KERYX BIOPHARMACEUTICALS INC
Form 10-Q
April 28, 2016
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended March 31, 2016

OR

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

For the transition period from _____ to _____

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	**13-4087132**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

One Marina Park Drive, 12th Floor

Boston, Massachusetts 02210

(Address 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 x No ¨

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§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 x No ¨

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of large accelerated filer, accelerated filer and smaller reporting company in Rule 12b-2 of the Exchange Act.

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

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

There were 105,820,947 shares of the registrant s common stock, $0.001 par value, outstanding as of April 22, 2016.

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KERYX BIOPHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2016

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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, 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, 2015, and under the captions Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Auryxia™ (ferric citrate) and market share;
- expectations for increases or decreases in expenses;
- expectations for pre-clinical and clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of Fexeric® (ferric citrate coordination complex) or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our development and manufacturing capabilities;
- expectations regarding our ability to successfully market Riona® through our Japanese partners, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd.;
- expectations regarding our ability to successfully develop and obtain FDA 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 in the European market;

expectations for generating revenue, positive cash flow or becoming profitable on a sustained basis;

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

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

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

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

expected losses; and

expectations for future capital requirements.

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

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.

Consolidated Balance Sheets as of March 31, 2016 and December 31, 2015

(in thousands, except share and per share amounts)

	March 31, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 170,531	$ 200,290
Inventory	42,198	41,881
Accounts receivable, net	4,325	3,656
Receivable from landlord	637	637
Other current assets	2,519	2,830
Total current assets	220,210	249,294
Property, plant and equipment, net	5,014	5,083
Goodwill	3,208	3,208
Other assets, net	1,100	1,100
Total assets	$ 229,532	$ 258,685
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,748	$ 21,322
Accrued compensation and related liabilities	3,580	5,473
Deferred revenue	3,718	3,526
Derivative liability	48,693	46,686
Deferred lease incentive, current portion	244	244
Other current liabilities	93	355
Total current liabilities	70,076	77,606
Convertible senior notes	106,521	90,773
Deferred lease incentive, net of current portion	1,445	1,506
Deferred tax liability	810	790
Other liabilities	1,285	1,076

Total liabilities	180,137	171,751
Commitments and contingencies		
Stockholders equity:		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)		
Common stock, $0.001 par value per share (130,000,000 shares authorized, 105,898,731 and 105,221,555 shares issued, 105,818,783 and 105,141,607 shares outstanding at March 31, 2016 and December 31, 2015, respectively)	106	105
Additional paid-in capital	764,613	761,189
Treasury stock, at cost, 79,948 shares at March 31, 2016 and December 31, 2015, respectively	(357)	(357)
Accumulated deficit	(714,967)	(674,003)
Total stockholders equity	49,395	86,934
Total liabilities and stockholders equity	$ 229,532	$ 258,685

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

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Operations

for the three months ended March 31, 2016 and 2015 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2016	**2015**
Revenues:		
Net U.S. Auryxia product sales	$ 5,616	$ 422
License revenue	1,209	753
Total revenues	6,825	1,175
Operating expenses:		
Cost of goods sold	1,071	76
License expenses	726	452
Research and development	7,616	9,591
Selling, general and administrative	20,809	18,880
Total operating expenses	30,222	28,999
Operating loss	(23,397)	(27,824)
Other income (expense):		
Amortization of debt discount	(15,748)	
Other income (expense), net	(1,799)	107
Total other income (expense)	(17,547)	107
Loss before income taxes	(40,944)	(27,717)
Income taxes	20	22
Net loss	$ (40,964)	$ (27,739)
Basic and diluted net loss per common share	$ (0.39)	$ (0.28)
Weighted average shares used in computing basic and diluted net loss per common share	105,649,571	100,553,490

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

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Cash Flows

for the three months ended March 31, 2016 and 2015 (Unaudited)

(in thousands)

	Three months ended March 31,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (40,964)	$ (27,739)
Adjustments to reconcile loss to cash flows used in operating activities:		
Stock-based compensation expense	3,293	4,321
Amortization of debt discount	15,748	
Change in fair value of derivative liability	2,007	
Depreciation and amortization	261	138
Amortization of deferred lease incentive	(61)	
Deferred income taxes	20	22
Changes in operating assets and liabilities:		
Other current assets	311	752
Accounts receivable, net	(669)	(449)
Inventory	371	(19,317)
Other current liabilities	(262)	(15)
Accounts payable and accrued expenses	(6,291)	8,923
Accrued compensation and related liabilities	(1,893)	(2,178)
Deferred revenue	192	300
Other liabilities	209	(34)
Net cash used in operating activities	(27,728)	(35,276)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(2,037)	(61)
Proceeds from maturity of held-to-maturity securities		11,508
Net cash (used in) provided by investing activities	(2,037)	11,447
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from public offerings, net		118,284
Proceeds from exercise of options	6	97

