. If we do not begin to market Fexeric in the EU by September 23, 2018, the EC may withdraw its approval of Fexeric.

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 EU are subject to these and other factors, and therefore we may never reach or maintain profitability in the EU.

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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 for CKD on dialysis in the United States included diarrhea (21%), discolored feces (19%), nausea (11%), constipation (8%), vomiting (7%), and cough (6%). Gastrointestinal adverse reactions were the most common reason for discontinuing Auryxia (14%) in clinical trials for that indication. The most commonly reported adverse reactions in the clinical trials that supported the approval of Auryxia in the United States for iron deficiency anemia in adults with CKD, not on dialysis included discolored feces (22%), diarrhea (21%), constipation (18%), nausea (10%), abdominal pain (5%) and hyperkalemia (5%). Diarrhea was the most common reason for discontinuing Auryxia (2.6%) in clinical trials for the iron deficiency anemia in adults with CKD, not on dialysis indication. 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;
- 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, as Auryxia is commercialized, we expect it will be used in wider populations 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 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 for the treatment of iron deficiency anemia in adults with CKD, not 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.

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The status of reimbursement from third-party payers 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 payers.

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 payers. Third-party payers, including Medicare and Medicaid, are challenging the prices charged for medical products and services. Government and other third-party payers 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, or PPACA, 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 payers do not provide adequate coverage and reimbursement levels for our product, Auryxia's market acceptance may be significantly reduced. In addition, the mix of our business that is reimbursed by different payers can negatively impact our net U.S. Auryxia product sales on a year-to-year and quarter-to-quarter basis with a larger mix of government payers generally increasing our adjustments to gross Auryxia sales in the particular period.

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, or HIPAA, 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, or FDCA, 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;

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- 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.

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.

We have assembled an experienced compliance team and implemented a compliance 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 compliance program is relatively new and the requirements in this area are constantly evolving, we cannot be certain that our compliance 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 drugs 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 acquire and/or 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), 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 that have received approval of Abbreviated New Drug Applications, or ANDAs, for generic Renvela with the FDA and launched the generic form in the United States. 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.

Auryxia is also competing in the United States with other FDA-approved treatments for iron deficiency anemia, such as Venofer® (iron sucrose) and Injectafer® (ferric carboxymaltose), both marketed by American Regent (a registered trademark of Luitpold Pharmaceuticals, Inc., a member of the Daiichi Sankyo Group), Feraheme® (ferumoxytol), marketed by AMAG Pharmaceuticals, Inc., Triferic® (ferric pyrophosphate citrate), marketed by Rockwell Medical, Inc., over-the-counter iron supplement products, as well as Erythropoiesis-stimulating agents, or ESAs, including Procrit® (epoetin alfa), marketed by Janssen Products, LP (a wholly-owned subsidiary of Johnson & Johnson) and Aranesp® (darbepoetin alfa), marketed by Amgen Inc.

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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 marketing our drug and also seeking to acquire and develop other drug products. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors.

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

As of December 31, 2017, we had 211 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.

Greg Madison has been our Chief Executive Officer since 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.

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

In July 2015, we appointed Scott Holmes as our Senior Vice President and Chief Financial Officer.

In January 2017, we appointed Christine Carberry as our Chief Operating Officer.

Although we have employment agreements with Greg Madison, John F. Neylan, M.D., Scott Holmes and Christine Carberry, 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.

Although we are not currently conducting registration trials for Auryxia, we continue to conduct clinical trials and post-marketing testing of Auryxia and we may have to complete the development of any product candidate that we develop, in-license or acquire in the future. As a result, the continued marketing of Auryxia and the clinical development of any other product is subject to the risks associated with the pre-clinical and clinical development of pharmaceutical products.

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, 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.

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Pre-clinical testing and clinical development are long, expensive and uncertain processes.

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 pre-clinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later 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 or acquire. If we experience delays in the testing or approval process for any drug we may commercialize or develop 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, or CROs, 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 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.

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Our reliance on third parties, such as 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, may dilute our stockholders 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. In addition, if we issue our equity securities as consideration in any acquisition, the ownership interests of our stockholders will be diluted.

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.

If we do not successfully integrate any acquisition into our business, our financial condition and operating results could be materially and negatively impacted.

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 payers 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 payers. 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.

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For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The final rule delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, 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 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 commercially and in clinical trials exposes us to liability claims. In addition, the use of any other drug candidate we develop or acquire in clinical trials, the future sale of any other approved drug and the use of new technology will also expose 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.

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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.

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.

The actual amount of cash that we will need to operate our business is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the timing and 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 any further clinical trials for ferric citrate. As a result of these factors, we will need to seek additional financing to provide the cash necessary to execute our current operations, including beyond the continued commercialization of Auryxia, and to develop and commercialize any drugs or 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:

- our ability to successfully market Auryxia as a drug for adults with CKD on dialysis and for the treatment of iron deficiency anemia in adults with CKD, not on dialysis;
- the timing and expenditures associated with commercial activities related to Auryxia and the timing and magnitude of cash received from product sales;
- the timing and expenditures associated with the build-up of inventory and capacity expansion;
- our ability to continue to supply Auryxia to the market without interruption;
- our ability to continue to grow Auryxia product sales following the resupply of Auryxia to the market following the recent interruption in its supply;
- the timing, design and conduct of, and results from, clinical trials that we may conduct;
- 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, through a commercialization partner or by us if we decide to commercialize in Europe on our own;
- 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;

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- 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, defending against post-grant proceedings initiated by third parties attempting to limit or cancel our intellectual property rights in the United States and elsewhere, such as U.S. inter partes review proceedings and/or European oppositions, 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, including pursuant to our Controlled Equity Offering[SM] Sales Agreement, or Sales Agreement, with Cantor Fitzgerald & Co., or Cantor Fitzgerald, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

Risks related to our intellectual property and third-party contracts

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

Our commercial success will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection on our drug product and technologies, and to successfully defend these patents against third-party challenges. We seek to protect our proprietary products and technology by filing patent applications in the United States and certain foreign jurisdictions. The process for obtaining patent protection is expensive and time consuming, and we may not be able to file and prosecute all necessary or desirable patent applications in a cost effective or timely manner. In addition, we may fail to identify patentable subject matter before it is too late to obtain patent protection. Further, license agreements with third parties may not allow us to control the preparation, filing and prosecution of patent applications, or the maintenance or enforcement of patents. Such third parties may decide not to enforce such patents or enforce such patents without our involvement. Thus, these patent applications and patents may not under these circumstances be prosecuted or enforced in a manner consistent with the best interests of the company.

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.

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. Changes in the patent laws or the interpretation of the patent laws in the United States and other jurisdictions may diminish the value of our patents or narrow the scope of our patent protection. Accordingly, the patents we own or license 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, or USPTO, 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 own or license may be challenged or invalidated or may fail to provide us with any competitive advantage. Since we have licensed or sublicensed many patents 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. For example, claims in a patent application directed to methods of treatment of the human body are not patentable or are restricted in many non-U.S. countries. Further, we may not pursue or obtain patent protection in all major markets. 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.

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Generally, the first to file a patent application is entitled to the patent if all other requirements of patentability are met. However, prior to March 16, 2013, in the United States, the first to invent was entitled to the patent. Since publications of discoveries in the scientific literature often lag behind the actual discoveries, and patent applications in the United States and other jurisdictions are typically not published until 18 months after filing, or in some cases not at all, we cannot know with certainty whether we were the first to make the inventions claimed in our patents or pending patent applications, or that we were the first to file for patent protection of such inventions. Moreover, the laws enacted by the Leahy-Smith America Invents Act of 2011, or the Act, which reformed certain patent laws in the United States, are still being interpreted and those laws introduce procedures that permit competitors to challenge our patents in the USPTO after grant, including inter partes review and post grant review. Similar laws exist outside of the United States. The laws of the European Patent Convention, for example, provide for post-grant opposition procedures that permit competitors to challenge our patents at the European Patent Office. We currently have two issued European patents involved in such post-grant opposition proceedings.

We may become involved in addressing patentability objections based on third-party submission of references, or we may become involved in defending our patent rights in oppositions, derivation proceedings, reexamination, inter partes review, post grant review, interference proceedings or other patent office proceedings or litigation, in the United States or elsewhere, challenging our patent rights or the patent rights of others. An adverse result in any such proceeding or litigation could reduce the scope of, or invalidate, our patent rights, allow third parties to commercialize our technology or products and compete directly with us, without payment to us.

The issuance of a patent is not conclusive as to its inventorship, scope, validity or enforceability, and our owned and licensed patents may be challenged on such a basis in the courts or patent offices in the United States and abroad. As a result of such challenges, we may lose exclusivity or freedom-to-operate, or patent claims may be narrowed, invalidated or held unenforceable, in whole or in part, which could limit our ability to prevent third parties from using or commercializing similar or identical products, or limit the duration of the patent protection for our products.

In addition, patents protecting our product candidate might expire before or shortly after such candidate is commercialized. Thus, our patent portfolio may not provide sufficient rights to exclude others from commercializing products similar or identical to ours.

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. For example, a third-party may design around our owned or licensed composition of matter patent claims or not market a product for methods of use covered by our owned or licensed patents.

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.

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In addition to patent protection, we may utilize, if granted by the FDA, pediatric exclusivity or other provisions of the 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 a new drug application, or NDA, for an NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an 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.

We may be subject to claims by third parties asserting that we or our employees have misappropriated their intellectual property, or claiming ownership of what we regard as our own intellectual property.

A number of our employees were previously employed at universities, or pharmaceutical or biotechnology companies, some of which may be a competitor or potential competitor. We try to ensure that our employees do not use the proprietary information or know-how of third parties in their work for us. Nonetheless, we may be subject to claims that we or these employees have used or disclosed intellectual property, including trade secrets or other proprietary information, of any such employee's former employer. As a result, litigation may be necessary to defend against these claims.

In addition, although we typically require our employees and contractors who may be involved in the development of intellectual property to execute agreements assigning such intellectual property to us, we may be unsuccessful in executing such an agreement with each party who in fact develops intellectual property that we regard as our own. Such assignment agreements may not be self-executing or may be breached, and we may be forced to bring claims against third parties, or defend claims they may bring against us, to determine the ownership of what we regard as our intellectual property.

In the event that we fail in prosecuting or defending any such claims, we may need to pay monetary damages as well as lose valuable intellectual property rights or personnel. However, regardless of the success in prosecuting or defending against such claims, such litigation may result in substantial costs and distract management.

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Risks related to our common stock

The Baupost Group, L.L.C, or 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, 2017, Baupost beneficially owns approximately 22% of our issued and outstanding common stock. If Baupost converts all of the convertible notes it holds into shares of our common stock, Baupost would beneficially own approximately 39% of our issued and outstanding 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 in which we raise additional funds;
- 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;
- 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 addition, Baupost has the right to appoint a director to our Board and 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 November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the SEC declared effective on December 6, 2016, which registered the issuance from time to time of up to $250 million of our securities. At that time, we also entered into the Sales Agreement with Cantor Fitzgerald, pursuant to which we were initially able to offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million. In July 2017, we filed a new prospectus supplement with the SEC relating to the Sales Agreement under which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an additional aggregate offering price of up to $75.0 million. During the year ended December 31, 2017, we sold 11,937,174 shares under the Sales Agreement for aggregate net proceeds of $75.7 million, which included all of the initial $75.0 million shares issuable pursuant to the Sales Agreement. As of the date hereof, we may sell up to an additional $72.4 million under the Sales Agreement pursuant to the July 2017 prospectus supplement. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock issuable pursuant to the Sales Agreement are included as part of the $250 million registered on the registration statement referred to above.

In October 2015, we raised $125 million through the private placement of Convertible Senior Notes due 2020, with funds managed by Baupost. 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 is equal to the $3.74 per share closing price of our common stock on the day prior to the issuance of the Notes in October 2015, 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 SEC.

We will need to seek additional financings to provide cash necessary to execute our current operations, including, but not limited to, beyond commercializing Auryxia, and to develop and commercialize any drugs or drug candidates we may in-license or acquire. Future issuances of common stock could depress the market for our common stock.

