KERYX BIOPHARMACEUTICALS INC
Form 10-Q
November 09, 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 September 30, 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 105,960,364 shares of the registrant s common stock, $0.001 par value, outstanding as of November 4, 2016.

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KERYX BIOPHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 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 in our subsequent Quarterly Reports on Form 10-Q as well as under the captions Risk Factors, Management s Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Auryxia® (ferric citrate), market share and product sales guidance;
- expectations regarding the commercialization of Auryxia, including statements relating to the interruption in the supply of Auryxia and when Auryxia may be available to patients again;
- 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® (ferric citrate coordination complex) in the European market;
- expectations for generating revenue, positive cash flow or becoming profitable on a sustained basis;
- estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements;
- expected losses;
- expectations for future capital requirements;

expectations for increases or decreases in expenses;

expectations for pre-clinical and clinical development and regulatory progress, including manufacturing, commercialization and reimbursement (including market acceptance) of ferric citrate or any other products that we may acquire or in-license;

expectations for incurring capital expenditures to expand our development and manufacturing capabilities;

expectations regarding our ability to successfully market Riona® through our Japanese partner, Japan Tobacco, Inc. and its subsidiary Torii Pharmaceutical Co., Ltd.;

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

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

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

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

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.

Condensed Consolidated Balance Sheets as of September 30, 2016 and December 31, 2015

(in thousands, except share and per share amounts)

	September 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 132,172	$ 200,290
Inventory	24,313	41,881
Accounts receivable, net		3,656
Receivable from landlord		637
Other current assets	3,469	2,830
Total current assets	159,954	249,294
Property, plant and equipment, net	4,439	5,083
Goodwill	3,208	3,208
Other assets, net	1,024	1,100
Total assets	$ 168,625	$ 258,685
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 13,115	$ 21,322
Accrued compensation and related liabilities	4,923	5,473
Deferred revenue		3,526
Derivative liability		46,686
Deferred lease incentive, current portion	244	244
Other current liabilities		355
Total current liabilities	18,282	77,606
Convertible senior notes	125,000	90,773
Deferred lease incentive, net of current portion	1,323	1,506
Deferred tax liability	850	790
Other liabilities	1,181	1,076

Total liabilities		146,636		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 (180,000,000 and 130,000,000 shares authorized, 106,040,312 and 105,221,555 shares issued, 105,960,364 and 105,141,607 shares outstanding at September 30, 2016 and December 31, 2015, respectively)		106		105
Additional paid-in capital		823,554		761,189
Treasury stock, at cost, 79,948 shares at September 30, 2016 and December 31, 2015		(357)		(357)
Accumulated deficit		(801,314)		(674,003)
Total stockholders equity		21,989		86,934
Total liabilities and stockholders equity	$	168,625	$	258,685

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

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Keryx Biopharmaceuticals, Inc.

Condensed Consolidated Statements of Operations

for the three and nine months ended September 30, 2016 and 2015 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
Revenues:				
Net U.S. Auryxia product sales	$ 5,050	$ 3,191	$ 18,945	$ 5,371
License revenue	1,287	1,017	3,505	2,526
Total revenues	6,337	4,208	22,450	7,897
Operating expenses:				
Cost of goods sold	18,196	3,065	24,365	3,445
License expenses	772	611	2,103	1,516
Research and development	8,674	11,150	23,320	28,704
Selling, general and administrative	20,521	20,205	61,518	59,847
Total operating expenses	48,163	35,031	111,306	93,512
Operating loss	(41,826)	(30,823)	(88,856)	(85,615)
Other income (expense):				
Amortization of debt discount			(34,226)	
Other income (expense), net	150	100	(4,169)	321
Total other income (expense)	150	100	(38,395)	321
Loss before income taxes	(41,676)	(30,723)	(127,251)	(85,294)
Income taxes	20	22	60	67
Net loss	$ (41,696)	$ (30,745)	$ (127,311)	$ (85,361)
Basic and diluted net loss per common share	$ (0.39)	$ (0.29)	$ (1.20)	$ (0.83)
Weighted average shares used in computing basic and diluted net loss per common share	105,924,106	105,205,170	105,805,669	103,458,248

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

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Keryx Biopharmaceuticals, Inc.

Condensed Consolidated Statements of Cash Flows

for the nine months ended September 30, 2016 and 2015 (Unaudited)

(in thousands)

	Nine months ended September 30,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (127,311)	$ (85,361)
Adjustments to reconcile loss to cash flows used in operating activities:		
Stock-based compensation expense	10,563	12,950
Amortization of debt discount	34,226	
Change in fair value of derivative liability	4,718	
Depreciation and amortization	776	431
Loss on disposal of fixed assets	54	
Write-down of inventory to net realizable value	16,352	
Cash received from landlord	637	
Amortization of deferred lease incentive	(183)	(102)
Deferred income taxes	60	67
Changes in operating assets and liabilities:		
Other current assets	(563)	(197)
Accounts receivable, net	3,656	(1,794)
Accrued interest receivable		48
Inventory	(2,148)	(27,519)
Security deposits		(807)
Other current liabilities	(355)	
Accounts payable and accrued expenses	(2,763)	(2,357)
Accrued compensation and related liabilities	(550)	(312)
Deferred revenue	(3,526)	1,571
Other liabilities	105	514
Net cash used in operating activities	(66,252)	(102,868)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(2,064)	(432)
Proceeds from maturity of held-to-maturity securities		11,508
Net cash (used in) provided by investing activities	(2,064)	11,076

CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from public offerings, net		118,284
Surrender of common stock for tax withholding		(15)
Proceeds from exercise of options	198	1,447
Net cash provided by financing activities	198	119,716
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(68,118)	27,924
Cash and cash equivalents at beginning of year	200,290	74,284
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 132,172	$ 102,208
Non-cash financing activities:		
Reclassification of derivative liability to equity	$ 51,404	$
Increase of receivable from landlord and deferred lease incentive	$	$ 1,913

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

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Keryx Biopharmaceuticals, Inc.