Net cash provided by financing activities	6	118,381
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(29,759)	94,552
Cash and cash equivalents at beginning of year	200,290	74,284
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 170,531	$ 168,836

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

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Keryx Biopharmaceuticals, Inc.

Notes to 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 biopharmaceutical company focused on bringing innovative medicines to market for people with renal disease. Our product, Auryxia (ferric citrate), is an oral, absorbable iron-based medicine, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. Ferric citrate is also approved in Japan under the tradename Riona and marketed by our Japanese partner, Japan Tobacco Inc. or JT, and approved in Europe as Fexeric. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our investigational medicine in Phase 3, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on approximately 5,000 target nephrologists and their associated dialysis centers.

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with stage 3-5 non-dialysis dependent chronic kidney disease, or NDD-CKD. This study s primary endpoint was the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period of the study. Secondary endpoints in the Phase 3 study included the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The top-line results demonstrated statistically significant differences between ferric citrate- and placebo-treated patients for the primary endpoint and all pre-specified secondary endpoints. The majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period as comparted to 19 percent in the placebo group ($p<0.001$). Additionally, the safety profile of the drug candidate was consistent with previously reported clinical studies of ferric citrate, with the majority of adverse events reported as mild to moderate. We believe these initial data support our plan to submit a supplemental new drug application, or sNDA, in the third quarter of 2016 seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD.

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

sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

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

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

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Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible notes, option and warrant exercises, interest income, upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Even though we are commercializing Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for Auryxia, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize Auryxia alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of Auryxia. In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C., or Baupost. In order to accommodate the full conversion of the Notes into shares of our common stock, we will seek stockholder approval of an amendment to our certificate of incorporation at the 2016 Annual Meeting of Stockholders to increase the number of authorized shares of our common stock. If the necessary share increase is not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. As of March 31, 2016, Baupost beneficially owns approximately 24% of our issued and outstanding common stock. If all of the Notes were converted prior to the approval of the necessary increase in authorized shares, Baupost would beneficially own approximately 28% of our issued and outstanding common stock and Baupost s beneficial ownership of our issued and outstanding common stock would increase to approximately 43% if the remaining Notes were converted into our common stock. In addition, in January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses, in an underwritten public offering of our common stock.

Most of our biopharmaceutical development and substantially all of our administrative operations during the three months ended March 31, 2016 and 2015 were conducted in the United States of America.

NOTE 2 BASIS OF PRESENTATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Basis of Presentation

The accompanying unaudited 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 the consolidated financial statements have been included. Nevertheless, these unaudited 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, 2015. The results of operations for the three months ended March 31, 2016, 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 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 consolidated financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to these consolidated financial statements.

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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, 2016 and December 31, 2015, 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 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. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at March 31, 2016 and December 31, 2015.

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

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery,

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

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

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

Product Returns: For the year ended December 31, 2015, the first full period in which we began selling Auryxia, and continuing into the three months ended March 31, 2016, we were not able to reasonably estimate product returns for all product sold to Customers. Once sufficient data exists or we are able to reasonably estimate the amount of Auryxia that will be returned, we will deduct these estimated amounts from our gross revenues at the time that revenues are recognized. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of March 31, 2016, we have experienced an immaterial number of product returns.

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

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

(in thousands)	Three months ended March 31, 2016	Percent of gross Auryxia product sales	Three months ended March 31, 2015	Percent of gross Auryxia product sales

Gross Auryxia product sales	$	8,625		$	964	
Less provision for product sales allowances and accruals						
Trade allowances		1,146	13%		100	10%
Rebates, chargebacks and discounts		1,678	20%		30	3%
Product returns						
Other incentives (1)		185	2%		412	43%
Total		3,009	35%		542	56%
Net U.S. Auryxia product sales	$	5,616		$	422	

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

The following table summarizes U.S. Auryxia product sales recognized and deferred during the three months ended March 31, 2016 and 2015, and the year ended December 31, 2015:

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(in thousands)	March 31, 2016	March 31, 2015	December 31, 2015
Net U.S. Auryxia sales recognized	$ 5,616	$ 422	$ 10,141
Deferred product sales	3,718	714	3,526
	$ 9,334	$ 1,136	$ 13,667

We recognize license revenue in accordance with Accounting Standards Codification 605, *Revenue Recognition*, or ASC 605. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

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 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 product sales recognized during the period.