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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:

- actual or anticipated variations in quarterly or annual operating results, including, in particular with respect to net U.S. Auryxia product sales;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments involving us or our competitors;
- changes in financial estimates by securities analysts;
- developments relating to the marketing, safety and efficacy of our drug product, and regulatory filing 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, following our August 1, 2016 announcement of the supply interruption of Auryxia, four purported class action lawsuits were filed against us and certain of our current and former executive officers alleging false and/or misleading statements concerning the company and its business operations and future prospects, and two stockholder derivative complaints were filed against certain of our current and former executive officers and members of our board of directors. These litigations and any other 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. For example, our amended and restated bylaws have provisions specifying how and when stockholders may propose director nominations and other business to be brought before meetings of our stockholders and also provide that only certain parties may 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.

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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.

ITEM 3. LEGAL PROCEEDINGS.

For a description of our legal proceedings, see Note 13 – Commitments and Contingencies to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

ITEM 4. MINE SAFETY DISCLOSURES.

Not applicable.

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PART II

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

Market Information

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

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

	High	Low
Fiscal Year Ended December 31, 2017		
Fourth Quarter	$7.95	$4.39
Third Quarter	$8.25	$6.35
Second Quarter	$7.23	$5.55
First Quarter	$6.40	$4.59

	High	Low
Fiscal Year Ended December 31, 2016		
Fourth Quarter	$6.41	$4.16
Third Quarter	$7.53	$4.10
Second Quarter	$6.76	$4.54
First Quarter	$5.38	$3.17

Holders

The number of record holders of our common stock as of February 9, 2018 was 45.

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 8 – Debt to the consolidated financial statements included in this report, 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, 2017, 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.

	Equity Compensation Plan Information		
Plan Category	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	11,967,815	$ 6.73	2,026,423

For information about all of our equity compensation plans, see Note 9 – Stockholders' (Deficit) Equity to the consolidated financial statements included in this report.

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Issuer's Purchase of Equity Securities

As part of our equity compensation program, we sometimes allow, with the approval of our Compensation Committee, recipients of restricted stock awards the opportunity to sell their shares to us at the time of vesting to satisfy tax withholding obligations in connection with such vesting. The following table provides information concerning shares of our common stock purchased by us in connection with the forfeiture of shares to satisfy the employees' obligations with respect to withholding taxes in connection with the vesting of certain shares of restricted stock during the three months ended December 31, 2017. Upon purchase, these shares are immediately retired.

Period	Total Number of Shares Purchased	Average Price Paid per Share	Total Number of Shares Purchased as Part of Publicly Announced Plans or Programs	Maximum Number (or Approximate Dollar Value) of Shares that May Yet be Purchased Under the Plans or Programs
October 1 - 31, 2017	—	$ —	—	$ —
November 1 - 30, 2017	58,813	5.15	58,813	—
December 1 - 31, 2017	258	4.53	258	—
Total	59,071	$ 5.15	59,071	$ —

COMMON STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2012 through December 31, 2017, 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, 2012, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of all dividends. Measurement points are December 31 of each year.

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ITEM 6. SELECTED FINANCIAL DATA.

The following Statement of Operations Data for the years ended December 31, 2017, 2016, 2015, 2014 and 2013, and Balance Sheet Data as of December 31, 2017, 2016, 2015, 2014 and 2013, 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.

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	Years ended December 31,				
	2017	2016	2015	2014	2013
	(in thousands, except per share data)				
Statement of Operations Data:					
Net U.S. Auryxia product sales	$55,514	$27,173	$10,141	$—	$—
License revenue	5,127	4,810	3,539	10,825	7,000
Total revenues	60,641	31,983	13,680	10,825	7,000
Costs and expenses:					
Cost of goods sold	21,955	37,803	4,520	—	—
License expense	3,076	2,886	2,124	495	—
Research and development	37,679	29,504	36,694	51,502	34,734
Selling, general and administrative	99,622	84,553	81,410	70,057	19,349
Total costs and expenses:	162,332	154,746	124,748	122,054	54,083
Operating loss	(101,691)	(122,763)	(111,068)	(111,229)	(47,083)
Other (expense) income:					
Amortization of debt discount	(62,965)	(34,227)	(11,357)	—	—
Other (expense) income, net	981	(4,025)	(630)	411	351
Total other (expense) income	(61,984)	(38,252)	(11,987)	411	351
Loss before income taxes	(163,675)	(161,015)	(123,055)	(110,818)	(46,732)
Income tax (benefit) expense	(235)	80	90	700	—
Net loss	(163,440)	(161,095)	(123,145)	(111,518)	(46,732)
Basic and diluted net loss per common share	$(1.43)	$(1.52)	$(1.19)	$(1.23)	$(0.58)

	As of December 31,				
(in thousands)	2017	2016	2015	2014	2013
Balance Sheet Data:					
Cash and cash equivalents, interest receivable and short-term investment securities	$93,526	$111,810	$200,290	$85,840	$55,696
Working capital	$96,146	$111,346	$171,688	$69,285	$41,600
Total assets	$158,872	$141,427	$258,685	$103,628	$60,766
Convertible senior notes	$125,000	$125,000	$90,773	$—	$—
Total liabilities	$172,967	$149,723	$171,751	$30,144	$15,366
Total stockholders' (deficit) equity	$(14,095)	$(8,296)	$86,934	$73,484	$45,400

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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 commercial stage biopharmaceutical company focused on bringing innovative medicines to people with kidney disease. Our long-term vision is to build a multi-product kidney care company. Our marketed product, Auryxia (ferric citrate) tablets, is an orally available, absorbable, iron-based medicine. Auryxia is approved by the U.S. Food and Drug Administration, or FDA, for two indications. Auryxia was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Additionally, in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. With two FDA-approved indications, we will leverage our U.S. clinical and commercial infrastructure to make Auryxia available to millions of people with CKD and either iron deficiency anemia or elevated levels of serum phosphorus, which is referred to as hyperphosphatemia. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco, Inc., or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, and approved in Europe as Fexeric. We use the brand name Auryxia when we refer to ferric citrate for use in the approved indications in the United States. We refer to the product as ferric citrate when referring to its investigational use. Our vision of building a multi-product kidney care company includes expansion of our product portfolio with other medicines that can help patients with kidney disease.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines to the market for the treatment of people with kidney disease that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

Auryxia is approved for two indications in the United States. We developed and subsequently launched Auryxia in the United States in late December 2014 following the FDA's approval of Auryxia for the control of serum phosphorus levels in adult patients with CKD on dialysis. In November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adult patients with CKD, not on dialysis. Auryxia is a non-calcium, non-chewable, orally-administered phosphate binder. Auryxia is the first FDA-approved oral iron medication that was specifically developed to treat iron deficiency anemia in CKD patients, not on dialysis. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist for CKD have iron deficiency anemia, not on dialysis, including approximately 650,000 adults currently being treated by nephrologists for iron deficiency anemia. Iron deficiency anemia is common in the non-dialysis population and the prevalence and severity increases as CKD advances. Iron deficiency anemia is symptomatic and can significantly impact quality of life. Auryxia is being marketed in the United States to nephrologists and renal care teams through our specialty salesforce and commercial infrastructure. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. These target nephrologists treat CKD patients on dialysis and those not on dialysis. We believe strong fundamentals are in place to drive commercial adoption of Auryxia in the dialysis setting and maximize the potential of Auryxia as a treatment of iron deficiency anemia in adults with CKD, not on dialysis.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that can help patients with kidney disease. Our business development activities include evaluating clinical-stage drug candidates, as well as commercially available medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the potential to provide additional revenues to us in the future.

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Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a workforce of high-quality and talented people to support our potential growth.

Financial Performance Overview

Revenues

Product revenue is currently derived from sales of our sole commercial product, Auryxia, in the United States. License revenue relates to our license agreement with JT and Torii and includes license fees, milestone payments and royalties on net product sales.

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis and for the treatment of iron deficiency anemia in patients with CKD, not 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, 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.

Operating Expenses

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 inventory manufactured prior to regulatory approval of a product or a new contract manufacturer, 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, 2017, 2016 and 2015 were $37.7 million, $29.5 million and $36.7 million, respectively.

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

	Years ended December 31,		
(in thousands)	2017	2016	2015
Auryxia (ferric citrate)	$35,046	$26,692	$32,911
Other	—	—	264
Stock-based compensation expense	2,633	2,812	3,519
Total	$37,679	$29,504	$36,694

Our selling, general and administrative expenses consist primarily of salaries and related expenses, including stock-based compensation, for executive, finance, legal, sales, pharmacovigilance, 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 awards. Stock-based 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 expense. The expense is classified by expense categories in the consolidated statements of operations. We expect to continue to incur significant stock-based compensation expenses.

RESULTS OF OPERATIONS

Years Ended December 31, 2017 and 2016

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Net U.S. Auryxia Product Sales. For the year ended December 31, 2017, we recognized $55.5 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $27.2 million for the year ended December 31, 2016. In November 2017, we received FDA approval to market Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. We expect our revenues to be favorably impacted by the FDA approval of Auryxia in a second indication.

(in thousands)	2017	Percent of gross Auryxia product sales	2016	Percent of gross Auryxia product sales
Gross Auryxia product sales	$111,845		$44,557	
Less provision for product sales allowances and accruals				
Trade allowances	13,093	12%	5,157	12%
Rebates and chargebacks	40,482	36%	10,703	24%
Product returns	1,362	1%	879	2%
Other incentives [1]	1,394	1%	645	1%
Total	56,331	50%	17,384	39%
Net U.S. Auryxia product sales	$55,514		$27,173	

[1] Includes co-pay assistance 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 filling patient prescriptions. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns. Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers.

Gross Auryxia product sales increased for the year ended December 31, 2017 as compared to the same period in 2016 primarily as a result of an increase in patient prescriptions and related units sold, partially offset by a higher gross-to-net adjustment. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the year ended December 31, 2017 as compared to the same period in 2016 increased primarily as a result of a higher percentage of sales through government (Medicare Part D) contracts that generally receive a larger rebate. Our gross-to-net adjustments may increase depending on our mix of business between Medicare Part D and commercial payers as well as the portion of our business coming from the use of Auryxia as a treatment for hyperphosphatemia as compared to the portion of our business coming from the use of Auryxia as a treatment for iron deficiency anemia.

The following table sets forth customers which represented 10% or more of our total revenues for 2017 and 2016:

(in thousands)	December 31, 2017		December 31, 2016	
Fresenius Medical Care Rx	29	%	22	%
McKesson Corporation	19	%	31	%
DaVita Rx	18	%	10	%
Cardinal Health, Inc.	15	%	11	%
AmerisourceBergen Drug Corporation	15	%	23	%

License Revenue. For the year ended December 31, 2017, we recognized $5.1 million in license revenue on royalty payments from sales of Riona in Japan as compared to $4.8 million for the year ended December 31, 2016. This increase was directly attributable to increased sales of Riona in Japan.

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Cost of Goods Sold. Cost of goods sold decreased by $15.8 million, or 42%, to $22.0 million for the year ended December 31, 2017, as compared to $37.8 million for the year ended December 31, 2016. The decrease is primarily a result of approximately $3.5 million in write-offs of inventory that were determined to be no longer suitable for commercial manufacture in 2017, as compared to $28.0 million in 2016. Cost of goods sold in 2016 also 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 Expense. For the year ended December 31, 2017, we recognized $3.1 million in license expense related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $2.9 million for the year ended December 31, 2016. This increase was due to an increase in sales of Riona in Japan in 2017 as compared to 2016.

Research and Development Expenses. Research and development expenses increased by $8.2 million, or 28%, to $37.7 million for the year ended December 31, 2017, as compared to $29.5 million for the year ended December 31, 2016. The increase in research and development expenses was primarily due to an increase in process development-related manufacturing costs as we seek to increase our manufacturing capabilities, as well as an increase in clinical trial costs. Research and development expenses included $2.6 million and $2.8 million in non-cash stock-based compensation expense for the years ended December 31, 2017 and 2016, respectively. We expect research and development expenses in 2018 to remain relatively consistent as compared to 2017.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $15.1 million, or 18%, to $99.6 million for the year ended December 31, 2017, as compared to $84.6 million for the year ended December 31, 2016. The increase was due to an increase in non-cash stock-based compensation expense recorded in 2017 related to the achievement of performance conditions tied to the vesting of equity awards of $4.6 million, as well as personnel costs attributable to the continued commercialization of Auryxia and costs associated with preparing for the approval and launch of Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. Selling, general and administrative expenses included $15.6 million and $11.2 million in non-cash stock-based compensation expense for the years ended December 31, 2017 and 2016, respectively. We expect selling, general and administrative expenses in 2018 to remain relatively consistent as compared to 2017.