Notes to Condensed Consolidated Financial Statements (unaudited)

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

NOTE 1 DESCRIPTION OF BUSINESS

We are a biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our marketed 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 trade name Riona and marketed by our Japanese partner, Japan Tobacco Inc., or JT, and its subsidiary, Torii Pharmaceutical Co. Ltd., or Torii, and approved in Europe as Fexeric. 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 target nephrologists and their associated dialysis centers.

On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue in converting active pharmaceutical ingredient, or API, to finished drug product at our existing contract manufacturer. This issue resulted in variable production yields of finished drug product and, as a result, we exhausted our reserve of finished drug product. Inventories of Auryxia were not sufficient to ensure uninterrupted patient access to this medicine. The supply interruption does not affect the safety profile of currently available Auryxia. We are working with our existing manufacturer to resolve the production-related issue. In addition, since approval of Auryxia in 2014, we have been working to bring a secondary manufacturer online to supply finished drug product. We recently filed for approval of this manufacturer with the FDA and the FDA has assigned a Prescription Drug User Fee Act, or PDUFA, action date of November 13, 2016. Pending FDA approval of our second manufacturing site on the assigned PDUFA action date, we expect to make Auryxia available to patients during the fourth quarter of 2016, however, there can be no assurances that this manufacturer will be approved or that Auryxia will be available to patients within this time period. This supply interruption does not affect the supply of Riona manufactured and sold by JT in Japan.

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 investigational medicine was consistent with previously reported clinical studies of ferric citrate, with the majority of adverse events reported as mild to moderate. We believe this initial data supports our plan to submit a supplemental new drug application, or sNDA, with the FDA seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD. The Company has completed the sNDA and is ready to submit to the FDA pending final agreement on its pediatric plan.

Our Japanese partner, JT and 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. Additionally, in the third quarter of 2016, JT and Torii commenced enrollment in a Phase 2 clinical trial of ferric citrate for the treatment of IDA. 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.

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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 net product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, license revenue from the sublicensing of rights to ferric citrate in Japan to our Japanese partner. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible senior notes, option and warrant exercises, interest income, upfront and milestone payments from our agreement with JT and Torii, sales of Auryxia 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 January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses, in an underwritten public offering of our common stock. Additionally, in October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C., or Baupost. As of September 30, 2016, Baupost beneficially owns approximately 24% of our issued and outstanding common stock. If all of the Notes were converted into our common stock, Baupost would beneficially own approximately 42% of our issued and outstanding common stock.

Most of our biopharmaceutical development and substantially all of our administrative operations during the three and nine months ended September 30, 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 condensed consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles, or GAAP, for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of these interim financial statements have been included. These interim 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 and nine months ended September 30, 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 condensed consolidated financial statements include our financial statements and those of our wholly-owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities

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at the date of these condensed consolidated financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to these condensed consolidated financial statements.

Cash and Cash Equivalents

We consider liquid investments with original maturities of three months or less when purchased to be cash and cash equivalents. At September 30, 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 net realizable value. We determine the cost of our inventory, which includes amounts related to materials, third-party contract manufacturing and packaging services, and manufacturing overhead, on a first-in, first-out basis. We capitalize inventory costs at our suppliers when, based on management s judgment, the realization of future economic benefit is probable at each given supplier. We received FDA approval for Auryxia on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers was included as a component of research and development expense.

Accounts Receivable, Net

We extend credit to our customers for U.S. Auryxia product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to certain of our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the condensed consolidated balance sheets net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at September 30, 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) collectibility 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 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 condensed consolidated balance sheets, until revenue

related to such product sales is recognized. We will change our method of revenue recognition from the sell-through (deferred) method based on the fulfillment of patient prescriptions to the pull-through (ex-factory) method based on sales to our Customers beginning in the fourth quarter of 2016, based on our ability to reasonably estimate product returns.

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

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sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid reimbursements, (c) reserves for expected product returns, upon our ultimate transition to a sell-in revenue recognition model and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services, such as fees for certain data that Distributors provide to us. The payment terms for sales to Distributors generally include a prompt-pay discount for payment made 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 nine months ended September 30, 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 generally occurs within a few months before Auryxia is delivered to Customers. As of September 30, 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 and nine months ended September 30, 2016 and 2015 were offset by provisions for allowances and accruals as set forth in the tables below.

(in thousands)	Three months ended September 30, 2016	Percent of gross Auryxia product sales	Three months ended September 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 8,711		$ 4,736	
Less provision for product sales allowances and accruals				
Trade allowances	750	9%	557	12%
Rebates, chargebacks and discounts	2,787	32%	654	14%
Product returns				
Other incentives (1)	124	1%	334	7%
Total	3,661	42%	1,545	33%
Net U.S. Auryxia product sales	$ 5,050		$ 3,191	

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

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(in thousands)	Nine months ended September 30, 2016	Percent of gross Auryxia product sales	Nine months ended September 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 29,896		$ 8,797	
Less provision for product sales allowances and accruals				
Trade allowances	3,451	12%	1,005	11%
Rebates, chargebacks and discounts	7,008	23%	824	9%
Product returns				
Other incentives (1)	492	2%	1,597	18%
Total	10,951	37%	3,426	38%
Net U.S. Auryxia product sales	$ 18,945		$ 5,371	

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

The following table summarizes net U.S. Auryxia product sales recognized and deferred during the three and nine months ended September 30, 2016 and 2015.