In conjunction with our recognition and deferral of U.S. Auryxia product sales, we expensed and capitalized the associated cost of goods, as follows, during the three months ended March 31, 2016 and 2015, and the year ended December 31, 2015:

(in thousands)	March 31, 2016	March 31, 2015	December 31, 2015
Cost of goods sold expensed	$ 1,071	$ 76	$ 4,520
Finished goods inventory held by others	803	107	231
	$ 1,874	$ 183	$ 4,751

Finished goods inventory held by others as of March 31, 2016 and 2015 represents the cost of goods sold that has been deferred to align with our deferral of U.S. Auryxia product sales.

License Expenses

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

Research and Development Costs

Research and development costs are expensed as incurred. Pre-approval inventory expenditures are recorded as research and development expense as incurred. The capitalization of inventory for our product candidate(s) commence when it is probable that the product will be approved for commercial marketing. Nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations,

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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, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Stock-Based Compensation

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

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

Basic and Diluted Net Loss Per Common Share

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options outstanding as of March 31, 2016 and 2015, which are not included in the computation of net loss per share amounts, were 6,491,921 and 6,257,851, respectively. No warrants were outstanding during each of these periods.

Acquisitions

We account for acquired businesses using the acquisition method of accounting, which requires that assets acquired and liabilities assumed be recognized at their estimated fair values as of the acquisition date. Acquisition-related costs are expensed as incurred. Any excess of the consideration transferred over the estimated fair values of the identifiable net assets acquired is recorded as goodwill.

Impairment

Long lived assets are reviewed for an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management s policy in determining

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

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Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit s carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit s goodwill is compared with the carrying amount of the unit s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. As of December 31, 2015, management concluded that there was no impairment of our goodwill. We will continue to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For the period ending March 31, 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 maintain our cash and cash equivalents and held-to-maturity investments, when applicable, with multiple financial institutions that invest in investment-grade securities with average maturities of less than twelve months. See Note 3 Fair Value Measurements.

Our accounts receivable, net at March 31, 2016 and December 31, 2015 represent amounts due to the Company from customers. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total accounts receivable, net as of March 31, 2016 and December 31, 2015:

	March 31, 2016	December 31, 2015
Davita Rx	24%	19%
AmerisourceBergen Drug Corporation	21%	17%
McKesson Corporation	21%	23%
Cardinal Health, Inc.	19%	24%
Fresenius Medical Care Rx	13%	15%

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

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, we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets useful lives or the remaining lease term, whichever is shorter.

The lease for our New York City office will expire on September 30, 2016 and we have notified our landlord that we will not renew our lease.

Recently Issued and Proposed Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update (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

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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. In March 2016, the FASB issued ASU No. 2016-08, *Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations*, which clarifies the implementation guidance on principal versus agent considerations. We are currently assessing the method of adoption and the expected impact that Topic 606 will have on our financial position and results of operations.

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. We are currently evaluating the potential impact that this standard may have on our results of operations.

In March 2016, the FASB issued ASU No. 2016-09, *Compensation - Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*. The new standard involves several aspects of the accounting for share-based payment transactions, including the income tax consequences, classification of awards as either equity or liabilities and classification on the statement of cash flows. The new standard will be effective for us on January 1, 2017. We are currently evaluating the potential impact that this standard may have on our financial position, results of operations and statement of cash flows.

NOTE 3 FAIR VALUE MEASUREMENTS

We measure certain financial assets and liabilities at fair value on a recurring basis in our 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.

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

The following table provides the fair value measurements of applicable financial assets as of March 31, 2016 and December 31, 2015:

(in thousands)	Financial assets at fair value as of March 31, 2016 Level 1	Level 2	Level 3	Financial assets at fair value as of December 31, 2015 Level 1	Level 2	Level 3
Assets:						
Money market funds (1)	$ 166,086	$	$	$ 193,886	$	$
Total assets	$ 166,086	$	$	$ 193,886	$	$
Liabilities:						
Derivative liability	$	$	$ 48,693	$	$	$ 46,686
Total liabilities	$	$	$ 48,693	$	$	$ 46,686

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

In October 2015, we issued the Notes. As of March 31, 2016 and December 31, 2015, the fair value of our Notes was $138.3 million and $132.9 million, respectively, which differs from their carrying value. The fair value of our Notes is influenced by interest rates and our stock price and stock price volatility. See Note 8 Debt for additional information on our debt obligations.

