

**UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549**

FORM 10-Q

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

For the quarterly period ended March 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
(State or other jurisdiction of
incorporation or organization)

13-4087132
(I.R.S. Employer
Identification No.)

**One Marina Park Drive, 12th Floor
Boston, Massachusetts 02210**
(Address including zip code of principal executive offices)

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

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 ☒ 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 (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☒ No ☐

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 the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	<input checked="" type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/> (Do not check if a smaller reporting company)	Smaller reporting company	<input type="checkbox"/>
Emerging growth company	<input type="checkbox"/>		

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 checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

There were 108,466,747 shares of the registrant's common stock, \$0.001 par value, outstanding as of April 28, 2017.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED MARCH 31, 2017

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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,” “will,” “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 caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2016, as well as under the caption “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 develop and obtain U.S. Food and Drug Administration approval of Auryxia for the treatment of iron deficiency anemia in non-dialysis dependent chronic kidney disease patients;
- 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, positive cash flow or becoming profitable on a sustained basis;
- 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 pre-clinical and 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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.

Condensed Consolidated Balance Sheets as of March 31, 2017 and December 31, 2016

(in thousands, except share and per share amounts)

	March 31, 2017 (Unaudited)	December 31, 2016
Assets		
Current assets:		
Cash and cash equivalents	\$ 90,909	\$ 111,810
Inventory	12,592	12,681
Accounts receivable, net	6,153	5,236
Other current assets	9,653	3,170
Total current assets	119,307	132,897
Property, plant and equipment, net	3,982	4,211
Goodwill	3,208	3,208
Other assets, net	1,199	1,111
Total assets	\$ 127,696	\$ 141,427
Liabilities and stockholders' deficit		
Current liabilities:		
Accounts payable and accrued expenses	\$ 21,756	\$ 21,190
Deferred lease incentive, current portion	244	244
Other current liabilities	124	117
Total current liabilities	22,124	21,551
Convertible senior notes	125,000	125,000
Deferred lease incentive, net of current portion	1,200	1,262
Deferred tax liability	890	870
Other liabilities	1,007	1,040
Total liabilities	150,221	149,723
Commitments and contingencies		
Stockholders' deficit:		
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 (180,000,000 shares authorized, 107,762,090 and 105,921,052 shares issued, 107,682,142 and 105,841,104 shares outstanding at March 31, 2017 and December 31, 2016, respectively)	108	106
Additional paid-in capital	835,838	827,053
Treasury stock, at cost, 79,948 shares	(357)	(357)
Accumulated deficit	(858,114)	(835,098)
Total stockholders' deficit	(22,525)	(8,296)
Total liabilities and stockholders' deficit	\$ 127,696	\$ 141,427

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

Keryx Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
for the three months ended March 31, 2017 and 2016 (Unaudited)
(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2017	2016
Revenues:		
Net U.S. Auryxia product sales	\$ 10,505	\$ 5,616
License revenue	1,314	1,209
Total revenues	11,819	6,825
Costs and expenses:		
Cost of goods sold	4,273	1,071
License expenses	789	726
Research and development	6,764	7,616
Selling, general and administrative	23,103	20,809
Total costs and expenses	34,929	30,222
Operating loss	(23,110)	(23,397)
Other income (expense):		
Amortization of debt discount	—	(15,748)
Other income (expense), net	114	(1,799)
Total other income (expense)	114	(17,547)
Loss before income taxes	(22,996)	(40,944)
Income taxes	20	20
Net loss	\$ (23,016)	\$ (40,964)
Basic and diluted net loss per common share	\$ (0.21)	\$ (0.39)
Weighted average shares used in computing basic and diluted net loss per common share	107,071,634	105,649,571

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

Keryx Biopharmaceuticals, Inc.
Condensed Consolidated Statements of Cash Flows
for the three months ended March 31, 2017 and 2016 (Unaudited)
(in thousands)

	Three months ended March 31,	
	2017	2016
Cash flows from operating activities		
Net loss	\$ (23,016)	\$ (40,964)
Adjustments to reconcile loss to cash flows used in operating activities:		
Stock-based compensation expense	3,664	3,293
Amortization of debt discount	—	15,748
Change in fair value of derivative liability	—	2,007
Depreciation and amortization	229	261
Amortization of deferred lease incentive	(62)	(61)
Write-down of inventory to net realizable value	225	—
Deferred income taxes	20	20
Changes in operating assets and liabilities:		
Other current assets	(6,483)	311
Accounts receivable, net	(917)	(669)
Inventory	928	371
Other assets	(88)	—
Other current liabilities	7	(262)
Accounts payable and accrued expenses	(437)	(8,184)
Deferred revenue	—	192
Other liabilities	(33)	209
Net cash used in operating activities	(25,963)	(27,728)
Cash flows from investing activities		
Purchases of property, plant and equipment	—	(2,037)
Net cash used in investing activities	—	(2,037)
Cash flows from financing activities		
Proceeds from issuance of common stock, net of commission	5,080	—
Payments for common stock issuance costs	(28)	—
Proceeds from exercise of stock options	10	6
Net cash provided by financing activities	5,062	6
Net decrease in cash and cash equivalents	(20,901)	(29,759)
Cash and cash equivalents at beginning of the period	111,810	200,290
Cash and cash equivalents at end of the period	\$ 90,909	\$ 170,531