(in thousands)	Three months ended September 30, 2016	Three months ended September 30, 2015	Nine months ended September 30, 2016	Nine months ended September 30, 2015
Net U.S. Auryxia sales recognized	$ 5,050	$ 3,191	$ 18,945	$ 5,371
Change in deferred product sales	(3,358)	455	(3,526)	1,571
	$ 1,692	$ 3,646	$ 15,419	$ 6,942

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 is not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

For arrangements for which royalty revenue information becomes available and collectibility is reasonably assured, we recognize revenue during the applicable period earned. When collectibility is reasonably assured but a reasonable

estimate of royalty revenue cannot be made, the royalty revenue is recognized in the quarter that the licensee provides the written report and related information to us.

Cost of Goods Sold

Cost of goods sold includes the cost of API for Auryxia on which product sales were recognized during the period, as well as the associated costs for tableting, packaging, shipment, insurance and quality assurance, as well as any idle capacity charges we may incur at our contract manufacturers and write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture. Cost of goods sold also includes expenses due to the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

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In conjunction with our recognition and deferral of net U.S. Auryxia product sales, we expensed and capitalized the associated cost of goods, as follows, during the three and nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2016	2015	2016	2015
Cost of goods sold expensed	$ 18,196	$ 3,065	$ 24,365	$ 3,445
Change in finished goods inventory held by others	(1,233)	35	(231)	121
	$ 16,963	$ 3,100	$ 24,134	$ 3,566

Finished goods inventory held by others as of September 30, 2015 represents the cost of goods sold that has been deferred to align with our deferral of net U.S. Auryxia product sales. We did not have any finished goods inventory held by others as of September 30, 2016. During the three and nine months ended September 30, 2016, we expensed $13.8 million and $16.0 million, respectively, of work-in-process inventory no longer suitable for commercial manufacture, which was recorded in cost of goods sold.

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. Non-refundable advance payments for goods or services that will be used or rendered for future research and development activities are deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial 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 condensed 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 condensed 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

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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 September 30, 2016 and 2015, which are not included in the computation of net loss per share amounts, were 8,823,096 and 5,340,559, 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.

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, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For the period ending September 30, 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 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 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 December 31, 2015. We did not have any accounts receivable, net as of September 30, 2016.

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

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We currently depend on a single supply source for Auryxia drug product. On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue at this supplier of Auryxia. We have been working to bring a secondary manufacturer online to supply finished Auryxia drug product. The FDA has assigned a PDUFA action date of November 13, 2016 for our application for approval of this manufacturer. Pending FDA approval of this manufacturer on the PDUFA action date, we expect to make Auryxia available to patients during the fourth quarter of 2016, however, there can be no assurances that this manufacturer will be approved or that Auryxia will be available to patients within this time period. As a result of this supply interruption, we expect revenues to decline significantly for at least the remainder of 2016. In addition, if any of our other suppliers were to limit or terminate production, or otherwise fail to meet the quality or delivery requirements needed to supply Auryxia at adequate levels, we could experience additional losses of revenue, which could materially and adversely impact our results of operations.

Leases

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

The lease for our New York City office expired on September 30, 2016 and we did not renew our lease.

Recently Issued and Proposed Accounting Pronouncements

In May 2014, the Financial Accounting Standards Board, or the FASB, issued Accounting Standards Update, or ASU, No. 2014-09, *Revenue from Contracts with Customers (Topic 606)*, a comprehensive new standard which amends revenue recognition principles and provides a single set of criteria for revenue recognition among all industries. The new standard provides a five-step framework whereby revenue is recognized when promised goods or services are transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. The standard also requires enhanced disclosures pertaining to revenue recognition in both interim and annual periods. The 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. In April 2016, the FASB issued ASU No. 2016-10, *Revenue from Contracts with Customers (Topic 606): Identifying Performance Obligations and Licensing*, which clarifies certain aspects of identifying performance obligations and licensing implementation guidance. In May 2016, the FASB issued ASU No. 2016-12, *Revenue from Contracts with Customers (Topic 606): Narrow-Scope Improvements and Practical Expedients*, which amends narrow aspects of Topic 606, including guidance on assessing collectibility, non-cash consideration, contract modifications and completed contracts at transition, and the presentation of sales and other similar taxes collected from customers. 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.

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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. This standard is not expected to have a material impact on our financial position, results of operations or statement of cash flows upon adoption.

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

NOTE 3 FAIR VALUE MEASUREMENTS

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

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

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

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

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 condensed 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 September 30, 2016 and December 31, 2015:

	Financial assets at fair value as of September 30, 2016			Financial assets at fair value as of December 31, 2015		
(in thousands)	Level 1	Level 2	Level 3	Level 1	Level 2	Level 3
Assets:						
Money market funds (1)	$ 129,942	$	$	$ 193,886	$	$
Total assets	$ 129,942	$	$	$ 193,886	$	$

Liabilities:					
Derivative liability	$	$	$	$	$ 46,686
Total liabilities	$	$	$	$	$ 46,686

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

In October 2015, we issued the Notes in a private financing to funds managed by Baupost. As of September 30, 2016 and December 31, 2015, the fair value of the Notes was $177.5 million and $132.9 million, respectively, which differs from their carrying value. The fair value of the Notes is influenced by interest rates, our stock price and stock price volatility. See Note 8 Debt for additional information on our debt obligations.