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NOTE 4 INVENTORY

Upon approval of Auryxia on September 5, 2014 by the FDA, we began capitalizing our purchases of saleable inventory of Auryxia from suppliers. Inventory consists of the following at March 31, 2016 and December 31, 2015:

(in thousands)	March 31, 2016	December 31, 2015
Raw materials	$ 525	$ 495
Work in process	39,100	40,124
Finished goods	1,770	1,031
Finished goods inventory held by others	803	231
Total inventory	$ 42,198	$ 41,881

NOTE 5 STOCKHOLDERS EQUITY

Common Stock

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

Change in Stockholders Equity

Total stockholders equity decreased by $37.5 million during the three months ended March 31, 2016. This decrease was primarily attributable to our net loss of $41.0 million, partially offset by $3.5 million related to stock-based compensation and stock option exercises.

NOTE 6 STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

Total shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 1,055,849 shares at March 31, 2016.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2016:

	Number of shares	Weighted-average exercise price	Weighted-average contractual term	Aggregate intrinsic value

				(in years)	
Outstanding at December 31, 2015	5,411,557	$	10.96	7.2	$ 2,049,329
Granted	1,690,550		3.44		
Exercised	(22,425)		2.75		$ 52,698
Forfeited	(218,087)		9.09		
Expired	(369,674)		14.72		
Outstanding at March 31, 2016	6,491,921	$	8.88	7.9	$ 3,544,992
Vested and expected to vest at March 31, 2016	6,240,311	$	8.90	7.9	$ 3,401,256
Exercisable at March 31, 2016	2,708,307	$	9.85	6.1	$ 1,383,548

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Upon the exercise of stock options, we issue new shares of our common stock. As of March 31, 2016, 100,000 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 to four years. The following table summarizes restricted share activity for the three months ended March 31, 2016:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2015	1,344,747	$ 11.59	$ 6,790,972
Granted	747,825	3.35	
Vested	(114,806)	14.50	$ 520,704
Forfeited	(93,074)	8.99	
Outstanding at March 31, 2016	1,884,692	$ 8.27	$ 8,801,512

As of March 31, 2016, 560,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred $3.3 million and $4.3 million of non-cash compensation expense related to equity incentive grants during the three months ended March 31, 2016 and 2015, respectively. The following table reflects stock-based compensation expense for the three month period ended March 31, 2016 and 2015:

	Three months ended March 31,	
(in thousands)	2016	2015
Cost of goods sold	$ 6	$ 1
Research and development	705	921
Selling, general and administrative	2,582	3,399
Total stock-based compensation expense	$ 3,293	$ 4,321

Stock-based compensation costs capitalized as part of inventory were immaterial for the three months ended March 31, 2016 and 2015.

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data, 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.

Black-Scholes Option Valuation Assumptions	**Three months ended March 31,**	
	2016	**2015**
Risk-free interest rates	1.6%	1.7%
Dividend yield		
Volatility	82.0%	91.6%
Weighted-average expected term	6.0 years	6.0 years

The weighted average grant date fair value of options granted for the three months ended March 31, 2016 and 2015 was $2.41 and $10.83, respectively. We used historical information to estimate forfeitures within the valuation model. As of March 31, 2016, there was $17.2 million and $7.8 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.2 years and 1.6 years, respectively. These amounts do not include, as of March 31, 2016, 100,000 options outstanding and 560,000 shares of restricted stock outstanding 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.

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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, JT s pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan, which is being marketed in the United States under the trade name Auryxia. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective as of June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, 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 2013, JT and Torii filed its new drug application, or NDA, with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of $7.0 million in January 2013 for the achievement of the NDA filing milestone.

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 being 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 license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens and may also receive up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred. For the three months ended March 31, 2016 and 2015, we recorded $1.2 million and $0.8 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of ferric citrate, in the same period as the royalty revenue from JT and Torii is recorded. For the three months ended March 31, 2016 and 2015, we recorded $0.7 million and $0.5 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. Under the terms of the Indenture, the Notes may be converted into shares of our common stock at the discretion of Baupost. In furtherance thereof, we will seek stockholder approval of an amendment to our certificate of incorporation to increase in the number of authorized shares of our common stock to ensure that we have an adequate authorized share reserve to cover any conversions of the Notes by Baupost, and if the necessary share increase is not approved by our stockholders by July 1, 2016, we may pay a portion of the

conversion amount in cash. Further, the Indenture subjects us to certain financial and business covenants and contains restrictions on the payments of cash dividends.