Other (expense) income, net. Other (expense) income, net for the year ended December 31, 2017 was $62.0 million (expense) compared to $38.3 million (expense) for the year ended December 31, 2016. The increase was primarily due to an increase in the amortization of the debt discount of $29.0 million offset by a change in the fair value adjustment to the derivative liability related to our convertible senior notes of $5.0 million.

Income Tax (Benefit) Expense. Income tax (benefit) expense for the year ended December 31, 2017 was $0.2 million (benefit) compared to $0.1 million expense for the year ended December 31, 2016. The net income tax benefit recognized in 2017 relates to a tax benefit recorded in connection with the new corporate tax rate that was signed into law at the end of 2017, which was partially offset by the income tax expense recorded in each period 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.

Years Ended December 31, 2016 and 2015

Net U.S. Auryxia Product Sales. For the year ended December 31, 2016, we recognized $27.2 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks as compared with $10.1 million for the year ended December 31, 2015.

(in thousands)	2016	Percent of gross Auryxia product sales	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$44,557		$16,295	
Less provision for product sales allowances and accruals				
Trade allowances	5,157	12%	1,897	12%
Rebates and chargebacks	10,703	24%	2,418	15%
Product returns	879	2%	—	—%
Other incentives [1]	645	1%	1,839	11%

Total	17,384	39%	6,154	38%
Net U.S. Auryxia product sales	$27,173		$10,141	

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

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Gross Auryxia product sales increased for the year ended December 31, 2016 as compared to the same period in 2015 primarily as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the year ended December 31, 2016 as compared to the same period in 2015 increased primarily as a result of additional rebates and discounts given to our third-party payors. The transition to the ex-factory revenue recognition method resulted in the need to establish an accrual for product returns, which increased the provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales. Further, our sales of Auryxia in 2016 were negatively impacted by the interruption in the supply of Auryxia during portions of the third and fourth quarters of 2016 due to a production-related issue in converting API to finished drug product at our contract manufacturer. In November 2016, the FDA approved a second manufacturer to produce finished Auryxia drug product, after which we made Auryxia available for sale again.

As a result of the change in revenue recognition method during the fourth quarter of 2016, we did not have any deferred revenue at December 31, 2016, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and chargebacks.

The following table sets forth customers or partners who represented 10% or more of our total revenues for 2016 and 2015:

(in thousands)	December 31, 2016		December 31, 2015	
McKesson Corporation	31	%	23	%
AmerisourceBergen Drug Corporation	23	%	17	%
Fresenius Medical Care Rx	22	%	15	%
Cardinal Health, Inc.	11	%	24	%
DaVita Rx	10	%	19	%

License Revenue. For the year ended December 31, 2016, we recognized $4.8 million in license revenue on royalty payments from sales of Riona in Japan as compared to $3.5 million for the year ended December 31, 2015. This increase was directly attributable to increased sales of Riona in Japan.

Cost of Goods Sold. For the year ended December 31, 2016, we recognized $37.8 million in cost of goods sold as compared to $4.5 million for the year ended December 31, 2015. Cost of goods sold in 2016 includes approximately $25.6 million in write-offs of work-in-process inventory that was determined to be no longer suitable for commercial manufacture. Cost of goods sold during each of 2015 and 2016 also 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 Expense. For the year ended December 31, 2016, we recognized $2.9 million in license expense related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $2.1 million for the year ended December 31, 2015. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $7.2 million, or 20%, to $29.5 million for the year ended December 31, 2016, as compared to $36.7 million for the year ended December 31, 2015. The decrease in research and development expenses was primarily due to a $3.0 million decrease in expenses related to clinical trial activity following the completion of our Phase 3 clinical trial of ferric citrate in IDA, NDD-CKD, in early 2016, as well as a decrease of $2.5 million in manufacturing-related expenses that were expensed to research & development as a result of a decrease in development work and fees due to our licensor related to lower API production. Regulatory consulting expenses also decreased by approximately $1.4 million after the completion of our European filing for Fexeric in 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $3.1 million, or 4%, to $84.6 million for the year ended December 31, 2016, as compared to $81.4 million for the year ended December 31, 2015. The increase was primarily due to a $16.2 million increase in selling expense related to the commercialization of Auryxia, including an increased sales force for a full year in 2016 versus a partial year in 2015. This was partially offset by decreases in personnel costs as a result of severance payments and related costs incurred in 2015.

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Other (expense) income, net. Other (expense) income, net for the year ended December 31, 2016 was $38.3 million (expense) compared to $12.0 million (expense) for the year ended December 31, 2015. This increase in expense was primarily the result of $34.2 million of expense recorded related to the amortization of the debt discount recognized in connection with the issuance of the Convertible Senior Notes, due 2020, or the Notes, in October 2015, as compared to $11.4 million recorded in 2015. Additionally, we recorded $4.7 million of expense in 2016 related to the increase in fair value of the derivative liability associated with the Notes, as compared to $1.1 million in 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 8 – Debt for additional details.

Income Taxes. For the years ended December 31, 2016 and 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. 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.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public offerings of our common stock, the issuance of convertible notes, the upfront, royalty and milestone payments from our agreement with JT and Torii, sales of Auryxia, option and warrant exercises, interest income, 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 if we successfully commercialize Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to successfully manufacture and commercialize our drug alone or in partnership, as well as successfully complete any post-approval regulatory obligations. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In November 2016, we filed a registration statement on Form S-3 (No. 333-214513), which the SEC declared effective on December 6, 2016, which registered the issuance from time to time of up to $250.0 million of our securities. At that time, we also entered into a Controlled Equity Offering^{SM} Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we were initially able to offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million. In July 2017, we filed a new prospectus supplement with the SEC relating to the Sales Agreement under which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an additional aggregate offering price of up to $75.0 million. During the year ended December 31, 2017, we sold 11,937,174 shares under the Sales Agreement for aggregate net proceeds of $75.7 million, which included all of the initial $75.0 million shares issuable pursuant to the Sales Agreement. As of the date hereof, we may sell up to an additional $72.4 million under the Sales Agreement pursuant to the July 2017 prospectus supplement. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock issuable pursuant to the Sales Agreement are included as part of the $250 million registered on the registration statement referred to above.

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. 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.

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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 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, 2017, we had $93.5 million in cash and cash equivalents, as compared to $111.8 million in cash and cash equivalents at December 31, 2016, representing a decrease of $18.3 million. This decrease was primarily a result of cash used in operations, partially offset by net proceeds from the sale of common stock.

We believe that our existing cash and cash equivalents will be sufficient to fund our current and planned operations for at least the next twelve months. The actual amount of cash that we will need to execute our current business objectives is subject to many factors, including, but not limited to, the timing and magnitude of cash received from product sales, the timing and expenditures associated with commercial activities related to Auryxia, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of any further clinical trials for ferric citrate. As a result of these factors, we may need to seek additional financing to provide the cash necessary to execute our current operations, including working capital needs. Our capital raising activities may include, but may not be limited to, one or more of the following: the issuance of common stock or other securities via private placement or public offerings, including the potential future sales of our common stock under the Sales Agreement; the issuance of debt, including potential working capital lines of credit; or possible business combinations. While we may seek capital through a number of means, there can be no assurance that additional financing will be available on acceptable terms, if at all, and our negotiating position in capital-raising efforts may worsen as existing resources are used. Additional equity financings may be dilutive to our stockholders; and debt financing, if available may involve significant cash payment obligations and covenants that restrict our ability to operate as a business. 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, 2017 was $93.5 million, primarily attributable to our net loss of $163.4 million, adjusted for non-cash stock-based compensation expense and amortization of the debt discount recognized in connection with the Notes, as well as changes in operating assets and liabilities, principally the increase of inventory and other assets related to prepayments for manufacturing services, and corresponding increase of accrued expenses as compared to December 31, 2016. Net cash used in operating activities for the year ended December 31, 2016 was $86.6 million, primarily attributable to our net loss of $161.1 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 decrease of deferred revenue and accrued expenses from December 31, 2015.

Net cash used in investing activities for the year ended December 31, 2017 was $1.3 million as compared to $2.1 million for the year ended December 31, 2016, all of which was attributable to capital expenditures.

Net cash provided by financing activities for the year ended December 31, 2017 was $76.5 million, attributable to the net proceeds from the issuance of common stock under the Sales Agreement and exercise of stock options. Net cash provided by financing activities for the year ended December 31, 2016 was $0.2 million, attributable to proceeds from the exercise of stock options.

OFF-BALANCE SHEET ARRANGEMENTS

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

OBLIGATIONS AND COMMITMENTS

Our contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to our facility lease, purchases of inventory and other purchases related to our product, debt obligations, consulting services and subscription fees, among others.

The following table summarizes our contractual obligations as of December 31, 2017.

(in thousands)	Payment due by period				
Contractual obligations	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Convertible senior notes	$125,000	$—	$125,000	$—	$ —
Facility lease	8,703	1,628	3,338	3,447	290
Purchase commitments	206,581	58,263	72,994	75,324	—
Total	$340,284	$59,891	$201,332	$78,771	$ 290

Convertible Senior Notes

The debt obligation of $125 million in the table above 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 8 – Debt).

Facility Lease

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.

Purchase Commitments

Purchase commitments in the table above relate to agreements with certain contract manufacturers, for which we are not contractually able to terminate for convenience and avoid any and all future obligations. These amounts do not represent our entire anticipated purchases in the future, but generally represent our estimate of those items for which we have a contractual commitment to pay, including minimum purchase quantities of product. Such obligations also include inventory purchase orders based on our current manufacturing needs and require significant lead times to be fulfilled by our vendors. Purchase commitments exclude agreements that are cancelable without penalty, including open purchase orders that represent authorizations to purchase rather than legally binding agreements.

Contingent Milestone Payments

Under one of our existing manufacturing agreements, we may be required to pay up to $10.0 million in contingent manufacturing milestone payments to a contract manufacturer related to certain construction related matters if such activities are achieved by the contract manufacturer within a pre-specified time frame. These milestones will be capitalized, if achieved, as a deferred cost on our balance sheet until such time that we begin to receive product from the new facility being constructed by our contract manufacturer. As of December 31, 2017, one such milestone in the amount of $5.0 million was achieved. This amount is recorded on our balance sheet as an accrued expense and deferred cost in other long-term assets as of December 31, 2017. As the achievement of the remaining milestones was not considered probable as of December 31, 2017, such contingencies have not been recorded in our consolidated financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain manufacturing milestones.

Legal Proceedings

For a discussion of our legal proceedings as of December 31, 2017, see Note 13 – Commitments and Contingencies, to our consolidated financial statements included in this report.

CRITICAL ACCOUNTING POLICIES

The preparation of our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, requires us to make estimates, judgments and assumptions that affect the reported amount of assets, liabilities, equity revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, judgments and assumptions. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances. These estimates are subject to an inherent degree of uncertainty, and as a result, actual results may differ from these estimates under different assumptions or conditions.

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Revenue Recognition and Related Sales Allowances and Accruals

Our commercial launch of Auryxia occurred in 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 filling patient prescriptions. In accordance with current 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) collectibility is reasonably assured, and (iv) the price is fixed or determinable. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns.

Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers. As a result, prior to the fourth quarter of 2016, we deferred 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 was recorded net of discounts, rebates, and chargebacks.

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 deferred 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 related sales allowances. 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 reserve estimates from our gross product sales related to (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) expected product returns and (d) costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide discounts on Auryxia sales to our Customers in the form of a discount for prompt payment of invoices or a discount directly off the invoice amount. The prompt-pay discount is generally given for payment made within 35 days. Based on our judgment and industry experience, we expect our Customers to earn these discounts. We deduct the full amount of these discounts from our gross product sales and accounts receivable at the time such revenues are recognized. We also pay fees to our Distributors for distribution services which are generally based on a contractual percentage of total purchases made by each Distributor during the period. These fees are also deducted from our gross product sales at the time such revenues are recognized.