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

Keryx Biopharmaceuticals, Inc.
Notes to Condensed Consolidated Financial Statements (unaudited)

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

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. 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 are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that can help patients with kidney disease. We use the brand name Auryxia only when we refer to ferric citrate for use in the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

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

Basis of Presentation

The accompanying unaudited condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of these interim financial statements have been included. These interim condensed consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2016. The year-end condensed consolidated balance sheet data was derived from audited financial statements, but does not include all disclosures required by U.S. GAAP. The results of operations for the three months ended March 31, 2017 are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Principles of Consolidation

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

Use of Estimates

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

Cash and Cash Equivalents

We consider liquid investments with original maturities of three months or less when purchased to be cash and cash equivalents. At March 31, 2017 and December 31, 2016, all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

Inventory

Inventory is stated at the lower of cost or estimated net 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 approval for Auryxia from the U.S. Food and Drug Administration, or FDA, on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers was included as a component of research and development expense.

Accounts Receivable, Net

We extend credit to our customers for U.S. Auryxia product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to certain of our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. Accounts receivable are reported in the condensed consolidated balance sheets net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at March 31, 2017 and December 31, 2016.

Revenue Recognition

Our commercial launch of our only product, Auryxia, in the United States, occurred in late December 2014. We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectability is reasonably assured, and (iv) the price is fixed or determinable. 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 based on our prior sales and return history.

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 also deferred the related cost of product sales and recorded such amounts as finished goods inventory held by others, which was included in inventory on our condensed consolidated balance sheet, until revenue related to such product sales was recognized.

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

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services. The payment terms for sales to Distributors generally include a prompt-pay discount for payments made within 35 days. Based on our judgment and industry experience, we expect our Distributors to earn these discounts, and we deduct the full amount of these discounts from our gross product sales and accounts receivable at the time such revenues are recognized. Fees for distribution services are deducted from our gross product sales and we accrue these fees which appear in our accrued expenses on our condensed consolidated balance sheets.

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

Product Returns: 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 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 our product, and our product being 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 March 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.

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 information regarding programs provided for similar specialty pharmaceutical products, we estimate the average 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 and deduct these estimated amounts from our gross product sales at the time the sales are recognized. We adjust our accruals for co-pay assistance and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

Classification of Product Sales Allowances and Accruals

Allowances against receivable balances primarily relate to prompt-pay discounts and chargebacks 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 and product returns 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 three months ended March 31, 2017 and 2016 were offset by provisions for allowances and accruals as set forth in the tables below.

<u>(in thousands)</u>	Three months ended March 31, 2017	Percent of gross Auryxia product sales	Three months ended March 31, 2016	Percent of gross Auryxia product sales
Gross Auryxia product sales	\$ 17,954		\$ 8,625	
Less provision for product sales allowances and accruals:				
Trade allowances	1,278	7%	1,146	13%
Rebates, chargebacks and discounts	5,818	33%	1,678	20%
Product returns	(69)	—	—	—
Other incentives (1)	422	2%	185	2%
Total	7,449	42%	3,009	35%
Net U.S. Auryxia product sales	\$ 10,505		\$ 5,616	

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

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

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

Cost of Goods Sold

Cost of goods sold includes the cost of active pharmaceutical ingredient, 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. Cost of goods sold also includes expenses due to the licensor of Auryxia related to the manufacturing of product and U.S. Auryxia product sales recognized during the period.

License Expenses

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

Research and Development Costs

Research and development costs are expensed as incurred. Pre-approval inventory expenditures are recorded as research and development expense as incurred. The capitalization of inventory for our product candidate(s) commences when it is probable that the product will be approved for commercial marketing. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and expensed 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 study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients and the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our condensed 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 study or trial contract.

Stock-Based Compensation

We grant stock options and restricted stock to employees, directors and consultants. We are required to estimate the 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 options. The aggregate fair value of awards calculated using the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting period. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment.

The 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.

For stock-based awards granted to consultants, we recognize compensation expense over the period during which services are rendered by such consultants until completed. At the end of each financial reporting period prior to completion of the service, we re-measure the fair value of these awards using the then-current fair value of our common stock and updated assumption inputs in the Black-Scholes option-pricing model.