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

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

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

Under the terms of the Indenture, prior to the Shareholder Approval Deadline, any conversion by Baupost shall be deemed a partial share settlement and partial cash settlement, based on a pro-rata portion of the Notes based on the original convertible and contingently convertible par values of the Notes. In such an event, the contingently convertible portion of the Notes would be settled subsequent to July 1, 2016 in a manner dictated by whether shareholder approval of the amendment to our certificate of incorporation discussed above is obtained by the Shareholder Approval Deadline. If we are required to satisfy our obligation partially in cash, we will pay an amount for each $1,000 principal amount of the Notes being converted equal to the sum of the Daily Conversion Values for each of the five consecutive trading days following conversion notice, where the Daily Conversion Value for each day is 20% of the product of (a) the conversion rate on such trading day and (b) the daily volume-weighted average price for such trading day.

In accordance with accounting guidance for debt with a conversion option, we separated the conversion option from the debt instrument and account for it separately as a derivative liability, due to the Notes being partially convertible

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

Our outstanding convertible notes and derivative liability balances as of March 31, 2016 and December 31, 2015 consisted of the following:

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(in thousands)	March 31, 2016	Fair Value Adjustment	December 31, 2015
Debt component:			
Principal	$ 125,000		$ 125,000
Less: debt discount	(18,479)		(34,227)
Net carrying amount	$ 106,521		$ 90,773
Derivative liability	$ 48,693	$ 2,007	$ 46,686

We determined the expected life of the debt was equal to the period through July 1, 2016, as this represents the point at which a portion of the Notes is contingently convertible into cash. Accordingly, 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. As of March 31, 2016 and December 31, 2015, the carrying value of the Notes was $106.5 million and $90.8 million, respectively, and the fair value of the Notes was $138.3 million and $132.9 million, respectively.

NOTE 9 OTHER INCOME (EXPENSE), NET

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

(in thousands)	Three months ended March 31, 2016	2015
Interest income	$ 202	$ 107
Other income	6	
Fair value adjustment to derivative liability	(2,007)	
	$ (1,799)	$ 107

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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, 2015 as updated under the heading Risk Factors in this report. 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 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, 2015.

OVERVIEW

We are a biopharmaceutical company focused on bringing innovative medicines to market for people with renal disease. Our product, Auryxia (ferric citrate), also known as Riona in Japan and Fexeric in Europe, is an oral, absorbable iron-based medicine, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our investigational medicine in Phase 3, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

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

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with stage 3-5 non-dialysis dependent chronic kidney disease, or NDD-CKD. This study s primary endpoint was the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period of the study. Secondary endpoints in the Phase 3 study include the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The top-line results showed that treatment with ferric citrate in the registration trial demonstrated statistically significant differences as compared to placebo for the primary and all pre-specified secondary endpoints. The majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period as compared to 19 percent in the placebo group. Additionally, the safety profile of the drug candidate was consistent with previously reported clinical studies of ferric citrate. We believe the initial data support our plan to submit a supplemental new drug application, or sNDA in the third quarter of 2016 seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD.

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

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

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

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible notes, option and warrant exercises, interest income, and the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Even though we are commercializing Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for Auryxia, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize Auryxia alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of Auryxia. In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C., or Baupost. In order to accommodate the full conversion of the Notes into shares of our common stock, we will seek stockholder approval of an amendment to our certificate of incorporation at the 2016 Annual Meeting of Stockholders to increase the number of authorized shares of our common stock. If the necessary share increase is not approved by our stockholders by July 1, 2016, we may pay a portion of the conversion amount in cash. As of March 31, 2016, Baupost beneficially owns approximately 24% of our issued and outstanding common stock. If all of the Notes were converted prior to the approval of the necessary increase in authorized shares, Baupost would beneficially own approximately 28% of our issued and outstanding common stock and Baupost s beneficial ownership of our issued and outstanding common stock would increase to approximately 43% if the remaining Notes were converted into our common stock. In addition, in January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses, in an underwritten public offering of our common stock.