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Per the terms of the Notes, a portion of the Notes was contingently convertible into cash if our stockholders did not approve an increase in the number of authorized shares of our common stock by July 1, 2016. At our 2016 Annual Meeting of Stockholders held on May 25, 2016, the necessary stockholder approval of the increase in authorized shares was obtained. As a result, the entirety of the Notes is now convertible into shares of our common stock.

NOTE 4 INVENTORY

Inventory consists of the following at September 30, 2016 and December 31, 2015:

(in thousands)	September 30, 2016	December 31, 2015
Raw materials	$ 418	$ 495
Work in process	22,994	40,124
Finished goods	901	1,031
Finished goods inventory held by others		231
Total inventory	$ 24,313	$ 41,881

During the three months ended September 30, 2016, we expensed $13.8 million of work-in-process inventory no longer suitable for commercial manufacture, which was recorded in cost of goods sold.

NOTE 5 STOCKHOLDERS EQUITY

Change in Stockholders Equity

Total stockholders equity decreased by $65.0 million during the nine months ended September 30, 2016. This decrease was primarily attributable to our net loss of $127.3 million, partially offset by the reclassification of the derivative liability to equity of $51.4 million and $11.0 million related to stock-based compensation and stock option exercises.

NOTE 6 STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

As of September 30, 2016, a total of 6,912,531 shares were available for the issuance of stock options or other stock-based awards under our stock option and incentive plans.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2016:

	Number of shares	Weighted-average exercise price

Outstanding at December 31, 2015	5,411,557	$	10.96
Granted	4,806,250		4.54
Exercised	(66,775)		2.99
Forfeited	(526,695)		8.36
Expired	(801,241)		13.97
Outstanding at September 30, 2016	8,823,096	$	7.40
Vested and expected to vest at September 30, 2016	8,090,266	$	7.73
Exercisable at September 30, 2016	3,025,391	$	10.01

Upon the exercise of stock options, we issue new shares of our common stock. As of September 30, 2016, 2,515,000 options issued to employees are unvested, performance-based options.

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Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under our equity incentive plans. The time-vesting restricted stock grants vest primarily over a period of three to four years. The following table summarizes restricted share activity for the nine months ended September 30, 2016:

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2015	1,344,747	$ 11.59
Granted	953,175	3.81
Vested	(371,890)	12.72
Forfeited	(201,193)	7.79
Outstanding at September 30, 2016	1,724,839	$ 7.49

As of September 30, 2016, 570,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred $3.7 million and $4.6 million of stock-based compensation expense related to equity incentive grants during the three months ended September 30, 2016 and 2015, respectively, and $10.6 million and $13.0 million during the nine months ended September 30, 2016 and 2015, respectively. The following table reflects stock-based compensation expense for the three- and nine-month periods ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2016	2015	2016	2015
Cost of goods sold	$ 39	$ 1	$ 53	$ 4
Research and development	542	937	2,127	2,699
Selling, general and administrative	3,120	3,637	8,367	10,247
Total stock-based compensation expense	$ 3,717	$ 4,575	$ 10,563	$ 12,950

Stock-based compensation costs capitalized as part of inventory were immaterial for the three and nine months ended September 30, 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.

The weighted average grant date fair value of stock options granted during the three months ended September 30, 2016 and 2015 was $5.94 and $5.33, respectively, and during the nine months ended September 30, 2016 and 2015 was $4.54 and $9.62, respectively. We used historical information to estimate forfeitures of stock options. As of September 30, 2016, there was $11.3 million and $4.9 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 1.2 years and 1.4 years, respectively. These amounts do not include 2,530,000 options outstanding and 570,000 shares of restricted stock outstanding as of September 30, 2016 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, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, or Revised Agreement, with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the Sublicense Agreement.

In January 2013, JT and Torii filed its new drug application, or NDA, with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD. Under the terms of the Revised Agreement, we received a non-refundable milestone payment of $7.0 million in January 2013 for the achievement of the NDA filing milestone.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, launched in May 2014 and is marketed in Japan by Torii under the brand name Riona, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the Revised Agreement, we 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 September 30, 2016 and 2015, we recorded $1.3 million and $1.0 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. For the nine months ended September 30, 2016 and 2015, we recorded $3.5 million and $2.5 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 September 30, 2016 and 2015, we recorded $0.8 million and $0.6 million, respectively, in license expenses related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan. For the nine months ended September 30, 2016 and 2015, we recorded $2.1 million and $1.5 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. The Indenture subjects us to certain financial and business covenants and contains restrictions on the payments of cash dividends.

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

Further, in connection with the Private Placement, we entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration

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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 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.