Rebates and Chargebacks: We contract with various commercial and Medicare Part D private insurance providers, Medicaid and other government agencies, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We estimate the rebates and chargebacks we will provide to Third-party Payors and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We estimate the rebates and chargebacks that we will provide to Third-Party Payors based upon (i) our contracts with these Third-Party Payors, (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: Consistent with industry practice, we generally offer our Customers a limited right to return our Auryxia based on the product's expiration date. 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. We estimate product returns based on the historical return patterns and we track actual returns by individual manufacturing lots. We expect that Distributors and pharmacies will not stock significant inventory due to the cost of the product, the expense to store the product and the fact that the product is readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available. As of December 31, 2017, we have experienced a

relatively limited number of product returns; however, our returns experience may change over time. As we continue to gain more historical experience with actual returns, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

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Other Incentives: Other incentives that we offer to indirect customers include co-pay assistance rebates provided by us to commercially insured patients who have coverage for Auryxia and who reside in states that permit co-pay assistance programs, and vouchers for a small supply of Auryxia at no patient cost. Our co-pay assistance 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 data obtained from the third parties which administer the program, we estimate the co-pay assistance amounts and the percentage of patients that we expect to participate in the program in order to establish our accruals for co-pay assistance rebates. We deduct these estimated amounts from our gross product sales at the time the revenues are recognized.

We recognize license revenue in accordance with Accounting Standards Codification 605, Revenue Recognition. 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 net 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 collectibility is reasonably assured, we recognize revenue during the applicable period earned. When collectibility 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 grant stock options and restricted stock awards to employees, directors and consultants. We estimate an expected forfeiture rate and only recognize expense for those equity awards that are expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes model has several inputs, including the volatility in the price of our stock, the risk-free interest rate, the expected term of the option, the closing market price of our stock on the grant date and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the fair value calculation, we assume that no dividends will be paid during the life of the stock options. The aggregate fair value of awards calculated using the Black-Scholes option pricing model is generally expensed on a straight line basis over the requisite service period. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment.

The aggregate fair value of restricted stock granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures. This aggregate fair value is generally expensed on a straight line basis over the requisite service period.

The total stock-based compensation recorded in a given period is dependent upon the assumptions utilized. 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 stock options issued to employees, consultants and other third-parties vest upon the achievement of certain performance conditions or milestones, the total expense is uncertain.

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Research and Development Costs

Research and development costs are expensed as incurred. Inventory expenditures prior to regulatory approval of the product candidate or prior to regulatory approval of the contract manufacturing site, if required, are recorded as research and development expense as incurred. The capitalization of inventory for our product candidates commences when management determines that the realization of future economic benefit is probable. 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, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a trial. 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 consolidated financial statements to the actual services received and efforts expended. As such, expenses 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 trial contract.

Inventory

Inventory is stated at the lower of cost or estimated realizable value. We determine the cost of our inventory, which includes 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 in research and development expense. For an approved product that requires additional regulatory approval for a new manufacturing process or at a new contract manufacturing site, we include costs of product purchases from such suppliers in research and development expense until such time that process or contract manufacturing site is approved.

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, if necessary, 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, cash discounts and chargebacks. There was no allowance for doubtful accounts at December 31, 2017 and 2016.

Accounting Related to Goodwill

Goodwill is reviewed for impairment annually, as of December 31, or when events arise that could indicate that an impairment exists. In 2017, we early adopted a new accounting pronouncement related to the testing of goodwill impairment; refer to Note 2 – Basis of Presentation and Summary of Significant Accounting Policies to the consolidated financial statements included in this report. Under the new guidance, we test for goodwill impairment by comparing 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, an impairment charge is recognized for the amount by which the carrying amount exceeds the reporting unit's fair value.

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Accounting for Income Taxes

In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the consolidated statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets.

For the years ended December 31, 2017, 2016 and 2015, we recognized $(0.2) million, $0.1 million and $0.1 million, respectively, in income tax (benefit) 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

For a discussion of new accounting standards, see Note 2 – Basis of Presentation and Summary of Significant Accounting Policies to our consolidated financial statements included in this report.

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

Interest Rate Risk

The primary objective of our investment activities is to preserve capital while maximizing our income from investments and minimizing our market risk. As of December 31, 2017, our portfolio of financial instruments consisted of cash equivalents. 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 provisions that are based on the price of our common stock at conversion or at maturity of the notes. 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, Part 1, are incorporated by reference into this Item 8.

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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, 2017, 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, 2017, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2017. 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, 2017, 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, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity (deficit) and cash flows for each of the years in the three-year period ended December 31, 2017, included in this annual report on page F-2. UHY LLP has issued an attestation report on our internal control over financial reporting as of December 31, 2017, 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, 2017, 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Board of Directors and
Stockholders of Keryx Biopharmaceuticals, Inc.

Opinion on Internal Control over Financial Reporting
We have audited Keryx Biopharmaceuticals, Inc.’s (the "Company") internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2017, based on criteria established in Internal Control—Integrated Framework (2013) issued by COSO.
We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States) (PCAOB), the consolidated balance sheets and the related consolidated statements of operations, stockholders’ equity (deficit), and cash flows of the Company, and our report dated February 21, 2018, expressed an unqualified opinion.
Basis for Opinion
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 the accompanying Annual Report. Our responsibility is to express an opinion on the Company’s internal control over financial reporting based on our audit. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.
We conducted our audit in accordance with the standards of the PCAOB. 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.
Definition and Limitations of Internal Control over Financial Reporting
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.

/s/ UHY LLP
New York, New York
February 21, 2018
ITEM 9B. OTHER INFORMATION.
None.

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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 2018 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 2018 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 2018 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 2018 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 2018 Annual Meeting of Stockholders.

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PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

1. Consolidated Financial Statements
The following 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.

ITEM 16. FORM 10-K SUMMARY.
None.

3. Exhibits
The following is a list of exhibits filed as part of this Annual Report on Form 10-K.

Exhibit Number	Exhibit Description
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated December 17, 2003, and the Amendment thereto, dated June 18, 2004, 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	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 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment 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 (File No. 000-30929), and incorporated herein by reference.

3.4	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated May 25, 2016, filed as Exhibit 3.4 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 5, 2016 (File No. 000-30929), and incorporated herein by reference.
3.5	Certificate of Validation of the filing and effectiveness of the Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated June 13, 2017, filed as Exhibit 3.5 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed on July 27, 2017 (File No. 000-30929), and incorporated herein by reference.

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3.6	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated June 13, 2017, filed as Exhibit 3.6 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2017, filed on July 27, 2017 (File No. 000-30929), and incorporated herein by reference.
3.7	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., adopted on December 13, 2017, filed as Exhibit 3.1 to the Registrant's Current Report on Form 8-K, filed on December 19, 2017 (File No. 000-30929), 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 Registrant's Current Report on Form 8-K, filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.
4.3	First Supplemental Indenture, dated as of April 10, 2017, by and among Keryx Biopharmaceuticals, Inc., The Bank of New York Mellon Trust Company, N.A. and the note holder signatory thereto, to the Indenture, dated as of October 15, 2015, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on April 10, 2017 (File No. 000-30929), and incorporated herein by reference.
10.1†	Keryx Biopharmaceuticals, Inc. 1999 Stock Option Plan, as amended, filed as Exhibit 10.2 to the Registrant's Quarterly Report on 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 (File No. 000-30929), 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 (File No. 000-30929), and incorporated herein by reference.
10.4†	2007 Incentive Plan, filed as Annex D to the Registrant's Definitive Proxy Statement on Schedule 14A filed on April 30, 2007 (File No. 000-30929), and incorporated herein by reference.
10.5†	Keryx Biopharmaceuticals, Inc. Amended and Restated 2013 Incentive Plan, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on May 27, 2016 (File No. 000-30929), and incorporated herein by reference.
10.6†	Keryx Biopharmaceuticals, Inc. Fourth Amended and Restated Directors Equity Compensation Plan, filed as Exhibit 10.2 to the Registrant's Current Report on Form 8-K, filed on May 27, 2016 (File No. 000-30929), 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 (File No. 000-30929), 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 (File No. 000-30929), and incorporated herein by reference.
10.9!	Amended and Restated Sub-License Agreement, dated June 8, 2009, as amended by the First Amendment thereto, dated June 12, 2013, by and between Keryx Biopharmaceuticals, Inc., Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 7, 2017 (File No. 000-30929), and incorporated herein by reference.
10.10!	Master Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Patheon Manufacturing Services LLC and certain of its affiliates dated September 27, 2016, and related Product Agreement dated September 27, 2016, and related Product Agreement dated October 12, 2016, filed as Exhibit 10.12 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017 (File No. 000-30929), and incorporated herein by reference.

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10.11!	Product Agreement, dated August 29, 2017, by and between Keryx Biopharmaceuticals, Inc. and Patheon Inc. (an affiliate of Patheon Manufacturing Services LLC) related to the Master Manufacturing Services Agreement by and between Keryx Biopharmaceuticals, Inc. and Patheon Manufacturing Services LLC and certain of its affiliates dated November 12, 2016, filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, filed on November 7, 2017 (File No. 000-30929), and incorporated herein by reference.
10.12!	Product Manufacture and Supply and Facility Construction Agreement, dated December 11, 2017, by and between Keryx Biopharmaceuticals, Inc. and BioVectra Inc.
10.13!	Master Manufacturing Services and Supply Agreement, dated December 20, 2017, by and between Keryx Biopharmaceuticals, Inc. and Siegfried Evionnaz SA.
10.14†	Employment Agreement with Gregory P. Madison dated March 10, 2015.
10.15†	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 (File No. 000-30929), and incorporated herein by reference.
10.16†	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 (File No. 000-30929), and incorporated herein by reference.
10.17†	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 (File No. 000-30929), and incorporated herein by reference.
10.18†	Second Amendment to Employment Agreement with Brian Adams dated December 15, 2016, filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017 (File No. 000-30929), and incorporated herein by reference.
10.19†	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 (File No. 000-30929), and incorporated herein by reference.
10.20†	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 (File No. 000-30929), and incorporated herein by reference.
10.21†	Second Amendment to Employment Agreement with John F. Neylan, M.D. dated January 6, 2017, filed as Exhibit 10.23 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017 (File No. 000-30929), and incorporated herein by reference.

10.22†	Employment Agreement with Scott Holmes dated June 26, 2015, filed as Exhibit 10.1 to the Registrant's Current Report on Form 8-K, filed on July 27, 2015 (File No. 000-30929), and incorporated herein by reference.
10.23†	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 (File No. 000-30929), and incorporated herein by reference.
10.24†	Second Amendment to Employment Agreement with Scott Holmes dated January 6, 2017, filed as Exhibit 10.22 to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017 (File No. 000-30929), and incorporated herein by reference.
10.25†	Employment Agreement with Christine A. Carberry dated January 6, 2017, filed as Exhibit 10.1 to the Registrant’s Current Report on Form 8-K, filed on January 9, 2017 (File No. 000-30929), and incorporated herein by reference.
10.26†	Form of Indemnification Agreement between Keryx Biopharmaceuticals, Inc. and its directors and officers, filed as Exhibit 10.1 to the Registrant’s Quarterly Report on Form 10-Q for the quarter ended September 30, 2016, filed on November 9, 2016 (File No. 000-30929), 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 Registrant's Current Report on Form 8-K filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.

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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 Registrant's Current Report on Form 8-K, filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.
10.29	Controlled Equity OfferingSM Sales Agreement dated November 9, 2016, by and between Keryx Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co., filed as Exhibit 1.2 to the Registrant's Registration Statement on Form S-3, filed on November 9, 2016 (File No. 333-214513), and incorporated herein by reference.
10.30	One Marina Park Drive Office Lease dated April 29, 2015, by and between Keryx Biopharmaceuticals, Inc. and Fallon Cornerstone One MPD LLC, filed as Exhibit 10.29 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2016, filed on March 1, 2017 (File No. 000-30929), 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 21, 2018.
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 21, 2018.
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 21, 2018.
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 21, 2018.
101	The following financial information from Keryx Biopharmaceuticals, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2017, formatted in XBRL (eXtensible Business Reporting Language): (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders' (Deficit) Equity, (iv) Consolidated Statements of Cash Flows, (v) the Notes to Consolidated Financial Statements.