Most of our biopharmaceutical development and substantially all of our administrative operations during the three months ended March 31, 2016 and 2015 were conducted in the United States of America.

Financial Performance Overview

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

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

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

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

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

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

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

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

Even though our trials demonstrated that Auryxia is effective in the control of serum phosphorus levels in patients with CKD on dialysis, there is no guarantee that we will be able to record meaningful commercial sales of Auryxia in the future or become profitable. In addition, we expect losses to continue as we continue to fund the development and commercialization of Auryxia, including, but not limited to, supplemental new drug application submissions building of inventory, commercial activities, ongoing and additional clinical trials, and the potential acquisition and development of additional drug candidates in the future. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RECENT DEVELOPMENTS

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent chronic kidney disease, or NDD-CKD. This study s primary endpoint was the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period. Secondary endpoints in the Phase 3 study include the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The top-line results showed that the registration trial demonstrated statistically significant differences versus placebo for the primary and all pre-specified secondary endpoints. The study showed

that the majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL increase in hemoglobin vs. 19 percent in the placebo group. Additionally, the safety profile was consistent with previously reported clinical studies. These data support our plan to submit a supplemental new drug application, or sNDA, in the third quarter of 2016 seeking to expand ferric citrate s indication.

In March 2016, we announced that Steven C. Gilman, Ph.D., and Michael Rogers were appointed as independent directors to our Board of Directors. Additionally, we announced that Michael Tarnok, Jack Kaye, Senator Wyche Fowler, Jr., and Joseph Feczko, M.D. will not seek re-election to our Board of Directors when their terms expire at our upcoming 2016 Annual Meeting of Stockholders.

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

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

Revenue Recognition and Related Sales Allowances and Accruals

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

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of

payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product sales from the sales to Customers and (ii) reasonably estimate our net product sales. We calculate gross product sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns and (d) estimated costs of incentives offered to certain indirect customers, including patients.

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

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

Product Returns: For the three months ended March 31, 2016, and for the year ended December 31, 2015, the first full period in which we began selling Auryxia, we were not able to reasonably estimate product returns for all product sold to Customers. Once sufficient data exists or we are able to reasonably estimate the amount of Auryxia that will be returned, we will deduct these estimated amounts from our gross revenues at the time that revenues are recognized. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of March 31, 2016, we have experienced an immaterial number of product returns.

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

The following table summarizes U.S. Auryxia product sales recognized and deferred during the three months ended March 31, 2016 and 2015, and the year ended December 31, 2015:

(in thousands)	March 31, 2016	March 31, 2015	December 31, 2015
Net U.S. Auryxia sales recognized	$ 5,616	$ 422	$ 10,141
Deferred product sales	3,718	714	3,526

$ 9,334	$ 1,136	$ 13,667

In conjunction with our recognition and deferral of U.S. Auryxia product sales, we expensed and capitalized the associated cost of goods, as follows, during the three months ended March 31, 2016 and 2015, and the year ended December 31, 2015:

(in thousands)	**March 31, 2016**	**March 31, 2015**	**December 31, 2015**
Cost of goods sold expensed	$ 1,071	$ 76	$ 4,520
Finished goods inventory held by others	803	107	231
	$ 1,874	$ 183	$ 4,751

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We recognize license revenue in accordance with Accounting Standards Codification 605, *Revenue Recognition*, or ASC 605. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

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

Stock-Based Compensation

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

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

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

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset 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

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agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our consolidated financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Inventory

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

Accounts Receivable, Allowances for Doubtful Accounts and Cash Discounts

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 consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at March 31, 2016 and December 31, 2015.

Accounting Related to Goodwill

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit s carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit s goodwill is compared with the carrying amount of the unit s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

RECENTLY ISSUED ACCOUNTING PRONOUNCEMENTS

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

RESULTS OF OPERATIONS

Three months ended March 31, 2016 and March 31, 2015

Net U.S. Auryxia Product Sales. For the three months ended March 31, 2016, we recognized $5.6 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $0.4 million for the three months ended March 31, 2015.