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 March 31, 2017 and 2016, which are not included in the computation of net loss per share amounts, were 12,737,385 and 6,491,921, 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.

Goodwill is reviewed for impairment annually, 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 to the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than its fair value, an impairment is recorded equal to the difference between the carrying value and the fair value, not to exceed the carrying amount of goodwill. As of December 31, 2016, management concluded that there was no impairment of our goodwill. The impairment test as of December 31, 2016 was based on the existing guidance for goodwill impairment tests. We will continue to perform impairment tests annually, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For the periods ended March 31, 2017 and 2016, management determined that there were no impairment indicators that would trigger a goodwill impairment analysis.

Concentrations of Credit Risk

We do not have significant off-balance-sheet risk or credit risk concentrations. We primarily maintain our cash and cash equivalents in institutional money market funds. As of March 31, 2017, approximately \$87.7 million of our total \$90.9 million cash and cash equivalents balance was invested in institutional money market funds. See Note 3 – Fair Value Measurements.

Our accounts receivable, net at March 31, 2017 and December 31, 2016 represent amounts due to us 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 March 31, 2017 and December 31, 2016.

	March 31, 2017	December 31, 2016
McKesson Corporation	23%	31%
Fresenius Medical Care Rx	23%	22%
Cardinal Health, Inc.	18%	11%
Davita Rx	17%	10%
AmerisourceBergen Drug Corporation	16%	23%

We currently have two suppliers with three approved sites for the supply of Auryxia drug product. If any of our suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at adequate levels, we could experience losses of revenue, which could materially and adversely impact our results of operations.

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 reduced 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 amortized over the assets' useful lives or the remaining lease term, whichever is shorter.

New Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or the FASB, or other standard setting bodies that we adopt as of the specified effective date.

We adopted the following new standards on January 1, 2017:

- Accounting Standards Update, or ASU, No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*.
- ASU No. 2017-04, *Intangibles – Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment*. The new standard simplifies how an entity is required to test goodwill for impairment by eliminating Step 2 from the goodwill impairment test. Step 2 measures a goodwill impairment loss by comparing the implied fair value of a reporting unit's goodwill with the carrying amount of that goodwill. Under the new standard, entities would recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value, and any loss recognized should not exceed the total amount of goodwill allocated to that reporting unit. This standard will be effective for us on January 1, 2020; however, we have adopted this standard as of January 1, 2017 with prospective application to our goodwill impairment tests.

The adoption of these standards did not have a material impact on our financial position, results of operations or statement of cash flows. For additional information related to these and other standards, see Note 2 – Basis of Presentation and Summary of Significant Accounting Policies, to our consolidated financial statements included in our 2016 Form 10-K.

In May 2014, the FASB issued 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 standard is effective for interim and annual periods beginning after December 15, 2017 and allows for adoption using a full retrospective method, or a modified retrospective method. The FASB has subsequently issued amendments to ASU No. 2014-09 that have the same effective date and transition date of January 1, 2018. We expect to adopt these standards using the modified retrospective method and continue to evaluate the expected impact that Topic 606 will have on our financial position, results of operations and disclosures.

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. The adoption of this standard is expected to have a material impact on our financial position as it will impact the amount of our assets and liabilities. We are currently evaluating the potential impact that this standard may have on our results of operations.

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 will be 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.

NOTE 3 – FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in our condensed consolidated financial 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 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 of applicable financial assets as of March 31, 2017 and December 31, 2016:

(in thousands)	Financial assets at fair value as of March 31, 2017			Financial assets at fair value as of December 31, 2016		
	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
<i>Assets:</i>						
Cash equivalents ⁽¹⁾	\$ 87,701	\$ —	\$ —	\$ 107,084	\$ —	\$ —
Total assets	\$ 87,701	\$ —	\$ —	\$ 107,084	\$ —	\$ —

⁽¹⁾ Cash equivalents as of March 31, 2017 and December 31, 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 Baupost Group Securities, L.L.C., or Baupost. As of March 31, 2017 and December 31, 2016, the fair value of the Notes was \$205.9 million and \$195.9 million, respectively, which differs from their carrying value. The fair value of the Notes is influenced by our stock price and stock price volatility. See Note 8 – Debt and Note 11 – Subsequent Events for additional information on our debt obligations.

NOTE 4 – INVENTORY

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

(in thousands)	March 31, 2017	December 31, 2016
Raw materials	\$ 540	\$ 418
Work in process	10,219	11,430
Finished goods	1,833	833
Total inventory	\$ 12,592	\$ 12,681

NOTE 5 – STOCKHOLDERS' DEFICIT

Change in Stockholders' Deficit

Total stockholders' deficit increased by \$14.2 million during the three months ended March 31, 2017. This increase was primarily attributable to our net loss of \$23.0 million, partially offset by the proceeds from the issuance of common stock of \$5.1 million and \$3.7 million related to stock-based compensation and stock option exercises.