! Confidential treatment has been granted or is being sought with respect to the omitted portions of this exhibit.

† Indicates management contract or compensatory plan or arrangement.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.
Date: February 21, 2018

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 21, 2018, and in the capacities indicated:

Signatures	Title
/s/ Gregory P. Madison Gregory P. Madison	Chief Executive Officer and Director (principal executive officer)
/s/ Scott A. Holmes Scott A. Holmes	Chief Financial Officer (principal financial and accounting officer)
/s/ Michael Rogers Michael Rogers	Chairman of the Board of Directors
/s/ Kevin J. Cameron Kevin J. Cameron	Director
/s/ Daniel P. Regan Daniel P. Regan	Director
/s/ Steven C. Gilman Steven C. Gilman	Director
/s/ Michael T. Heffernan Michael T. Heffernan	Director
/s/ Jodie Morrison Jodie Morrison	Director

/s/ Mark J. Enyedy Mark J. Enyedy	Director

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Keryx Biopharmaceuticals, Inc.
Consolidated Financial Statements as of December 31, 2017

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM
To the Board of Directors and
Stockholders of Keryx Biopharmaceuticals, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Keryx Biopharmaceuticals, Inc. (the "Company") as of December 31, 2017 and 2016, and the related consolidated statements of operations, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the three-year period ended December 31, 2017, 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) (PCAOB), the Company's internal control over financial reporting as of December 31, 2017, 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 21, 2018, expressed an unqualified opinion.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the PCAOB and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ UHY LLP

We have served as the Company's auditor since 2009.

New York, New York
February 21, 2018

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Keryx Biopharmaceuticals, Inc.
Consolidated Balance Sheets as of December 31,

(in thousands, except share and per share amounts)

	2017	2016
Assets		
Current assets:		
Cash and cash equivalents	$93,526	$111,810
Inventory	28,695	12,681
Accounts receivable, net	8,146	5,236
Other current assets	11,199	3,170
Total current assets	141,566	132,897
Property, plant and equipment, net	4,521	4,211
Goodwill	3,208	3,208
Other assets, net	9,577	1,111
Total assets	$158,872	$141,427
Liabilities and stockholders' (deficit) equity		
Current liabilities:		
Accounts payable and accrued expenses	$45,031	$21,190
Deferred lease incentive, current portion	244	244
Other current liabilities	145	117
Total current liabilities	45,420	21,551
Convertible senior notes	125,000	125,000
Deferred lease incentive, net of current portion	1,018	1,262
Deferred tax liability	635	870
Other liabilities	894	1,040
Total liabilities	172,967	149,723
Commitments and contingencies		
Stockholders' (deficit) 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 (230,000,000 and 180,000,000 shares authorized, 119,272,304 and 105,921,052 shares issued, 119,192,356 and 105,841,104 shares outstanding at December 31, 2017 and 2016, respectively)	119	106
Additional paid-in capital	984,681	827,053
Treasury stock, at cost, 79,948 shares at December 31, 2017 and 2016	(357)	(357)
Accumulated deficit	(998,538)	(835,098)
Total stockholders' deficit	(14,095)	(8,296)
Total liabilities and stockholders' deficit	$158,872	$141,427

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

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Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Operations for the Years Ended December 31,

(in thousands, except share and per share amounts)

	2017	2016	2015
Revenues:			
Net U.S. Auryxia product sales	$55,514	$27,173	$10,141
License revenue	5,127	4,810	3,539
Total revenues	60,641	31,983	13,680
Costs and expenses:			
Cost of goods sold	21,955	37,803	4,520
License expense	3,076	2,886	2,124
Research and development	37,679	29,504	36,694
Selling, general and administrative	99,622	84,553	81,410
Total costs and expenses	162,332	154,746	124,748
Operating loss	(101,691)	(122,763)	(111,068)
Other (expense) income:			
Amortization of debt discount	(62,965)	(34,227)	(11,357)
Other (expense) income, net	981	(4,025)	(630)
Total other expense:	(61,984)	(38,252)	(11,987)
Loss before income taxes	(163,675)	(161,015)	(123,055)
Income tax (benefit) expense	(235)	80	90
Net loss	$(163,440)	$(161,095)	$(123,145)
Basic and diluted net loss per common share	$(1.43)	$(1.52)	$(1.19)
Weighted average shares used in computing basic and diluted net loss per common share	114,507,668	105,845,121	103,898,399

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

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Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Stockholders' (Deficit) Equity
for the Years Ended December 31, 2017, 2016 and 2015
(in thousands, except share amounts)

	Common stock		Additional paid-in	Treasury stock		Accumulated	
	Shares	Amount	capital	Shares	Amount	deficit	Total
Balance at January 1, 2015	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
Issuance of restricted stock	974,325	1	—	—	—	—	1
Forfeiture of restricted stock	(341,603)	— *	—	—	—	—	— *
Issuance of common stock in connection with the exercise of options	66,775	—	198				198
Reclassification of derivative liability to equity	—	—	51,404				51,404
Stock-based compensation	—	—	14,262	—	—	—	14,262
Net loss	—	—	—	—	—	(161,095)	(161,095)
Balance at December 31, 2016	105,921,052	$ 106	$827,053	79,948	$(357)	$(835,098)	$(8,296)
Issuance of restricted stock, net of tax withholdings	1,231,825	1	(303)	—	—	—	(302)
Forfeiture of restricted stock	(142,251)	—	—	—	—	—	— *
Retirement of restricted stock	(59,071)	—	—	—	—	—	—
Issuance of common stock in connection with exercise of options	383,575	— *	1,146	—	—	—	1,146
At-the-market issuance of common stock, net of $1,928 of issuance costs	11,937,174	12	75,607	—	—	—	75,619
Increase in value of conversion feature in connection with modification of convertible notes	—	—	5	—	—	—	5
Reclassification of derivative liability to equity	—	—	62,735	—	—	—	62,735
Stock-based compensation	—	—	18,438	—	—	—	18,438
Net loss	—	—	—	—	—	(163,440)	(163,440)
Balance at December 31, 2017	119,272,304	$ 119	$984,681	79,948	$(357)	$(998,538)	$(14,095)

* Amount less than one thousand dollars.

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

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Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows for the Years Ended December 31,

(in thousands)

	2017	2016	2015
Cash flows from operating activities			
Net loss	$(163,440)	$(161,095)	$(123,145)
Adjustments to reconcile loss to cash flows used in operating activities:			
Stock-based compensation expense	18,272	13,989	16,500
Amortization of debt discount	62,965	34,227	11,357
Change in fair value of derivative liability	(225)	4,718	1,102
Depreciation and amortization	937	1,005	596
Loss on disposal of fixed assets	10	54	507
Write-down of inventory to net realizable value	3,467	27,968	—
Cash received from landlord	—	637	1,276
Amortization of deferred lease incentive	(244)	(244)	(163)
Deferred income taxes	(235)	80	90
Changes in operating assets and liabilities:			
Other current assets	(8,029)	(340)	1,262
Accounts receivable, net	(2,910)	(1,580)	(2,822)
Accrued interest receivable	—	—	47
Inventory	(19,496)	(2,300)	(29,189)
Other current liabilities	28	(238)	—
Security deposits	—	—	(807)
Other assets	(8,466)	(11)	355
Accounts payable and accrued expenses	24,023	88	(8,478)
Deferred revenue	—	(3,526)	3,112
Other liabilities	(146)	(36)	943
Net cash used in operating activities	(93,489)	(86,604)	(127,457)
Cash flows from investing activities			
Purchases of property, plant and equipment	(1,257)	(2,074)	(2,777)
Investment in held-to-maturity short-term securities	—	—	—
Proceeds from maturity of held-to-maturity short-term securities	—	—	11,508
Net cash (used in) provided by investing activities	(1,257)	(2,074)	8,731
Cash flows from financing activities			
Proceeds from issuance of common stock, net of commission	75,720	—	118,284
Proceeds from issuance of convertible senior notes	—	—	125,000
Payments for common stock issuance costs	(102)	—	—
Proceeds from exercise of options	1,146	198	1,463
Payments for repurchase of common stock for employee tax withholding	(302)	—	(15)
Net cash provided by financing activities	76,462	198	244,732
Net (decrease) increase in cash and cash equivalents	(18,284)	(88,480)	126,006
Cash and cash equivalents at beginning of year	111,810	200,290	74,284
Cash and cash equivalents at end of year	$93,526	$111,810	$200,290
Non-cash investing and financing activities			
Reclassification of derivative liability to equity	62,735	51,404	—
Increase of receivable from landlord and deferred lease incentive	—	—	637

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

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Keryx Biopharmaceuticals, Inc.
Notes to the Consolidated Financial Statements

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

NOTE 1 – DESCRIPTION OF BUSINESS

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with kidney disease. Our long-term vision is to build a multi-product kidney care company. Our marketed product, Auryxia (ferric citrate) tablets, is an orally available, absorbable, iron-based medicine. Auryxia is approved by the U.S. Food and Drug Administration, or FDA, for two indications. Auryxia was originally approved in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Additionally, in November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adults with CKD, not on dialysis. With two FDA-approved indications, we will leverage our U.S. clinical and commercial infrastructure to make Auryxia available to millions of people with CKD and either iron deficiency anemia or elevated levels of serum phosphorus, which is referred to as hyperphosphatemia. Ferric citrate is also approved in Japan under the trade name Riona and marketed by our Japanese partner, Japan Tobacco, Inc., or JT, and its subsidiary, Torii Pharmaceutical Co., Ltd., or Torii, and approved in Europe as Fexeric. We use the brand name Auryxia when we refer to ferric citrate for use in the approved indications in the United States. We refer to the product as ferric citrate when referring to its investigational use. Our vision of building a multi-product kidney care company includes expansion of our product portfolio with other medicines that can help patients with kidney disease.

OUR STRATEGY

Our business is focused on creating long-term stockholder value by bringing differentiated medicines to the market for the treatment of people with kidney disease that provide meaningful benefits to patients and their healthcare providers. The three pathways to our strategy are:

Maximize Auryxia's Potential

Auryxia is approved for two indications in the United States. We developed and subsequently launched Auryxia in the United States in late December 2014 following the FDA's approval of Auryxia for the control of serum phosphorus levels in adult patients with CKD on dialysis. In November 2017, the FDA approved Auryxia for the treatment of iron deficiency anemia in adult patients with CKD, not on dialysis. Auryxia is a non-calcium, non-chewable, orally-administered phosphate binder. Auryxia is the first FDA-approved oral iron medication that was specifically developed to treat iron deficiency anemia in CKD patients, not on dialysis. In the United States, there are approximately 450,000 adult patients with CKD requiring dialysis (referred to as End Stage Renal Disease, or ESRD), including approximately 350,000 adults currently taking a phosphate binder. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist for CKD have iron deficiency anemia, not on dialysis, including approximately 650,000 adults currently being treated by nephrologists for iron deficiency anemia. Iron deficiency anemia is common in the non-dialysis population and the prevalence and severity increases as CKD advances. Iron deficiency anemia is symptomatic and can significantly impact quality of life. Auryxia is being marketed in the United States to nephrologists and renal care teams through our specialty salesforce and commercial infrastructure. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. These target nephrologists treat CKD patients on dialysis and those not on dialysis. We believe strong fundamentals are in place to drive commercial adoption of Auryxia in the dialysis setting and maximize the potential of Auryxia as a treatment of iron deficiency anemia in adults with CKD, not on dialysis.

Expand Our Portfolio

We will evaluate opportunities to expand our product portfolio with other medicines that can help patients with kidney disease. Our business development activities include evaluating clinical-stage drug candidates, as well as commercially available medicines to in-license or acquire to add to our portfolio and provide us with new commercial opportunities. We will seek to add assets that leverage the infrastructure we have built to support our foundational medicine, Auryxia, including our clinical development and commercial teams. We believe these efforts have the

potential to provide additional revenues to us in the future.