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	Three months ended March 31,			
(in thousands)	2016	Percent of gross Auryxia product sales	2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 8,625		$ 964	
Less provision for product sales allowances and accruals				
Trade allowances	1,146	13%	100	10%
Rebates, chargebacks and discounts	1,678	20%	30	3%
Product returns				
Other incentives (1)	185	2%	412	43%
Total	3,009	35%	542	56%
Net U.S. Auryxia product sales	$ 5,616		$ 422	

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

We sell product to a limited number of major wholesalers, which we refer to as our Distributors, as well as certain pharmacies, which we refer to collectively as our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with our revenue recognition policy, until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue recognition is deferred until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product), and not based on sales from us to our Customers. At March 31, 2016, we have deferred revenues of $3.7 million, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and chargebacks. U.S. Auryxia product sales and patient prescriptions have increased on a quarter-by-quarter basis since Auryxia s launch in December 2014. We expect Auryxia product sales and patient prescriptions to increase on a quarter-by-quarter basis throughout 2016 as we continue the commercialization of Auryxia and as physicians continue to gain experience treating their patients with Auryxia.

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

License Revenue. For the three months ended March 31, 2016, we recognized $1.2 million in license revenue on royalty payments from sales of Riona in Japan as compared to $0.8 million for the three months ended March 31, 2015. 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, 2016, we recognized $1.1 million in cost of goods sold related to product sales of Auryxia, as compared to $0.1 million for the three months ended March 31, 2015. The increase is attributable to increased sales of Auryxia.

License Expenses. For the three months ended March 31, 2016, we recognized $0.7 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.5 million for the three months ended March 31, 2015. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $2.0 million, or 21%, to $7.6 million for the three months ended March 31, 2016, as compared to $9.6 million for the three months ended March 31, 2015. The decrease in research and development expenses was due to a decrease in regulatory, clinical and medical affairs expenses related to the development of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD. We expect our research and development expenses to remain relatively consistent on a quarterly basis throughout 2016. In total, we expect 2016 research and development expenses to decline from 2015 following the completion of our pivotal Phase 3 study of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD.

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Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $1.9 million, or 10%, to $20.8 million for the three months ended March 31, 2016, as compared to $18.9 million for the three months ended March 31, 2015. The increase was primarily due to an increase in personnel and related costs associated with the continued commercialization of Auryxia. We expect our selling, general and administrative costs to remain relatively consistent on a quarterly basis throughout 2016. In total, we expect 2016 selling, general and administrative expenses to decline slightly from 2015.

Other income (expense), net. Other income (expense), net for the three months ended March 31, 2016 was a $17.6 million expense as compared to $0.1 million in income for the three months ended March 31, 2015. This increase in expense was primarily the result of $15.7 million of interest expense recorded related to the amortization of the debt discount recognized in connection with the issuance of the Notes in October 2015. Additionally, we recorded $2.0 million of expense for the three months ended March 31, 2016 related to the increase in fair value of the derivative liability from December 31, 2015 to March 31, 2016. This derivative liability was recorded in connection with the issuance of the Notes in October 2015 and represents the portion of the Notes that is required to be accounted for separately. See Note 8 Debt for additional details.

Income Taxes. For the three months ended March 31, 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, as compared to $22,000 in income tax expense for the three months ended March 31, 2015. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP, since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. We continue to maintain a full valuation allowance against the entire amount of our net deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible notes, option and warrant exercises, interest income, and from the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. The commercial launch of our product, Auryxia, occurred in late December 2014 and we began to recognize revenue from the sales of Auryxia in 2015. Even though we are commercializing Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

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

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

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In January 2014, our Japanese partner, JT and Torii, received manufacturing and marketing approval of Riona from the Japanese Ministry of Health, Labour and Welfare. We receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

As of March 31, 2016, we had $170.5 million in cash and cash equivalents, as compared to $200.3 million in cash and cash equivalents at December 31, 2015, representing a decrease of $29.8 million.

We currently expect that our existing capital resources and future anticipated cash flows will be sufficient to execute our current business objectives. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the continued commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire. For a detailed discussion regarding the risks and uncertainties related to our liquidity and capital resources, please refer to our Risk Factor, Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated included in our Annual Report on Form 10-K for the year ended December 31, 2015 and the other risk factors contained therein.

Net cash used in operating activities for the three months ended March 31, 2016 was $27.7 million as compared to $35.3 million net cash used in operating activities of for the same period in 2015. This decrease in net cash used in operating activities was primarily related to Auryxia commercial expenditures to support the launch in 2015, including the manufacturing of inventory.

Net cash used in investing activities for the three months ended March 31, 2016 was $2.0 million as compared to $11.4 million net cash provided by investing activities for the same period in 2015. The increase in cash used in investing activities was primarily attributable to maturities of short-term investments in 2015, with no such activity in 2016.