NOTE 6 – STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

As of March 31, 2017, a total of 2,034,530 shares were available for the issuance of stock options or other stock-based awards under our stock option and incentive plans.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2017:

	Number of shares	Weighted- average exercise price
Outstanding at December 31, 2016	8,677,998	\$ 7.28
Granted	4,144,550	5.32
Exercised	(3,326)	3.59
Forfeited	(22,019)	5.62
Expired	(59,818)	13.84
Outstanding at March 31, 2017	12,737,385	\$ 6.62
Vested and expected to vest at March 31, 2017	7,552,211	\$ 7.50
Exercisable at March 31, 2017	3,812,243	\$ 9.03

Upon the exercise of stock options, we issue new shares of our common stock. As of March 31, 2017, 4,572,500 options issued to employees are unvested, performance-based options.

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 years. The following table summarizes restricted share activity for the three months ended March 31, 2017:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2016	1,524,884	\$ 7.07
Granted	1,024,925	5.59
Vested	(266,707)	5.24
Forfeited	(7,779)	5.64
Outstanding at March 31, 2017	2,275,323	\$ 6.62

As of March 31, 2017, 435,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred \$3.7 million and \$3.3 million of stock-based compensation expense related to equity incentive grants during the three months ended March 31, 2017 and 2016, respectively. The following table reflects stock-based compensation expense for the three-months ended March 31, 2017 and 2016:

(in thousands)	Three months ended March 31,	
	2017	2016
Cost of goods sold	\$ 6	\$ 6
Research and development expenses	632	705
Selling, general and administrative expenses	3,026	2,582
Total stock-based compensation expense	\$ 3,664	\$ 3,293

Stock-based compensation costs capitalized as part of inventory were immaterial for the three months ended March 31, 2017 and 2016.

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, the expected vesting period and the full contractual term. 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.

The weighted average grant date fair value of stock options granted during the three months ended March 31, 2017 and 2016 was \$3.81 and \$2.41, respectively. We used historical information to estimate forfeitures of stock options. As of March 31, 2017, there was \$14.0 million and \$8.0 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.3 years and 2.4 years, respectively. These amounts do not include 4,572,500 unvested options and 435,000 shares of unvested restricted stock as of March 31, 2017 which are performance-based and vest upon achievement of certain corporate milestones. Stock-based compensation for these awards will be measured and recorded if and when it is probable that the milestone will be achieved.

NOTE 7—LICENSE AGREEMENTS

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 paid an aggregate of \$11.6 million of milestone payments to Panion, including the \$2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of ferric citrate in the licensed territory, as well as a manufacturing fee for product manufactured for use in the licensed territory.

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. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, or 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 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 is marketed in Japan by Torii 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 Revised Agreement, we 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. For the three months ended March 31, 2017 and 2016, we recorded \$1.3 million and \$1.2 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 three months ended March 31, 2017 and 2016, we recorded \$0.8 million and \$0.7 million, respectively, in license expenses related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan.

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, or the Indenture, dated as of October 15, 2015, with The Bank of New York Mellon Trust Company, N.A. as trustee, or the Trustee. 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, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement, or the Resale Registration Statement with the Securities and Exchange Commission, or 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.

At issuance, 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 carrying amount of the convertible senior notes represents the difference between the proceeds from the issuance of the Notes and the fair value of the derivative liability on the date of issuance. The excess of the principal amount of the debt component over its carrying amount, or debt discount, was amortized to interest expense using the effective interest method over the expected life of the debt.

Our outstanding convertible senior notes balance was \$125.0 million as of March 31, 2017 and December 31, 2016.

We determined the expected life of the debt was equal to the period through July 1, 2016, as this represented the earliest point at which a portion of the Notes was initially contingently convertible into cash. Accordingly, for the three months ended March 31, 2016 approximately \$15.7 million of interest expense was recognized related to the Notes, all of which was attributable to the amortization of the debt discount. No interest expense was recognized related to the Notes in the three months ended March 31, 2017. As of March 31, 2017 and December 31, 2016, the carrying value of the Notes was \$125.0 million, and the fair value of the Notes was \$205.9 million and \$195.9 million, respectively. During the year ended December 31, 2016, the derivative liability was reclassified to equity as a result of the Notes no longer being convertible into cash.

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. At our 2017 Annual Meeting of Stockholders to be held on June 8, 2017, we are seeking to ratify the filing and effectiveness of this certificate of amendment and to separately increase our authorized common stock to 230,000,000 shares. Pursuant to an amendment to the terms of the Notes we entered into in April 2017, Baupost may not convert the Notes, except in certain circumstances, until on or after June 8, 2017. See Note 11 – Subsequent Events for additional information on this amendment.