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

Our outstanding convertible senior notes balances as of September 30, 2016 and December 31, 2015 consisted of the following:

(in thousands)	**September 30, 2016**	**December 31, 2015**
Debt component:		
Principal	$ 125,000	$ 125,000
Less: debt discount	( )	(34,227)
Net carrying amount	$ 125,000	$ 90,773

We determined the expected life of the debt was equal to the period through July 1, 2016, as this represents the point at which a portion of the Notes was contingently convertible into cash. Accordingly, for the nine months ended September 30, 2016 approximately $34.2 million of interest expense was recognized related to the Notes, all of which was attributable to the amortization of the debt discount. No interest expense was recognized related to the Notes in the three months ended September 30, 2016. As of September 30, 2016 and December 31, 2015, the carrying value of the Notes was $125.0 million and $90.8 million, respectively, and the fair value of the Notes was $177.5 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 September 30, 2016	Three months ended September 30, 2015	Nine months ended September 30, 2016	Nine months ended September 30, 2015
Interest income	$ 169	$ 100	$ 556	$ 329
Other income (expense)	(19)		(7)	(8)
Fair value adjustment to derivative liability			(4,718)	
	$ 150	$ 100	$ (4,169)	$ 321

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NOTE 10 COMMITMENTS AND CONTINGENCIES

Commitments

As of September 30, 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.

Contingencies

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

Four purported class action lawsuits have been filed against us and certain of our current and former officers. Three of these actions have been filed in the United States District Court for the Southern District of New York, captioned respectively Terrell Jackson v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06131 filed on August 2, 2016, Richard J. Erickson v. Keryx Biopharmaceuticals, Inc., et al. No. 1:16-cv-06218, filed on August 4, 2016 and Richard King v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06233 on August 5, 2016. The Jackson complaint purports to be brought on behalf of stockholders who purchased our common stock between February 25, 2016 and August 1, 2016, the Erickson complaint purports to be brought on behalf of stockholders who purchased our common stock between March 2, 2016 and July 29, 2016, and the King complaint purports to be brought on behalf of stockholders who purchased our stock between February 25, 2016 and July 29, 2016. On August 26, 2016, the fourth complaint, captioned Tim Karth v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-11745, was filed in the United States District Court for the District of Massachusetts. The Karth complaint purports to be brought on behalf of stockholders who purchased our stock between September 2, 2013 and August 1, 2016. Each complaint generally alleges that we and certain of our officers violated Sections 10(b) and/or 20(a) of the Exchange Act and Rule 10b-5 promulgated thereunder by making allegedly false and/or misleading statements concerning the Company and its business operations and future prospects in light of the August 1, 2016 announcement of an imminent interruption in our supply of Auryxia. Each complaint seeks unspecified damages, interest, attorneys fees, and other costs. We deny any allegations of wrongdoing and intend to vigorously defend against these lawsuits. There is no assurance, however, that we or the other defendants will be successful in our defense of either of these lawsuits or that insurance will be available or adequate to fund any settlement or judgment or the litigation costs of these actions. Moreover, we are unable to predict the outcome or reasonably estimate a range of possible losses at this time. A resolution of these lawsuits adverse to us or the other defendants, however, could have a material effect on our financial position and results of operations in the period in which the particular lawsuit is resolved.

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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 subsequent Quarterly Reports on Form 10-Q, including 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 condensed consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management s discussion and analysis and the audited consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015.

OVERVIEW

We are a biopharmaceutical company focused on bringing innovative medicines to 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. We believe that there currently are approximately 450,000 adults in the United States on dialysis of whom approximately 350,000 are on phosphate binders and eligible for treatment with Auryxia. 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 target nephrologists and their associated dialysis centers. In 2015, we reported net U.S. Auryxia product sales of $10.1 million.

On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue. See below under Supply Interruption of Auryxia for more information regarding this supply interruption.

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. We believe there are approximately 650,000 adults in the United States with CKD currently being treated for IDA. The Phase 3 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 ($p<0.001$). 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 the initial data support our plan to submit a supplemental new drug application, or sNDA, with the FDA seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD. The Company has completed the sNDA and is ready to submit to the FDA pending final agreement on its pediatric plan.

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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. Additionally, in the third quarter of 2016, JT and Torii commenced enrollment in a Phase 2 clinical trial of ferric citrate for the treatment of IDA. 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.

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, license revenue from the sublicensing of rights to ferric citrate in Japan to our Japanese partner. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible senior notes, option and warrant exercises, interest income, and the upfront and milestone payments from our agreement with JT and Torii, sales of Auyxia 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 January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses, in an underwritten public offering of our common stock. Additionally, in October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C., or Baupost. As of September 30, 2016, Baupost beneficially owns approximately 24% of our issued and outstanding common stock. If all of the Notes were converted into our common stock, Baupost would beneficially own approximately 42% of our issued and outstanding common stock.

Most of our biopharmaceutical development and substantially all of our administrative operations during the three and nine months ended September 30, 2016 and 2015 were conducted in the United States of America.

Supply Interruption of Auryxia

On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue in converting active pharmaceutical ingredient, or API, to finished drug product at our existing contract manufacturer. This issue resulted in variable production yields of finished drug product and, as a result, we exhausted our reserve of finished drug product. Inventories of Auryxia were not sufficient to ensure

uninterrupted patient access to this medicine. The supply interruption does not affect the safety profile of currently available Auryxia. We are working with our existing manufacturer to resolve the production-related issue. In addition, since approval of Auryxia in 2014, we have been working to bring a secondary manufacturer online to supply finished drug product. We recently filed for approval of this manufacturer with the FDA and the FDA has assigned a Prescription Drug User Fee Act, or PDUFA, action date of November 13, 2016. As discussed below, we recently entered into a long-term arrangement with the manufacturer to supply finished Auryxia drug product. Pending FDA approval of our second manufacturing site on the assigned PDUFA action date, we expect to make Auryxia available to patients during the fourth quarter of 2016, however, there can be no assurances that this manufacturer will be approved or that Auryxia will be available to patients within this time period. This supply interruption does not affect the supply of Riona manufactured and sold by JT in Japan.