Net cash provided by financing activities for the three months ended March 31, 2016 was less than $0.1 million attributable the exercise of stock options. Net cash provided by financing activities for the same period in 2015 was $118.4 million, primarily attributable to the net proceeds received from our public offering of common stock in January 2015 of $118.3 million.

OBLIGATIONS AND COMMITMENTS

As of March 31, 2016, 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, 2015.

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, we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets useful lives or the remaining lease term, whichever is shorter.

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The lease for our New York City office will expire on September 30, 2016 and we have notified our landlord that we will not renew our lease.

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. To date, we have paid an aggregate of $11.6 million of milestone payments to Panion, including the $2.0 million paid upon European marketing approval in 2015. In addition, Panion is eligible to receive royalty payments based on a mid-single digit percentage of net sales of Auryxia in 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, 2016, our portfolio of financial instruments consists of cash equivalents, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

Equity Price Risk

Our Notes issued to Baupost include conversion and settlement provisions that are based on the price of our common stock at conversion or at maturity of the Notes. The amount of cash we may be required to pay upon conversion of the Notes is determined by the price of our common stock. The fair value of the Notes is 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. See Note 3 Fair Value Measurements and Note 8 Debt for a description of the Notes and their fair value.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of March 31, 2016, 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, 2016, our disclosure controls and procedures were effective.

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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, 2016, that have materially affected, or are reasonably likely to materially affect, our internal control 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

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

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, 2015. There have been no material changes from the risk factors previously disclosed in that Annual Report on Form 10-K , except as follows:

The second risk factor under the caption Risks associated with our product development efforts is replaced with the following risk factor:

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

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with non-dialysis dependent chronic kidney disease, or NDD-CKD. Despite our positive top-line results, the FDA may not concur with our interpretation of our Phase 3 study results, supportive data, conduct of the studies, or any other part of our regulatory submission and could ultimately deny approval of ferric citrate for the treatment of IDA in adults with stage 3-5 NDD-CKD. Additionally, we may need to conduct significant additional research and human testing before we may submit an application for regulatory approval. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product. It requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. The FDA may pose additional questions or request further toxicological, drug-drug interaction, pre-clinical or clinical data or substantiation. Negative, inconclusive, or insufficient results or medical events during a pre-clinical or clinical trial could cause us to delay or terminate our

development efforts. Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies.

Safety signals detected during clinical studies and pre-clinical animal studies, such as the gastrointestinal bleeding and liver toxicities that have been seen in some high-dose ferric citrate canine studies, may require us to perform additional safety studies or analyses, which could delay the development of the drug or lead to a decision to discontinue development of the drug. While both the FDA and EC have previously reviewed the data from our Phase 3 clinical program for CKD patients on dialysis and Phase 2 study in NDD CKD patients, we can provide no assurance that the FDA will not raise any safety concerns in the future from these studies. Drug candidates in the later stages of clinical development may fail to show the desired traits of safety and efficacy despite positive results in earlier clinical testing. The risk also remains that a clinical program conducted by one of our partners may raise efficacy or safety concerns that may prevent approval of the drug. In addition, qualitative, quantitative and statistical interpretation of any of the prior pre-clinical and clinical safety and efficacy data of our drug may be viewed as flawed by the FDA. In addition, there can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted by us or our consultants, which in subsequent, larger studies might appear and prevent approval of such drug candidate.

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

ITEM 2. UNREGISTERED SALES OF EQUITY SECURITIES AND USE OF PROCEEDS

Recent Sales of Unregistered Securities

On January 28, 2016, we issued an aggregate of 430,000 shares of restricted stock to eight of our employees as incentive compensation under our 2013 Incentive Plan. The offer, sale, and issuance of these shares of restricted stock were deemed to be exempt from registration under the Securities Act in reliance on Section 4(a)(2) of the Securities Act as transactions by an issuer not involving a public offering. Each of the recipients of the shares of restricted stock acquired the securities for investment only and not with a view to or for sale in connection with any distribution thereof and appropriate legends were affixed to the securities. Each of the recipients of the shares of restricted stock was an accredited investor and had adequate access, through employment relationships, to information about us.

ITEM 6. EXHIBITS

The exhibits listed on the Exhibit Index are included with this report.

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 April 28, 2016.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated April 28, 2016.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated April 28, 2016.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated April 28, 2016.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

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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: April 28, 2016

By: /s/ Scott A. Holmes
Chief Financial Officer
Principal Financial and Accounting Officer

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EXHIBIT INDEX

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

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