NOTE 9 – OTHER INCOME (EXPENSE), NET

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

(in thousands)	Three months ended March 31,	
	2017	2016
Interest income	\$ 117	\$ 202
Other (expense) income	(3)	6
Fair value adjustment to derivative liability	—	(2,007)
	<u>\$ 114</u>	<u>\$ (1,799)</u>

NOTE 10 – COMMITMENTS AND CONTINGENCIES***Commitments***

As of March 31, 2017, our contractual obligations and commitments primarily consist of our obligations under non-cancelable leases, convertible senior notes, and various agreements with third parties, including selling, general and administrative, research and development and manufacturing agreements.

Contingencies

We accrue a liability for legal contingencies when we believe that it is both probable that a liability has been incurred and that we can reasonably estimate the amount of the loss. We review these accruals and adjust them to reflect the best information available at the time. To the extent new information is obtained and our views on the probable outcomes of claims, suits, assessments, investigations or legal proceedings change, changes in our accrued liabilities would be recorded in the period in which such determination is made. For the matter referenced below, a liability is not probable or the amount cannot be reasonably estimated and, therefore, an accrual has not been made. In addition, in accordance with the relevant authoritative guidance, for any matters in which the likelihood of material loss is at least reasonably possible, we will provide disclosure of the possible loss or range of loss. If a reasonable estimate cannot be made, however, we will provide disclosure to that effect. We expense legal costs as they are incurred.

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 have been 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 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 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 stock between May 8, 2013 and August 1, 2016. The Jackson, Erickson and King matters were transferred to the District of Massachusetts. The Karth plaintiffs have filed a motion to consolidate the actions and the defendants have joined in that motion. 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 the Company and its business operations and future prospects in light of the August 1, 2016 announcement of an imminent interruption in our supply of Auryxia. Two stockholder derivative complaints were also filed on December 16, 2016 against the Company and certain of its current and former officers (Gregory P. Madison, Scott A. Holmes, Ron Bentsur and James Oliviero), certain of its current directors (Kevin J. Cameron, Daniel P. Regan, Steven C. Gilman, Michael Rogers and John P. Butler) and its former directors (Michael P. Tamok, 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 the Company, unjustly enriched themselves by their actions, abused their control positions with the Company, mismanaged the Company and wasted corporate assets since July 31, 2013 in light of the August 1, 2016 announcement by the Company of an interruption in the supply of the Company's product Auryxia. 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 11 – SUBSEQUENT EVENTS

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 may not be converted 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 will be 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. On or after June 8, 2017, the holders may, at their option, convert the Notes until the maturity date thereof. The First Supplement also changes the observation period for determining the cash conversion price of the Notes from the five (5) trading days following the conversion date of the Notes to the five (5) trading days preceding the conversion date of the Notes.

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

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

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 under the heading "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2016. 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 the unaudited condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2016.

OVERVIEW

We are a commercial stage biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our long-term vision is to build a leading renal company. Our marketed product, Auryxia (ferric citrate), which is an orally available, absorbable, iron-based medicine is approved in the United States for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. 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 are also investigating the use of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent CKD, or NDD-CKD, and, pending potential approval for this indication, plan to leverage our U.S. clinical and commercial infrastructure and treat many more people with CKD. Our vision of building a leading renal company includes expansion of our product portfolio with other medicines that can help patients with kidney disease. We use the brand name Auryxia only when we refer to ferric citrate for use in the approved indication in the United States. We refer to the product as ferric citrate when referring to its investigational use.

OUR STRATEGY

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

Maximize Auryxia's Potential

We developed and subsequently launched Auryxia in the United States in late December 2014. Auryxia is a non-chewable, orally-administered phosphate binder for patients on dialysis. Auryxia is being marketed in the United States to renal care teams through our specialty salesforce and commercial infrastructure. 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. Our field-based organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. We believe strong fundamentals are in place to continue to drive commercial adoption of Auryxia in the dialysis setting.

We also believe that we can maximize the potential of ferric citrate through potential label expansion for the treatment of IDA, NDD-CKD patients. We completed a pivotal Phase 3 clinical trial evaluating ferric citrate for this indication and presented results from this trial to the medical community at the American Society of Nephrology's Kidney Week 2016 Annual Meeting. The results from this trial were also published online in the *Journal of the American Society of Nephrology* in January 2017. We submitted a supplemental new drug application, or sNDA, to the U.S. Food and Drug Administration, or FDA, in January 2017 seeking to expand the label for Auryxia to include the treatment of IDA in NDD-CKD patients, which was accepted by the FDA for review in March 2017. A Prescription Drug User Fee Act, or PDUFA, target action date for the FDA's review of this sNDA was set for November 6, 2017, and, if approved, we could potentially make the medicine available to these patients immediately thereafter. We estimate that in the United States, approximately 1.7 million adults under the care of a nephrologist have IDA, NDD-CKD, including approximately 650,000 adults currently being treated by nephrologists for IDA. IDA is common in the NDD-CKD population and the prevalence and severity increases as CKD advances. IDA is symptomatic and can significantly impact quality of life. No oral iron medications are currently FDA-approved to treat IDA, NDD-CKD.