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Manage Growth and Talent

We are committed to creating a culture of success and continue to engage a workforce of high-quality and talented people to support our potential growth.

NOTE 2 – BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

RECENTLY ISSUED ACCOUNTING STANDARDS

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or FASB, or other standard setting bodies that we adopt as of the specified effective date. Unless otherwise discussed, we do not believe that the impact of recently issued standards that are not yet effective will have a material impact on our financial position or results of operations upon adoption.

In May 2014, the FASB issued Accounting Standards Update, or ASU, No. 2014-09, Revenue from Contracts with Customers (Topic 606), 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 FASB issued several amendments to ASU No. 2014-09 which have the same effective date and transition date. These standards became effective for us on January 1, 2018 and will be adopted using the modified retrospective method. As of the date of this report, we have finalized our assessments over the impact that these new standards will have on our consolidated results of operations, financial position and disclosures, and have not identified any accounting changes that would materially impact the amount of reported revenues with respect to our product revenues. As of January 1, 2018, we expect to recognize an immaterial adjustment to retained earnings reflecting the cumulative impact for the accounting changes made upon adoption of these new standards.

In July 2015, the FASB issued ASU No. 2015-11, Simplifying the Measurement of Inventory. Under this standard, the measurement principle for inventory changed 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 became effective for us on January 1, 2017. The adoption of this standard did not have a material impact on our consolidated financial statements.

In February 2016, the FASB issued ASU No. 2016-02, Leases. The new standard requires that all lessees recognize the assets and liabilities that arise from leases on the balance sheet and disclose qualitative and quantitative information about its leasing arrangements. The new standard will be effective for us on January 1, 2019 and must be applied using a modified retrospective transition approach which requires application of the new guidance for all periods presented. The adoption of this standard is expected to have a material impact on our financial position as it will increase the amount of our assets and liabilities. We do not expect this standard to have a material impact on our consolidated statement of operations.

In March 2016, the FASB issued ASU No. 2016-09, Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. This standard became effective for us on January 1, 2017. The adoptions of this standard did not have a material impact on our financial position, results of operations or statement of cash flows.

In August 2016, the FASB issued ASU No. 2016-15, Statement of Cash Flows (Topic 230): Classification of Certain Cash Receipts and Cash Payments. The new standard addresses eight specific cash flow issues with the objective of reducing the existing diversity in practice in how certain cash receipts and cash payments are presented and classified in the statement of cash flows. The new standard became effective for us on January 1, 2018. This standard is not expected to have a material impact on our statement of cash flows upon adoption.

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.

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USE OF ESTIMATES

The preparation of our consolidated financial statements, which have been prepared in accordance with U.S. generally accepted accounting principles, or GAAP, requires us to make estimates, judgments and assumptions that affect the reported amount of assets, liabilities, equity revenue and expenses and related disclosure of contingent assets and liabilities. On an ongoing basis, we evaluate our estimates, judgments and assumptions. We base our estimates on historical experience, known trends and events and various other factors that we believe to be reasonable under the circumstances. These estimates are subject to an inherent degree of uncertainty, and as a result, actual results may differ from these estimates under different assumptions or conditions.

CASH AND CASH EQUIVALENTS

We consider liquid investments with original maturities of three months or less at the time of purchase to be cash and cash equivalents. At December 31, 2017, all of our cash and cash equivalents were held in commercial bank accounts.

INVENTORY

Inventory is stated at the lower of cost or estimated realizable value. We determine the cost of our inventory, which includes 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 in research and development expense. For an approved product that requires additional regulatory approval for a new manufacturing process or at a new contract manufacturing site, we include costs of product purchases from such suppliers in research and development expense until such time that process or contract manufacturing site is approved.

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, if necessary, 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, cash discounts and chargebacks. There was no allowance for doubtful accounts at December 31, 2017 and 2016.

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 depreciated over the shorter of their useful life or the remaining term of the lease exclusive of renewal options.

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REVENUE RECOGNITION

Our commercial launch of Auryxia occurred in 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 filling patient prescriptions. In accordance with current 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) collectibility is reasonably assured, and (iv) the price is fixed or determinable. In the fourth quarter of 2016, we began to recognize revenue under the pull-through (ex-factory) method based on sales to our Customers as a result of our ability to reasonably estimate product returns.

Prior to the fourth quarter of 2016, we recognized revenue based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers as we did not have sufficient history such that we could reliably estimate returns based on sales to our Customers. As a result, prior to the fourth quarter of 2016, we deferred 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 was recorded net of discounts, rebates, and chargebacks.

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 deferred 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 related sales allowances. 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 reserve estimates from our gross product sales related to (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) expected product returns and (d) costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide discounts on Auryxia sales to our Customers in the form of a discount for prompt payment of invoices or a discount directly off the invoice amount. The prompt-pay discount is generally given for payment made within 35 days. Based on our judgment and industry experience, we expect our Customers to earn these discounts. We deduct the full amount of these discounts from our gross product sales and accounts receivable at the time such revenues are recognized. We also pay fees to our Distributors for distribution services which are generally based on a contractual percentage of total purchases made by each Distributor during the period. These fees are also deducted from our gross product sales at the time such revenues are recognized.

Rebates and Chargebacks: We contract with various commercial and Medicare Part D private insurance providers, Medicaid and other government agencies, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We estimate the rebates and chargebacks we will provide to Third-party Payors and deduct these estimated amounts from our gross product sales at the time the revenues are recognized. We estimate the rebates and chargebacks that we will provide to Third-Party Payors based upon (i) our contracts with these Third-Party Payors, (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: Consistent with industry practice, we generally offer our Customers a limited right to return our Auryxia based on the product’s expiration date. 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. We estimate product returns based on the historical return patterns and we track actual returns by individual manufacturing lots. We expect that Distributors and pharmacies will not stock significant inventory due to the cost of the product, the expense to store the product and the fact that the product is readily available for distribution. We record an estimate of returns at the time of sale. If necessary, our estimated rate of returns may be adjusted for actual return experience as it becomes available. As of December 31, 2017, we have experienced a

relatively limited number of product returns; however, our returns experience may change over time. As we continue to gain more historical experience with actual returns, we may be required to make a future adjustment to our product returns estimate, which would result in a corresponding change to our net product sales in the period of adjustment and could be significant.

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Other Incentives: Other incentives that we offer to indirect customers include co-pay assistance rebates provided by us to commercially insured patients who have coverage for Auryxia and who reside in states that permit co-pay assistance programs, and vouchers for a small supply of Auryxia at no patient cost. Our co-pay assistance 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 data obtained from the third parties which administer the program, we estimate the co-pay assistance amounts and the percentage of patients that we expect to participate in the program in order to establish our accruals for co-pay assistance rebates. We deduct these estimated amounts from our gross product sales at the time the revenues are recognized.

Classification of product sales allowances and accruals

Allowances against receivable balances primarily relate to prompt-pay discounts, chargebacks and product returns and are recorded at the time of sale, resulting in a reduction in product sales revenue and the recording of product sales receivables net of allowances. Accruals related to Medicaid, Medicare Part D and other government and commercial rebates, as well as wholesaler fees, are recorded at the time of sale, resulting in a reduction in product sales and the recording of an increase in accrued expenses.

Our U.S. Auryxia product sales for the years ended December 31, 2017, 2016 and 2015 were offset by provisions for allowances and accruals as set forth in the tables below.

(in thousands)	2017	Percent of gross Auryxia product sales	2016	Percent of gross Auryxia product sales	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$111,845		$44,557		$16,295	
Less provision for product sales allowances and accruals						
Trade allowances	13,093	12%	5,157	12%	1,897	12%
Rebates and chargebacks	40,482	36%	10,703	24%	2,418	15%
Product returns	1,362	1%	879	2%	—	—%
Other incentives [(1)]	1,394	1%	645	1%	1,839	11%
Total	56,331	50%	17,384	39%	6,154	38%
Net U.S. Auryxia product sales	$55,514		$27,173		$10,141	

[(1)] Includes co-pay assistance and voucher rebates.

We recognize license revenue in accordance with Accounting Standards Codification 605, Revenue Recognition. 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 net 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 collectibility is reasonably assured, we recognize revenue during the applicable period earned. When collectibility 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.

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The following table sets forth customers or partners who represented 10% or more of our total revenues for 2017, 2016 and 2015:

	December 31, 2017		December 31, 2016		December 31, 2015	
Fresenius Medical Care Rx	29	%	22	%	15	%
McKesson Corporation	19	%	31	%	23	%
DaVita Rx	18	%	10	%	19	%
Cardinal Health, Inc.	15	%	11	%	24	%
AmerisourceBergen Drug Corporation	15	%	23	%	17	%

COST OF GOODS SOLD

Cost of goods sold includes the cost of active pharmaceutical ingredient, or 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, as well as any idle capacity charges we may incur at our contract manufacturers and write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture. Cost of goods sold also includes royalties due to the licensor of Auryxia related to the U.S. product sales recognized during the period, as well as a manufacturing fee related to API manufactured by us in the licensed territory through September 2017.

LICENSE EXPENSE

License expense include royalty and other expenses due to the licensor of Auryxia related to our sublicense agreement with JT and Torii. Royalty expenses are directly related to the net sales recognized by JT and Torii during the period and is recognized in the same period as the license 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. Inventory expenditures prior to regulatory approval of the product candidate or prior to regulatory approval of the contract manufacturing site, if required, are recorded as research and development expense as incurred. The capitalization of inventory for our product candidates commences when management determines that the realization of future economic benefit is probable. 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, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a trial. 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 consolidated financial statements to the actual services received and efforts expended. As such, expenses 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 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.

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We, and our subsidiaries, file income tax returns in the United States 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 grant stock options and restricted stock awards to employees, directors and consultants. We estimate an expected forfeiture rate and only recognize expense for those equity awards that are expected to vest. Forfeitures are estimated based on historical experience at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The fair value of each stock option award is estimated on the date of grant using the Black-Scholes option pricing model. The Black-Scholes model has several inputs, including the volatility in the price of our stock, the risk-free interest rate, the expected term of the option, the closing market price of our stock on the grant date and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock; however, these estimates are neither predictive nor indicative of the future performance of our stock. For purposes of the fair value calculation, we assume that no dividends will be paid during the life of the stock options. The aggregate fair value of awards calculated using the Black-Scholes option pricing model is generally expensed on a straight line basis over the requisite service period. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment.

The aggregate fair value of restricted stock granted to our employees and directors is determined based upon the quoted closing market price per share on the date of grant, adjusted for estimated forfeitures. This aggregate fair value is generally expensed on a straight line basis over the requisite service period.

The total stock-based compensation recorded in a given period is dependent upon the assumptions utilized. 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 stock options issued to employees, consultants and other third-parties vest upon the achievement of certain performance conditions or milestones, the total expense is uncertain.

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, as their inclusion would be anti-dilutive. The options outstanding as of December 31, 2017, 2016 and 2015, which are not included in the computation of net loss per share amounts, were 11,967,815, 8,677,998 and 5,411,557, respectively.

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.

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In 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. 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, 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.

Goodwill is reviewed for impairment annually, as of December 31, or when events arise that could indicate that an impairment exists. We test for goodwill impairment by comparing 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, an impairment charge is recognized for the amount by which the carrying amount exceeds the reporting unit's fair value. As of December 31, 2017, 2016 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 with multiple financial institutions. See Note 3 – Fair Value Measurements.

Our accounts receivable, net at December 31, 2017 and 2016 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, 2017 and 2016:

	December 31, 2017		December 31, 2016	
Fresenius Medical Care Rx	43	%	22	%
Cardinal Health, Inc.	32	%	11	%
AmerisourceBergen Drug Corporation	26	%	23	%
McKesson Corporation	21	%	31	%
DaVita Rx	—	%	10	%

NOTE 3 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in our statements using a fair value hierarchy. 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 (unadjusted) 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.