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On October 12, 2016, we and Patheon Manufacturing Services LLC and certain of its affiliates, or Patheon, entered into a Master Manufacturing Services Agreement and two related Product Agreements for Patheon s manufacture of commercial supplies of finished Auryxia drug product tablets at Patheon s Greenville, North Carolina and Bourgoin-Jallieu Cedex, France manufacturing sites. Under the agreements with Patheon, we are responsible for supplying the API for Auryxia to Patheon. Patheon is responsible for manufacturing the Auryxia tablets, conducting quality control, quality assurance, analytical testing and stability testing, packaging, and providing related services for the Auryxia tablets. As discussed above, the FDA has assigned a PDUFA action date of November 13, 2016 for our application for approval of Patheon to manufacture finished Auryxia drug product at its Greenville, North Carolina facility.

Financial Performance Overview

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

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

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

Cost of goods sold includes the cost of API for Auryxia on which product sales were recognized during the period, the associated costs for tableting, packaging, shipment, insurance and quality assurance, as well as any idle capacity charges we may incur at our contract manufacturers and write-offs of inventory that fails to meet specifications or is otherwise no longer suitable for commercial manufacture. Cost of goods sold also includes expenses due to the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

Our license expenses consist of royalty and other expenses due to the licensor of Auryxia related to our license agreement with JT and Torii. With regard to license expense, such expense is directly related to the royalty revenue received from JT and Torii and is recognized in the same period as the 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 condensed consolidated statements of operations. We expect to continue to incur significant stock-based compensation expenses.

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

GENERAL CORPORATE

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

CRITICAL ACCOUNTING POLICIES

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

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

Revenue Recognition and Related Sales Allowances and Accruals

Our commercial launch of our only product, Auryxia, in the United States occurred in late December 2014. We sell product to a limited number of major wholesalers, 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) collectibility 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 condensed consolidated balance sheets, until revenue related to such product sales is recognized. We will change our method of revenue recognition from the sell-through (deferred) method based on the fulfillment of patient prescriptions to the pull-through (ex-factory) method based on sales to our Customers beginning in the fourth quarter of 2016, based on our ability to reasonably estimate product returns.

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

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services, such as fees for certain data that Distributors provide to us. The payment terms for sales to Distributors generally include a prompt-pay discount for payment made 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 nine months ended September 30, 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 generally occurs within a few months before Auryxia is delivered to Customers. As of September 30, 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.

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The following table summarizes net U.S. Auryxia product sales recognized and deferred during the three and nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2016	2015	2016	2015
Net U.S. Auryxia sales recognized	$ 5,050	$ 3,191	$ 18,945	$ 5,371
Change in deferred product sales	(3,358)	455	(3,526)	1,571
	$ 1,692	$ 3,646	$ 15,419	$ 6,942

In conjunction with our recognition and deferral of net U.S. Auryxia product sales, we expensed and capitalized the associated cost of goods, as follows, during the three and nine months ended September 30, 2016 and 2015:

	Three months ended September 30,		Nine months ended September 30,	
(in thousands)	2016	2015	2016	2015
Cost of goods sold expensed	$ 18,196	$ 3,065	$ 24,365	$ 3,445
Change in finished goods inventory held by others	(1,233)	35	(231)	121
	$ 16,963	$ 3,100	$ 24,134	$ 3,566

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

Stock-Based Compensation

We 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

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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 CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our condensed consolidated financial statements to the actual services received and efforts expended. As such, 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 net realizable value. We determine the cost of our inventory, which includes amounts related to materials, third-party contract manufacturing and packaging services, and manufacturing overhead, on a first-in, first-out basis. We capitalize inventory costs at our suppliers when, based on management s judgment, the realization of future economic benefit is probable at each given supplier. We received FDA approval for Auryxia on September 5, 2014, and on that date began capitalizing inventory purchases of saleable product from certain suppliers. Prior to FDA approval, all saleable product purchased from such suppliers was included as a component of research and development expense.

Accounts Receivable, 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 condensed consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at September 30, 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.

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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 condensed consolidated financial statements included in this report.

RESULTS OF OPERATIONS

Three months ended September 30, 2016 and September 30, 2015

Net U.S. Auryxia Product Sales. For the three months ended September 30, 2016, we recognized $5.1 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $3.2 million for the three months ended September 30, 2015.

(in thousands)	Three months ended September 30, 2016	Percent of gross Auryxia product sales	Three months ended September 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 8,711		$ 4,736	
Less provision for product sales allowances and accruals				
Trade allowances	750	9%	557	12%
Rebates, chargebacks and discounts	2,787	32%	654	14%
Product returns				
Other incentives (1)	124	1%	334	7%
Total	3,661	42%	1,545	33%
Net U.S. Auryxia product sales	$ 5,050		$ 3,191	

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

Gross Auryxia product sales increased for the three months ended September 30, 2016 as compared to the same period in 2015 primarily as a result of an increase in patient prescriptions and related units sold. Provisions for product sales allowances and accruals as a percentage of gross Auryxia product sales for the three months ended September 30, 2016 as compared to the same period in 2015 increased primarily as a result of additional rebates and discounts given to our Third-Party Payors.