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 several clinical-drug candidates and commercial 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 work force of high-quality and talented people to support our potential growth.

Financial Performance Overview

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

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

Cost of goods sold includes the cost of active pharmaceutical ingredient, or API, for Auryxia on which product sales were recognized during the period, 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 expenses due to the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

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

Our research and development expenses consist primarily of salaries and related personnel costs, including stock-based compensation, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, including pre-approval inventory build-up, regulatory, facilities-related and other expenses relating to the design, development, manufacture, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred.

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

Our results of operations include stock-based compensation expense as a result of the grants of stock options and restricted stock. 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 expenses. The expense is classified by expense categories in the condensed consolidated statements of operations. We expect to continue to incur significant stock-based compensation expenses.

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

GENERAL CORPORATE

We have devoted substantially all of our efforts to the identification, in-licensing, development and partnering of drug candidates, as well as pre-commercial/commercial activities related to Auryxia, and have incurred negative cash flow from operations each year since our inception. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our product development efforts, our clinical trials, commercial, partnership and licensing activities. Prior to the U.S. launch of Auryxia in late December 2014, we had not commercialized any drug. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug.

CRITICAL ACCOUNTING POLICIES

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

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

Revenue Recognition and Related Sales Allowances and Accruals

Our commercial launch of our only product, Auryxia, in the United States, occurred in late December 2014. We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable. 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 based on our prior sales and return history.

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 also deferred the related cost of product sales and recorded such amounts as finished goods inventory held by others, which was included in inventory on our condensed consolidated balance sheet, until revenue related to such product sales was recognized.

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

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services. The payment terms for sales to Distributors generally include a prompt-pay discount for payments made within 35 days. Based on our judgment and industry experience, we expect our Distributors to earn these discounts, and we deduct the full amount of these discounts from our gross product sales and accounts receivable at the time such revenues are recognized. Fees for distribution services are deducted from our gross product sales and we accrue these fees which appear in our accrued expenses on our condensed consolidated balance sheets.

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

Product Returns: 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 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 our product, and our product being 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 March 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.

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 information regarding programs provided for similar specialty pharmaceutical products, we estimate the average 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 and deduct these estimated amounts from our gross product sales at the time the sales are recognized. We adjust our accruals for co-pay assistance and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

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

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

Stock-Based Compensation

We grant stock options and restricted stock to employees, directors and consultants. We are required to estimate the 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 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 calculation, we assumed that no dividends would be paid during the life of the options. The aggregate fair value of awards calculated using the Black-Scholes option pricing model is generally amortized on a straight-line basis over the requisite service period, and is recognized based on the proportionate amount of the requisite service period that has been rendered during each reporting 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.

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 options issued to employees, consultants and other third-parties vest upon the achievement of certain performance conditions or milestones, the total expense is uncertain.

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients and the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our condensed 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 study or trial contract.

Inventory

Inventory is stated at the lower of cost or estimated net 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 as a component of research and development expense.

Accounts Receivable, Net

We extend credit to our customers for U.S. Auryxia product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to certain of our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. Accounts receivable are reported in the condensed consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at March 31, 2017 and December 31, 2016.

Accounting Related to Goodwill

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment by comparing the fair value of the reporting unit to the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than its fair value, an impairment is recorded equal to the difference between the carrying value and the fair value, not to exceed the carrying amount of goodwill.

We are required to perform impairment tests annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For the period ended March 31, 2017, management determined that there were no impairment indications that would trigger a goodwill impairment analysis.

NEW ACCOUNTING PRONOUNCEMENTS

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

RESULTS OF OPERATIONS

Three months ended March 31, 2017 and March 31, 2016

Net U.S. Auryxia Product Sales. For the three months ended March 31, 2017, we recognized \$10.5 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with \$5.6 million for the three months ended March 31, 2016.