The following table provides the fair value measurements made on a recurring basis of applicable financial assets as of December 31, 2017 and 2016:

	Financial assets at fair value as of December 31, 2017		
(in thousands)	Level 1	Level 2	Level 3
Assets:			
Cash equivalents [1]	$ 1,895	$ —	$ —
Total assets	$ 1,895	$ —	$ —

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	Financial assets at fair value as of December 31, 2016		
(in thousands)	Level 1	Level 2	Level 3
Assets:			
Cash equivalents [1]	$107,084	$—	—
Total assets	$107,084	$—	—

[1] Cash equivalents as of December 31, 2017 and 2016 consisted of institutional money market funds. The carrying value of our money market funds approximates fair value due to their short-term maturities.

Debt

In October 2015, we issued $125 million in Convertible Senior Notes due 2020, or the Notes, in a private financing to funds managed by The Baupost Group, L.L.C., or Baupost. As of December 31, 2017 and 2016 the fair value of our Notes was $155.4 million and $195.9 million, respectively, which differs from their carrying value. The fair value of our Notes is influenced by our stock price and stock price volatility. See Note 8 – Debt for additional information on our debt obligations.

NOTE 4 – INVENTORY

Inventory consisted of the following at December 31, 2017 and 2016:

(in thousands)	December 31, 2017	December 31, 2016
Raw materials	$ 469	$ 418
Work in process	25,160	11,430
Finished goods	3,066	833
Total inventory	$ 28,695	$ 12,681

During the years ended December 31, 2017 and 2016, we wrote off approximately $3.5 million and $28.0 million, respectively, of inventory that was determined to be no longer suitable for commercial manufacture, which was recorded to cost of goods sold. We did not have any write-offs of inventory during the year ended December 31, 2015. Total inventory as of December 31, 2017 increased by $16.0 million as compared to December 31, 2016 primarily as a result of inventory build-up in connection with capacity expansion initiatives, partially offset by inventory sold to customers.

NOTE 5 – PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2017	December 31, 2016
Leasehold improvements	$ 4,353	$ 3,916
Office furniture and equipment	1,544	747
Computers, software and related equipment	779	787
	6,676	5,450
Accumulated depreciation	(2,155)	(1,239)
Net book value	$ 4,521	$ 4,211

Depreciation expense for the years ended December 31, 2017, 2016 and 2015 was $0.9 million, $1.0 million and $0.6 million, respectively.

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NOTE 6 – OTHER ASSETS

Other current assets

Other current assets consisted of the following at December 31, 2017 and 2016:

(in thousands)	December 31, 2017	December 31, 2016
Prepaid manufacturing costs	$ 7,646	$ 289
Prepaid selling, general and administrative expenses	2,265	1,528
Prepaid research and development expenses	1,288	1,353
Total other current assets	$ 11,199	$ 3,170

Prepaid manufacturing costs as of December 31, 2017 primarily relate to upfront payments to our contract manufacturers related to 2018 production of inventory.

Other assets, net

Other assets, net consisted of the following at December 31, 2017 and 2016:

(in thousands)	December 31, 2017	December 31, 2016
Deferred manufacturing costs	$ 7,338	$ —
Deposits	1,099	1,055
Long-term prepaid manufacturing costs	1,000	—
Deferred registration fees	140	56
Total other long-term assets	$ 9,577	$ 1,111

Deferred costs as of December 31, 2017 consisted of amounts paid or payable under contract manufacturing agreements, including a $5.0 million milestone related to a facility construction agreement and $2.3 million in product premiums payable by us to our contract manufacturer. We capitalize certain expenses as deferred costs related to agreements with a contract manufacturer in connection with the construction of an expanded manufacturing facility. These costs will be capitalized as incurred and will begin to be expensed at such time that we begin to receive product from the newly-constructed facility. These costs will be expensed ratably over the supply period based on anticipated product to be received from the new facility. At December 31, 2017, the amounts included in deferred costs were also recorded as an accrued expense on our consolidated balance sheet as they had not been paid prior to year-end.

NOTE 7 – ACCOUNTS PAYABLE AND ACCRUED EXPENSES

Accounts payable and accrued expenses consisted of the following at December 31, 2017 and 2016:

(in thousands)	December 31, 2017	December 31, 2016
Commercial rebates and fees	$ 16,362	$ 4,616
Accrued manufacturing expenses	9,434	804
Accrued compensation and related liabilities	7,504	8,190
Accounts payable	6,474	2,225
Professional, license, and other fees and expenses	5,257	5,355
Total accounts payable and accrued expenses	$ 45,031	$ 21,190

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NOTE 8 – DEBT

In October 2015, we completed the sale of $125 million of Notes due 2020, in a private placement, or the Private Placement, to funds managed by Baupost pursuant to a Notes Purchase Agreement dated October 14, 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, or the Trustee. Under the terms of the Indenture, the Notes may be converted into shares of our common stock at the discretion of Baupost. 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 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.

Per the terms of the Notes, a portion of the Notes was contingently convertible into cash if our stockholders did not approve an increase in the number of authorized shares of our common stock by July 1, 2016. In accordance with accounting guidance for debt with a conversion option, we separated the conversion option from the debt instrument and accounted for it separately as a derivative liability, due to the Notes initially 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 initial carrying amount of the convertible notes represented 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") was amortized to interest expense using the effective interest method over the expected life of the debt.

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 was initially contingently convertible into cash. Accordingly, for the year ended December 31, 2016, $34.2 million of interest expense was recognized related to the Notes, all of which was attributable to the amortization of the debt discount.

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Following our 2016 Annual Meeting of Stockholders held on May 25, 2016, we filed a certificate of amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to increase the number of authorized shares of our common stock to allow for the full conversion of the Notes into our common stock. On April 10, 2017, we entered into the First Supplemental Indenture, or the First Supplement, to the Indenture. Under the terms of the First Supplement, the Notes issued under the Indenture were not convertible by the holders thereof until on or after June 8, 2017, except in connection with a "fundamental change" as defined in the Indenture. After June 8, 2017, the Notes are convertible entirely into shares of our common stock or cash depending upon the number of shares of our common stock authorized at the time of such conversion. At our 2017 Annual Meeting of Stockholders held on June 8, 2017, our stockholders ratified the filing and effectiveness of the certificate of amendment filed in May 2016. In addition, at the meeting our stockholders also approved a separate amendment to our certificate of incorporation to increase the number of authorized shares of our common stock to 230,000,000 shares. As a result, the full amount of the Notes is convertible into shares of our common stock. The holders of the Notes may, at their option, convert the Notes until the maturity date thereof.

In accordance with accounting guidance for debt modifications and exchanges, we assessed the terms of the First Supplement and determined that it resulted in a modification. During the three months ended June 30, 2017, we separated the conversion option from the debt instrument and accounted for it separately as a derivative liability, due to the Notes being contingently convertible to cash at the option of Baupost per the terms of the First Supplement. 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 date of the First Supplement, 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 senior notes represented the difference between the principal amount of the Notes and the fair value of the derivative liability on the date of the First Supplement. The excess of the principal amount of the debt component over its carrying amount, or debt discount, was amortized to interest expense using the effective interest method over the expected life of the debt. We determined the expected life of the debt was equal to the period through June 8, 2017, as this represented the point at which the Notes was contingently convertible into cash.

For the year ended December 31, 2017, $63.0 million of interest expense was recognized related to the Notes. As of December 31, 2017 and 2016, the balance of the Notes and the carrying value of the Notes was $125 million, and the fair value of the Notes was $155.4 million and $195.9 million, respectively.

NOTE 9 – STOCKHOLDERS' (DEFICIT) 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 SEC.

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, 2017, 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,

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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, 2017, 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, 2017, up to an additional 45,754 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, and at our 2016 Annual Meeting of Stockholders held on May 25, 2016, which increased the number of authorized shares issuable thereunder from 9,500,000 to 18,000,000. 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, 2017, up to an additional 1,980,669 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 2,026,423 shares at December 31, 2017.

Stock Options

The following table summarizes stock option activity for all plans for the year ended December 31, 2017:

	Number of shares	Weighted-average exercise price	Weighted-average remaining contractual term	Aggregate Intrinsic Value
Outstanding at December 31, 2016	8,677,998	$ 7.28	8.12	$8,840,412
Granted	4,669,150	5.46		
Exercised	(383,575)	2.99		$1,767,281
Forfeited or Expired	(995,758)	7.04		
Outstanding at December 31, 2017	11,967,815	$ 6.73	8.00	$2,395,566
Vested and expected to vest at December 31, 2017	7,963,262	$ 7.42	7.61	$2,303,825
Exercisable at December 31, 2017	4,816,619	$ 8.61	6.80	$1,678,842

The weighted-average grant-date fair value of stock options granted during 2017, 2016 and 2015 was $3.91, $3.47, and $8.47, respectively. The aggregate intrinsic value of options exercised during 2017, 2016 and 2015, measured as of the exercise date, was approximately $1.8 million, $0.2 million, and $8.6 million, respectively.

Upon the exercise of stock options, we issue new shares of our common stock. As of December 31, 2017, 3,753,750 options issued to employees are unvested, milestone-based options.

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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 stock activity for the year ended December 31, 2017:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2016	1,524,884	$ 7.07	$8,935,820
Granted	1,231,825	5.71	
Vested	(671,090)	6.49	$4,157,589
Forfeited or Retired	(201,322)	7.04	
Outstanding at December 31, 2017	1,884,297	$ 6.39	$8,761,981

The weighted-average grant-date fair value of restricted stock granted during 2017, 2016 and 2015 was $5.71, $3.86, and $4.76, respectively. The total fair value of restricted stock that vested during 2017, 2016 and 2015 was $4.2 million, $2.4 million and $4.7 million, respectively.

As of December 31, 2017, 310,000 shares of restricted stock issued to employees are unvested, milestone-based shares.

Stock-Based Compensation

The following tables summarize stock-based compensation expense information about equity incentive grants for the years ended December 31, 2017, 2016 and 2015:

	For the years ended December 31,		
(in thousands)	2017	2016	2015
Cost of goods sold	$167	$125	$14
Research and development expenses	2,466	2,687	3,519
Selling, general and administrative expenses	15,639	11,177	12,967
	$18,272	$13,989	$16,500

	For the years ended December 31,		
(in thousands)	2017	2016	2015
Stock-based compensation expense associated with restricted stock	$ 5,738	$ 4,159	$ 5,073
Stock-based compensation expense associated with stock options	12,534	9,830	11,427
	$ 18,272	$ 13,989	$ 16,500

Stock-based compensation costs capitalized as part of inventory were immaterial for the years ended December 31, 2017, 2016 and 2015.

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.

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Black-Scholes Option Valuation Assumptions	2017		2016		2015	
Risk-free interest rates	2.1	%	1.5	%	1.7	%
Dividend yield	—	%	—	%	—	%
Volatility	84.1	%	81.4	%	89.2	%
Weighted-average expected term	6.0 years		6.0 years		6.0 years	

We used historical information to estimate forfeitures within the valuation model. As of December 31, 2017, there was $9.0 million and $5.5 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 1.6 years, respectively. These amounts do not include, as of December 31, 2017, 3,753,750 options outstanding and 310,000 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. During the year ended December 31, 2017, we recognized $4.6 million of stock-based compensation expense related to milestone-based awards which vested in connection with certain corporate milestones.

Sales Agreement

On November 9, 2016, we entered into a Controlled Equity Offering[SM] Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we were initially able to offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an aggregate offering price of up to $75.0 million.

We are not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of the Nasdaq Capital Market to sell shares from time to time based upon our instructions, including any price, time or size limits specified by us. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an “at the market offering” as defined in Rule 415(a)(4) under the Securities Act. Cantor Fitzgerald’s obligations to sell shares under the Sales Agreement are subject to satisfaction of certain conditions. We will pay Cantor Fitzgerald a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares and have agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. We have also agreed to reimburse Cantor Fitzgerald for the reasonable and documented fees and expenses of its outside legal counsel, not to exceed $50,000 in the aggregate, in connection with entering into the Sales Agreement.