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. We will change our method of revenue recognition from the sell-through (deferred) method based on the fulfillment of patient prescriptions to the pull-through (ex-factory) method based on sales to our Customers beginning in the fourth quarter of 2016, based on our ability to reasonably estimate product returns. We did not have any deferred revenue at September 30, 2016, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and chargebacks. As a result of the supply interruption discussed above, we expect revenues for the remainder of 2016 to decline as compared to the three months ended September 30, 2016.

License Revenue. For the three months ended September 30, 2016, we recognized $1.3 million in license revenue on royalty payments from sales of Riona in Japan as compared to $1.0 million for the three months ended September 30, 2015. This increase was due to increased sales by JT and Torii of Riona in Japan.

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Cost of Goods Sold. For the three months ended September 30, 2016, we recognized $18.2 million in cost of goods sold, as compared to $3.1 million for the three months ended September 30, 2015. Cost of goods sold for the three months ended September 30, 2016 includes $13.8 million in write-offs of work-in-process inventory that was determined to no longer be suitable for commercial manufacture. In addition, we incurred $2.3 million of manufacturing charges as a result of not fully utilizing planned production at our existing third-party drug product manufacturer.

License Expenses. For the three months ended September 30, 2016, we recognized $0.8 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.6 million for the three months ended September 30, 2015. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $2.5 million, or 22%, to $8.7 million for the three months ended September 30, 2016, as compared to $11.2 million for the three months ended September 30, 2015. The decrease in research and development expenses was primarily due to a decrease in clinical expenses as a result of the completion of the Phase 3 study of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD. We expect our research and development expenses will remain relatively consistent for the remainder of 2016 as compared to the three months ended September 30, 2016. In total, we expect 2016 research and development expenses to decline as compared to 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.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $0.3 million, or 1.5%, to $20.5 million for the three months ended September 30, 2016, as compared to $20.2 million for the three months ended September 30, 2015. The increase was primarily due to an increase in personnel costs attributable to our expanded sales force. We expect our selling, general and administrative costs to remain relatively consistent for the remainder of 2016 as compared to the three months ended September 30, 2016. In total, we expect 2016 selling, general and administrative expenses to increase slightly as compared to 2015.

Other income (expense), net. Other income (expense), net for the three months ended September 30, 2016 was $0.2 million income as compared to $0.1 million income for the three months ended September 30, 2015.

Income Taxes. For the three months ended September 30, 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 September 30, 2015.

Nine months ended September 30, 2016 and September 30, 2015

Net U.S. Auryxia Product Sales. For the nine months ended September 30, 2016, we recognized $18.9 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $5.4 million for the nine months ended September 30, 2015.

(in thousands)	Nine months ended September 30, 2016	Percent of gross Auryxia product sales	Nine months ended September 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 29,896		$ 8,797	

Less provision for product sales allowances and accruals				
Trade allowances	3,451	12%	1,005	11%
Rebates, chargebacks and discounts	7,008	23%	824	9%
Product returns				
Other incentives (1)	492	2%	1,597	18%
Total	10,951	37%	3,426	38%
Net U.S. Auryxia product sales	$ 18,945		$ 5,371	

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

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Gross Auryxia product sales increased for the nine months ended September 30, 2016 as compared to the same period in 2015 primarily as a result of an increase in patient prescriptions and related units sold.

As discussed above, we defer revenue recognition until the earlier of our 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. We did not have any deferred revenue at September 30, 2016, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and chargebacks.

License Revenue. For the nine months ended September 30, 2016, we recognized $3.5 million in license revenue on royalty payments from sales of Riona in Japan as compared to $2.5 million for the nine months ended September 30, 2015. This increase was due to increased sales by JT and Torii of Riona in Japan.

Cost of Goods Sold. For the nine months ended September 30, 2016, we recognized $24.4 million in cost of goods sold, as compared to $3.4 million for the nine months ended September 30, 2015. Cost of goods sold for the nine months ended September 30, 2016 includes $13.8 million in write-offs of work-in-process inventory that was determined to no longer be suitable for commercial manufacture. In addition, we incurred $2.3 million of manufacturing charges as a result of not fully utilizing planned production at our existing third-party drug product manufacturer.

License Expenses. For the nine months ended September 30, 2016, we recognized $2.1 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $1.5 million for the nine months ended September 30, 2015. This increase was due to an increase in sales of Riona in Japan.

Research and Development Expenses. Research and development expenses decreased by $5.4 million, or 19%, to $23.3 million for the nine months ended September 30, 2016, as compared to $28.7 million for the nine months ended September 30, 2015. The decrease in research and development expenses was primarily due to a decrease in clinical expenses as a result of the completion of the Phase 3 study of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD, as well as a decrease in regulatory costs after our filings leading up to European approval of Fexeric in 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $1.7 million, or 2.8%, to $61.5 million for the nine months ended September 30, 2016, as compared to $59.8 million for the nine months ended September 30, 2015. The increase was primarily due to an increase in personnel and related costs attributable to our expanded sales force.

Other income (expense), net. Other income (expense), net for the nine months ended September 30, 2016 was a $38.4 million expense as compared to $0.3 million in income for the nine months ended September 30, 2015. This increase in expense was primarily the result of $34.2 million of interest expense recorded related to the amortization of the debt discount recognized in connection with the issuance of the Notes to Baupost in October 2015. Additionally, we recorded $4.7 million of expense for the nine months ended September 30, 2016 related to the increase in fair value of the portion of the Notes accounted for separately as a derivative liability from December 31, 2016 to June 30, 2016. See Note 8 Debt for additional details.