<u>(in thousands)</u>	<u>Three months ended</u> <u>March 31, 2017</u>	<u>Percent of gross</u> <u>Auryxia</u> <u>product sales</u>	<u>Three months ended</u> <u>March 31, 2016</u>	<u>Percent of gross</u> <u>Auryxia</u> <u>product sales</u>
Gross Auryxia product sales	\$ 17,954		\$ 8,625	
Less provision for product sales allowances and accruals				
Trade allowances	1,278	7%	1,146	13%
Rebates, chargebacks and discounts	5,818	33%	1,678	20%
Product returns	(69)	—	—	—
Other incentives ⁽¹⁾	422	2%	185	2%
Total	7,449	42%	3,009	35%
Net U.S. Auryxia product sales	\$ 10,505		\$ 5,616	

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

Gross Auryxia product sales increased for the three months ended March 31, 2017 as compared to the same period in 2016 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 three months ended March 31, 2017 as compared to the same period in 2016 increased primarily as a result of a higher percentage of sales through government and commercial contracts that receive a larger rebate. Net U.S. Auryxia product sales for the three months ended March 31, 2017 includes an approximate \$0.3 million adjustment to our product returns reserve to reduce the reserve based on product prescribed which can no longer be returned.

Beginning 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. We expect net Auryxia product sales to increase for the remainder of 2017 as compared to the first quarter of 2017 as we continue to focus our efforts on expanding the commercialization of Auryxia and continue to gain market share as a result of our selling efforts and broader reimbursement of Auryxia.

License Revenue. For the three months ended March 31, 2017, we recognized \$1.3 million in license revenue on royalty payments from sales of Riona in Japan as compared to \$1.2 million for the three months ended March 31, 2016. This increase was due to increased sales by JT and Torii of Riona in Japan.

Cost of Goods Sold. For the three months ended March 31, 2017, we recognized \$4.3 million in cost of goods sold, as compared to \$1.1 million for the three months ended March 31, 2016. This increase was primarily due to additional units sold during the 2017 period as compared to the 2016 period. Additionally, during the 2016 period, a portion of the units sold contained material manufactured prior to the approval of Auryxia which was recorded to research and development expense when manufactured, thereby reducing the cost of goods sold during the 2016 period.

License Expenses. For the three months ended March 31, 2017, we recognized \$0.8 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to \$0.7 million for the three months ended March 31, 2016. This increase was due to an increase in sales of Riona in Japan during the 2017 period.

Research and Development Expenses. Research and development expenses decreased by \$0.9 million, or 11%, to \$6.8 million for the three months ended March 31, 2017, as compared to \$7.6 million for the three months ended March 31, 2016. The decrease in research and development expenses was primarily due to a decrease in clinical expenses as a result of the completion of the Phase 3 study of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD, as well as a decrease in process development-related manufacturing prior to the approval of a new drug product contract manufacturer in the fourth quarter of 2016. These decreases were partially offset by an increase in filing fees related to our submission of the sNDA for ferric citrate in the NDD-CKD setting, which occurred in the first quarter of 2017. We expect our research and development expenses will increase for the remainder of 2017 as compared to the three months ended March 31, 2017, related to investigator sponsored research and pediatric study requirements and other post-marketing clinical trials which we expect will begin in 2017, as well as an increase in process development-related manufacturing costs.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by \$2.3 million, or 11%, to \$23.1 million for the three months ended March 31, 2017, as compared to \$20.8 million for the three months ended March 31, 2016. The increase was primarily due to an increase in personnel costs attributable to the continued commercialization of Auryxia. We expect our selling, general and administrative costs to increase slightly for the remainder of 2017 as compared to the three months ended March 31, 2017, due to costs associated with preparing for the potential approval and launch of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD.

Other income (expense), net. Other income (expense), net for the three months ended March 31, 2017 was \$0.1 million income as compared to \$17.5 million in expenses for the three months ended March 31, 2016. The other expense recorded for the three months ended March 31, 2016 relates to the amortization of the debt discount of \$15.7 million as well as \$2.0 million related to the change in fair value of the derivative liability in connection with the convertible senior notes, partially offset by interest income of \$0.2 million.

Income Taxes. For the three months ended March 31, 2017 and 2016, we recognized \$20,000 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.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible senior notes, from the upfront 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 complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In 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. We also entered into a Controlled Equity OfferingSM Sales Agreement, or the Sales Agreement, with Cantor Fitzgerald & Co., as sales agent, or Cantor Fitzgerald, pursuant to which we may 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. The \$75.0 million of common stock issuable pursuant to the Sales Agreement is included as part of the \$250.0 million registered on the registration statement referred to above. During the three months ended March 31, 2017, we sold 820,566 shares under the Sales Agreement for aggregate net proceeds of \$5.1 million. Subsequent to March 31, 2017 and through April 28, 2017, we sold 996,006 shares under the Sales Agreement for aggregate net proceeds of \$5.7 million. Through April 28, 2017, approximately \$63.9 million of shares remained available for sale under the Sales Agreement.

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. See Note 8 – Debt and Note 11 – Subsequent Events for a description of the Notes. 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.

As of March 31, 2017, we had \$90.9 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 \$20.9 million.