We filed a registration statement on Form S-3 (No. 333-214513) which was declared effective by the SEC on December 6, 2016, which included a prospectus covering the sale of the $75.0 million shares which could be sold by Cantor Fitzgerald under the Sales Agreement. In July 2017, we filed a new prospectus supplement with the SEC relating to the Sales Agreement under which we may offer and sell, from time to time, through Cantor Fitzgerald, shares of our common stock having an additional aggregate offering price of up to $75.0 million. During the year ended December 31, 2017, we sold 11,937,174 shares under the Sales Agreement for aggregate net proceeds of $75.7 million, which included all of the initial $75.0 million shares issuable pursuant to the Sales Agreement. As of the date hereof, we may sell up to an additional $72.4 million under the Sales Agreement pursuant to the July 2017 prospectus supplement. The initial $75.0 million of common stock issued pursuant to the Sales Agreement and the additional $75.0 million of common stock issuable pursuant to the Sales Agreement are included as part of the $250 million of our securities we registered on the registration statement on Form S-3 (No. 333-214513) we filed in November 2016, which the SEC declared effective on December 6, 2016.

The offering of shares of our common stock pursuant to the Sales Agreement will terminate upon the termination of the Sales Agreement as permitted therein. We and Cantor Fitzgerald may each terminate the Sales Agreement at any time upon ten days’ prior notice.

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NOTE 10 – 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 ferric citrate. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion, including $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 ferric citrate.

In September 2007, we entered into a Sublicense Agreement with JT and Torii, 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 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 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.

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, 2017 and 2016, we recorded $5.1 million and $4.8 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii is recorded. For the years ended December 31, 2017 and 2016, we recorded $3.1 million and $2.9 million, respectively, in license expense related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

NOTE 11 – INCOME TAXES

In December 2017, H.R.1, known as the Tax Cuts and Jobs Act, was signed into law. The Tax Cuts and Jobs Act, among other items, reduces the corporate income tax rate from 35% to 21%, effective January 1, 2018. As such, the Company has completed a revaluation of the Company's net deferred tax assets. The Company's deferred tax assets, net of deferred tax liabilities, represent expected corporate tax benefits anticipated to be realized in the future. The reduction in the federal corporate tax rate reduces these benefits.

The Company has evaluated the impact of the Tax Cuts and Jobs Act and has determined that this results in a reduction in the Company's deferred tax asset of $111.7 million in the fourth quarter of 2017. However, our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the utilization of the deferred tax assets is offset in full by a valuation allowance.

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 $216.0 million and $289.7 million as of December 31, 2017 and 2016, respectively, a decrease of $73.7 million.

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As of December 31, 2017, we have U.S. net operating loss ("NOL") carryforwards of approximately $812.2 million. For income tax purposes, these NOLs will expire in the years 2019 through 2037. 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.

For the years ended December 31, 2017, 2016 and 2015, we recognized $(0.2) million, $0.1 million and $0.1 million, respectively, in income tax (benefit) 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. However, with the reduction of the corporate income tax rate from 35% to 21%, effective January 1, 2018, the deferred tax liability associated with capitalized goodwill was reduced by $0.3 million generating current year income of $0.3 million.

The income tax provision consists of the following:

(in thousands)	December 31, 2017	December 31, 2016	December 31, 2015
Current:			
Federal	$ —	$ —	$ —
State	—	—	—
Total current	—	—	—
Deferred:			
Federal	(258)	73	81
State	23	7	9
Total deferred	(235)	80	90
Total income taxes	$ (235)	$ 80	$ 90

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

	For the years ended December 31,		
(in thousands)	2017	2016	2015
Loss before income taxes, as reported in the consolidated statements of operations	$(163,675)	$(161,015)	$(123,055)
Computed "expected" tax benefit	(55,650)	(54,745)	(41,838)
Increase (decrease) in income taxes resulting from:			
Expected (benefit) expense from state & local taxes	(5,307)	(5,222)	(3,991)
Stock-based compensation expense	(360)	(17)	(2,328)
Tax impact of derivative liability	23,450	—	16,977
Permanent differences	(305)	3,087	1,445
Impact of state NOL carryforward change	111,681	—	—
Prior year true-up	(2)	(58)	2,191
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	(73,742)	57,035	27,634
	$(235)	$80	$90

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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)	2017	2016	2015
Deferred tax expense (benefit)	$50,057	$(56,955)	$(44,521)
Tax impact of derivative liability	23,450	—	16,977
Increase in the valuation allowance for deferred tax asset	(73,742)	57,035	27,634
	$(235)	$80	$90

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2017 and 2016 are presented below.

(in thousands)	December 31, 2017	December 31, 2016
Deferred tax assets (liabilities):		
Net operating loss carryforwards	$ 193,310	$ 255,809
Stock-based compensation expense	14,315	16,735
Capitalized inventory	24	2,044
Inventory reserves	3,829	9,288
Research and development	2,242	2,087
Intangible assets due to different amortization methods	1,546	2,495
Tax-deductible goodwill	(635)	(870)
Other temporary differences	691	1,241
Net deferred tax asset, excluding valuation allowance	215,322	288,829
Less valuation allowance	(215,957)	(289,699)
Net deferred tax liabilities	$ (635)	$ (870)

We file income tax returns in the U.S federal and various state and local jurisdictions. For federal and state income tax purposes, the 2016, 2015 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 2017, 2016 and 2015. 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 12 – OTHER (EXPENSE) INCOME

The components of other (expense) income are as follows:

	For the years ended December 31,		
(in thousands)	2017	2016	2015
Interest income	$707	$698	$472
Amortization of debt discount	(62,965)	(34,227)	(11,357)
Other income (expense), net	274	(4,723)	(1,102)
	$(61,984)	$(38,252)	$(11,987)

NOTE 13 – COMMITMENTS AND CONTINGENCIES

Our contractual obligations include commitments and estimated purchase obligations entered into in the normal course of business. These include commitments related to our facility lease, purchases of inventory and other purchases related to our product, debt obligations, consulting services and subscription fees, among others.

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Facility Leases

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. In order to make the space usable for our operations, substantial improvements were made. Our landlord agreed to pay for up to approximately $1.9 million of the improvements, and we bore all additional costs that were 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, Operating Leases, 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, and the receivable was drawn down as cash was received from our landlord. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be depreciated over the assets' useful lives or the remaining lease term, whichever is shorter.

Future minimum payments under our non-cancelable facility lease as of December 31, 2017 are as follows (in thousands):

Period	Future Minimum Lease Payments
Year Ending December 31, 2018	$ 1,628
Year Ending December 31, 2019	1,655
Year Ending December 31, 2020	1,683
Year Ending December 31, 2021	1,710
Year Ending December 31, 2022	1,737
Thereafter	291
Total	$ 8,704

Total rental expense was approximately $1.2 million, $1.9 million and $2.2 million for the years ended December 31, 2017, 2016, and 2015, respectively.

Contingent Milestone Payments

We may be required to pay up to $10.0 million in contingent manufacturing milestone payments to a contract manufacturer related to certain construction related matters if such activities are achieved by the contract manufacturer within a pre-specified time frame. These milestones will be capitalized, if achieved, as a deferred cost on our balance sheet until such time that we begin to receive product from the new facility being constructed by our contract manufacturer. As of December 31, 2017, one such milestone in the amount of $5.0 million was achieved. This amount is recorded on our balance sheet as an accrued expense and a deferred cost in other assets, net as of December 31, 2017. As the achievement of the remaining milestones was not considered probable as of December 31, 2017, such contingencies have not been recorded in our consolidated financial statements. Amounts related to contingent milestone payments are not considered contractual obligations as they are contingent on the successful achievement of certain manufacturing milestones.

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Litigation

Four purported class action lawsuits have been filed against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur, and James Oliviero). Three of these actions were filed in the U.S. District Court for the Southern District of New York, captioned respectively Terrell Jackson v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06131, filed on August 2, 2016, Richard J. Erickson v. Keryx Biopharmaceuticals, Inc., et al. No. 1:16-cv-06218, filed on August 4, 2016, and Richard King v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06233, filed on August 5, 2016. The Jackson complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and August 1, 2016, the Erickson complaint purports to be brought on behalf of stockholders who purchased our common stock between March 2, 2016 and July 29, 2016, and the King complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and July 29, 2016. On August 26, 2016, the fourth complaint, captioned Tim Karth v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-11745, was filed in the U.S. District Court for the District of Massachusetts, which complaint was subsequently amended. The Karth complaint purports to be brought on behalf of stockholders who purchased our common stock between May 8, 2013 and August 1, 2016. The Jackson, Erickson and King matters were transferred to the U.S. District Court for the District of Massachusetts on April 5, 2017 and subsequently consolidated with the Karth action. Each complaint generally alleges that we and certain of our current and former officers violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning us and our business operations and future prospects in light of the August 1, 2016 announcement of an interruption in our supply of Auryxia. We have moved to dismiss the consolidated action. Two stockholder derivative complaints were also filed on December 16, 2016 against us and certain of our current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and James Oliviero), certain of our current directors (Kevin J. Cameron, Daniel P. Regan, Steven C. Gilman, Michael Rogers and John P. Butler) and our former directors (Michael P. Tarnok, Joseph Feczko, Jack Kaye and Wyche Fowler, Jr.), in the Superior Court of Massachusetts, one captioned Venkat Vara Prasad Malledi v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3865 and one captioned James Anderson v. Keryx Biopharmaceuticals, Inc., et al., No. 16-3866. Each of these two complaints generally allege that the individual defendants breached their fiduciary duties owed to us, unjustly enriched themselves by their actions, abused their control positions with us, mismanaged us and wasted corporate assets since July 31, 2013 in light of our August 1, 2016 announcement by us of an interruption in the supply of our product Auryxia. On June 27, 2017, the Superior Court granted the parties' motion to consolidate and stay the derivative litigations. All of the complaints seek unspecified damages, interest, attorneys’ fees, and other costs. We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits. There is no assurance, however, that we or the other defendants will be successful in our defense of either of these lawsuits or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits adverse to us or the other defendants, however, could have a material effect on our financial position and results of operations in the period in which the particular lawsuit is resolved.

NOTE 14 – BUSINESS SEGMENTS

We have determined that we conduct our operations in one business segment: the manufacture, development and commercialization of products for use in treating human diseases. Long-lived assets consist entirely of property, plant and equipment and are located in the United States for all periods presented.

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NOTE 15 – QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	2017			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenues:				
Net U.S. Auryxia product sales	$10,505	$14,116	$13,597	$17,296
License revenue	1,314	1,028	1,399	1,386
Total revenues	11,819	15,144	14,996	18,682
Costs and expenses:				
Cost of goods sold	4,273	4,379	5,856	7,447
License expense	789	617	838	832
Research and development	6,764	9,012	9,275	12,628
Selling, general and administrative	23,103	24,986	22,746	28,787
Total costs and expenses	34,929	38,994	38,715	49,694
Operating loss	(23,110)	(23,850)	(23,719)	(31,012)
Other (expense) income:				
Amortization of debt discount	—	(62,965)	—	—
Other (expense) income, net	114	338	241	288
Total other (expense) income:	114	(62,627)	241	288
Loss before income taxes	(22,996)	(86,477)	(23,478)	(30,724)
Income tax expense (benefit)	20	20	20	(295)
Net loss	$(23,016)	$(86,497)	$(23,498)	$(30,429)
Basic and diluted net loss per common share*	$(0.21)	$(0.77)	$(0.20)	$(0.26)

	2016			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenues:				
Product revenue, net	$5,616	$8,279	$5,050	$8,228
License revenue	1,209	1,009	1,287	$1,305
Total revenues	6,825	9,288	6,337	9,533
Operating expenses:				
Cost of goods sold	1,071	5,099	18,196	13,437
License expense:	726	605	772	783
Research and development	7,616	7,029	8,674	6,185
Selling, general and administrative	20,809	20,188	20,521	23,035
Total operating expenses	30,222	32,921	48,163	43,440
Operating loss	(23,397)	(23,633)	(41,826)	(33,907)
Other (expense) income:				
Amortization of debt discount	(15,748)	(18,479)	—	—
Other (expense) income, net	(1,799)	(2,519)	150	143
Total other (expense) income:	(17,547)	(20,998)	150	143
Loss before income taxes	(40,944)	(44,631)	(41,676)	(33,764)
Income taxes	20	20	20	20
Net loss	$(40,964)	$(44,651)	$(41,696)	$(33,784)
Basic and diluted net loss per common share*	$(0.39)	$(0.42)	$(0.39)	$(0.32)

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