Income Taxes. For the nine months ended September 30, 2016, we recognized $60,000 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 $67,000 in income tax expense for the nine months ended September 30, 2015.

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LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible senior notes, option and warrant exercises, interest income, and from the upfront and milestone payments from our agreement with JT and Torii, sales of Auryxia 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. The interruption in the supply of Auryxia, however, will negatively impact our net U.S. Auryxia product sales for at least the remainder of 2016. Even if we successfully commercialize Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize our drug alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

In October 2015, we completed the sale of $125 million of Convertible Senior Notes due 2020, or the Notes, to funds managed by The Baupost Group, L.L.C, or Baupost. The Notes may be converted into shares of our common stock at the discretion of Baupost at a conversion price of $3.74, subject to adjustment based on the occurrence of certain events. We also entered into a Registration Rights Agreement with the purchasers of the Notes, or the Registration Rights Agreement, pursuant to which we agreed to (i) file a registration statement with the 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.

In January 2014, 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 September 30, 2016, we had $132.2 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 $68.1 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 resolving the recently announced supply interruption of Auryxia, the successful re-supply of Auryxia upon resolution of the supply interruption, the build-up of inventory and capacity expansion, and the timing, design and conduct of clinical trials for

ferric citrate. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond commercializing 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 Quarterly Report on Form 10-Q for the quarter ended June 30, 2016 and the other risk factors contained in our Annual Report on Form 10-K for the year ended December 31, 2015 and in our subsequent Quarterly Reports on Form 10-Q and other SEC filings.

Net cash used in operating activities for the nine months ended September 30, 2016 was $66.3 million as compared to $102.9 million net cash used in operating activities of for the same period in 2015. This decrease in net

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cash used in operating activities was primarily related to commercial expenditures to support the launch of Auryxia in 2015, including the manufacturing of inventory, as well as write-offs of inventory to net realizable value in 2016 and an increase in total revenues in the first nine months of 2016 as compared to 2015.

Net cash used in investing activities for the nine months ended September 30, 2016 was $2.1 million as compared to $11.1 million net cash provided by investing activities for the same period in 2015. The change from net cash provided by investing activities to net 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 nine months ended September 30, 2016 was $198,000 attributable to the exercise of stock options. Net cash provided by financing activities for the same period in 2015 was $119.7 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 September 30, 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, *Operating Leases*, we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease, and the receivable was drawn down as cash was received from our landlord. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets useful lives or the remaining lease term, whichever is shorter.

The lease for our New York City office expired on September 30, 2016 and we did 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. As of September 30, 2016, 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.

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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 September 30, 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 September 30, 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 September 30, 2016, our disclosure controls and procedures were effective.

Changes in Internal Controls over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended September 30, 2016, that have materially affected, or are reasonably likely to materially affect, our internal controls over financial reporting.

Limitations on Effectiveness of Controls

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

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ITEM 1A. RISK FACTORS

Information regarding risk factors appears in Item 1A of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. There have been no material changes from the risk factors previously disclosed in that Form 10-Q.

ITEM 5. OTHER INFORMATION

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

We are not obligated to sell any shares under the Sales Agreement. Subject to the terms and conditions of the Sales Agreement, Cantor Fitzgerald will use commercially reasonable efforts consistent with its normal trading and sales practices, applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market to sell shares from time to time based upon our instructions, including any price, time or size limits specified by us. Under the Sales Agreement, Cantor Fitzgerald may sell shares by any method deemed to be an at the market offering as defined in Rule 415(a)(4) under the Securities Act. Cantor Fitzgerald s obligations to sell shares under the Sales Agreement are subject to satisfaction of certain conditions, including the effectiveness of a registration statement on Form S-3 covering the shares of common stock that may be sold by Cantor Fitzgerald under the Sales Agreement we expect to file with the SEC shortly after the filing of this report. We will pay Cantor Fitzgerald a commission of up to 3.0% of the aggregate gross proceeds from each sale of shares and have agreed to provide Cantor Fitzgerald with customary indemnification and contribution rights. We have also agreed to reimburse Cantor Fitzgerald for the reasonable and documented fees and expenses of its outside legal counsel, not to exceed $50,000 in the aggregate, in connection with entering into the Sales Agreement.

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

The foregoing summary of the Sales Agreement does not purport to be complete and is qualified in its entirety by reference to the full text of the Sales Agreement, a copy of which we will file with the registration statement referred to above.

Shares sold under the Sales Agreement will be issued pursuant to the registration statement referred to above and the sales agreement prospectus that will form a part of such registration statement, following such time as the registration statement is declared effective by the SEC. This report shall not constitute an offer to sell or the solicitation of an offer to buy any shares under the Sales Agreement, nor shall there be any sale of such shares in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

ITEM 6. EXHIBITS

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

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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: November 9, 2016

By: /s/ Scott A. Holmes
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:

Exhibit Number	Exhibit Description
10.1	Form of Indemnification Agreement between Keryx Biopharmaceuticals, Inc. and its directors and officers.
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 November 9, 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 November 9, 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 November 9, 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 November 9, 2016.
101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Condensed Consolidated Balance Sheets, (ii) Condensed Consolidated Statements of Operations, (iii) Condensed Consolidated Statements of Cash Flows, and (iv) the Notes to Condensed Consolidated Financial Statements.

Indicates management contract or compensatory plan or arrangement.