We currently expect that our existing capital resources, future anticipated cash flows from product sales and the funds from the future issuance of common stock will be sufficient to execute our current business objectives. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the 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 clinical trials for ferric citrate. As a result of these factors, we will need to seek additional financings to provide the cash necessary to execute our current operations, including beyond commercializing Auryxia, and to develop and commercialize any drugs or drug candidates we may in-license or acquire. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factor, “Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated” included in our Annual Report on Form 10-K for the year ended December 31, 2016 and the other risk factors contained therein.

Net cash used in operating activities for the three months ended March 31, 2017 was \$26.0 million as compared to \$27.7 million net cash used in operating activities of for the same period in 2016. This decrease in net cash used in operating activities was primarily related to a reduction in accounts payable and accrued expenses during the three months ended March 31, 2016, partially offset by an increase in other current assets during the three months ended March 31, 2017. The increase in other current assets during the three months ended March 31, 2017 primarily relates to approximately \$7.1 million of prepaid inventory costs to support the continued commercialization of Auryxia.

Net cash used in investing activities for the three months ended March 31, 2017 was zero as compared to \$2.0 million net cash used in investing activities for the same period in 2016. The net cash used in investing activities for the three months ended March 31, 2016 relates to capital expenditures in connection with the buildout of our Boston office.

Net cash provided by financing activities for the three months ended March 31, 2017 was \$5.1 million as compared to \$6,000 for the same period in 2016. Net cash provided by financing activities for the three months ended March 31, 2017 is attributable to the proceeds from the issuance of common stock under the Sales Agreement, net of commissions.

OBLIGATIONS AND COMMITMENTS

As of March 31, 2017, our contractual obligations and commitments primarily consist of our obligations under non-cancelable leases, convertible senior notes, and various agreements with third parties, including selling, general and administrative, research and development and manufacturing agreements.

There have been no other material changes to our contractual obligations and commitments outside the ordinary course of business from those disclosed in our Annual Report on Form 10-K for the year ended December 31, 2016.

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 amortized over the assets' useful lives or the remaining lease term, whichever is shorter.

Royalty and Contingent Milestone Payments

Under the license agreement with Panion, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate. As of March 31, 2017, we have paid an aggregate of \$11.6 million of milestone payments to Panion, including the \$2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia in the United States and of Riona in Japan. We record royalties on net sales of Auryxia in cost of goods sold and royalties on net sales of Riona in license expense.

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.

ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Risk

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. As of March 31, 2017, our portfolio of financial instruments consists of cash equivalents, which includes money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

Equity Price Risk

The 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 the 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 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of March 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 March 31, 2017, our disclosure controls and procedures were effective.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended March 31, 2017, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Limitations on 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 controls 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.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

See Note 10 – Commitments and Contingencies to our condensed consolidated financial statements included in this report, which is incorporated into this item by reference.

ITEM 1A. RISK FACTORS

Information regarding risk factors appears in Item 1A of our Annual Report on Form 10-K for the year ended December 31, 2016. There have been no material changes from the risk factors previously disclosed in that Form 10-K.

ITEM 6. EXHIBITS

The exhibits listed on the Exhibit Index immediately following the signatures to this report, which is incorporated herein by reference, are filed or furnished as part of this report.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

KERYX BIOPHARMACEUTICALS, INC.

Date: May 4, 2017

By: /s/ Scott A. Holmes

Scott A. Holmes

Chief Financial Officer

Principal Financial and Accounting Officer

EXHIBIT INDEX

The following exhibits are included as part of this Quarterly Report on Form 10-Q:

Exhibit Number	Exhibit Description
10.1†	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.
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 May 4, 2017.
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 May 4, 2017.
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 May 4, 2017.
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 May 4, 2017.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements.

† Indicates management contract or compensatory plan or arrangement.

**CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Gregory P. Madison, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Keryx Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2017

/s/ Gregory P. Madison

Gregory P. Madison

Chief Executive Officer

Principal Executive Officer

**CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE
SARBANES-OXLEY ACT OF 2002**

I, Scott A. Holmes, certify that:

1. I have reviewed this quarterly report on Form 10-Q of Keryx Biopharmaceuticals, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, 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;
 - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: May 4, 2017

/s/ Scott A. Holmes

Scott A. Holmes

Chief Financial Officer

Principal Financial and Accounting Officer

**CERTIFICATION OF CHIEF EXECUTIVE OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Gregory P. Madison, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 4, 2017

/s/ Gregory P. Madison

Gregory P. Madison

Chief Executive Officer

Principal Executive Officer

**CERTIFICATION OF CHIEF FINANCIAL OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the quarterly report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-Q for the quarterly period ended March 31, 2017 as filed with the Securities and Exchange Commission (the "Report"), I, Scott A. Holmes, Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

- 1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- 2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: May 4, 2017

/s/ Scott A. Holmes

Scott A. Holmes

Chief Financial Officer

Principal Financial and Accounting Officer

