KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 05, 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 June 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 105,895,226 shares of the registrant s common stock, $0.001 par value, outstanding as of July 29, 2016.

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KERYX BIOPHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 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 imminent interruption in the supply of Auryxia and when an adequate supply of Auryxia may be restored;
- 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 partners, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd.;

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

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 June 30, 2016 and December 31, 2015

(in thousands, except share and per share amounts)

	June 30, 2016 (Unaudited)	December 31, 2015
Assets		
Current assets:		
Cash and cash equivalents	$ 155,796	$ 200,290
Inventory	39,671	41,881
Accounts receivable, net	5,101	3,656
Receivable from landlord		637
Other current assets	2,152	2,830
Total current assets	202,720	249,294
Property, plant and equipment, net	4,755	5,083
Goodwill	3,208	3,208
Other assets, net	1,024	1,100
Total assets	$ 211,707	$ 258,685
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 14,713	$ 21,322
Accrued compensation and related liabilities	5,075	5,473
Deferred revenue	3,358	3,526
Derivative liability		46,686
Deferred lease incentive, current portion	244	244
Other current liabilities	15	355
Total current liabilities	23,405	77,606
Convertible senior notes	125,000	90,773
Deferred lease incentive, net of current portion	1,384	1,506
Deferred tax liability	830	790
Other liabilities	1,234	1,076

Total liabilities	151,853	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, 105,949,886 and 105,221,555 shares issued, 105,869,938 and 105,141,607 shares outstanding at June 30, 2016 and December 31, 2015, respectively)	106	105
Additional paid-in capital	819,723	761,189
Treasury stock, at cost, 79,948 shares at June 30, 2016 and December 31, 2015, respectively	(357)	(357)
Accumulated deficit	(759,618)	(674,003)
Total stockholders equity	59,854	86,934
Total liabilities and stockholders equity	$ 211,707	$ 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 six months ended June 30, 2016 and 2015 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2016	**2015**	**2016**	**2015**
Revenues:				
Net U.S. Auryxia product sales	$ 8,279	$ 1,758	$ 13,895	$ 2,180
License revenue	1,009	756	2,218	1,509
Total revenues	9,288	2,514	16,113	3,689
Operating expenses:				
Cost of goods sold	5,099	304	6,170	380
License expenses	605	453	1,331	905
Research and development	7,029	7,963	14,645	17,554
Selling, general and administrative	20,188	20,762	40,997	39,642
Total operating expenses	32,921	29,482	63,143	58,481
Operating loss	(23,633)	(26,968)	(47,030)	(54,792)
Other income (expense):				
Amortization of debt discount	(18,479)		(34,226)	
Other income (expense), net	(2,519)	114	(4,319)	221
Total other income (expense)	(20,998)	114	(38,545)	221
Loss before income taxes	(44,631)	(26,854)	(85,575)	(54,571)
Income taxes	20	23	40	45
Net loss	$ (44,651)	$ (26,877)	$ (85,615)	$ (54,616)
Basic and diluted net loss per common share	$ (0.42)	$ (0.26)	$ (0.81)	$ (0.53)
Weighted average shares used in computing basic and diluted net loss per common share	105,842,030	104,564,971	105,745,800	102,570,312

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 six months ended June 30, 2016 and 2015 (Unaudited)

(in thousands)

	Six months ended June 30,	
	2016	**2015**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (85,615)	$ (54,616)
Adjustments to reconcile loss to cash flows used in operating activities:		
Stock-based compensation expense	6,846	8,375
Amortization of debt discount	34,226	
Change in fair value of derivative liability	4,718	
Depreciation and amortization	520	283
Write-down of inventory to net realizable value	2,736	
Cash received from landlord	637	
Amortization of deferred lease incentive	(122)	(42)
Deferred income taxes	40	45
Changes in operating assets and liabilities:		
Other current assets	754	1,323
Accounts receivable, net	(1,445)	(604)
Accrued interest receivable		48
Inventory	(3,808)	(26,011)
Security deposits		(807)
Other current liabilities	(340)	
Accounts payable and accrued expenses	(1,337)	(2,642)
Accrued compensation and related liabilities	(398)	(691)
Deferred revenue	(168)	1,115
Other liabilities	158	178
Net cash used in operating activities	(42,598)	(74,046)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(2,040)	(164)
Proceeds from maturity of held-to-maturity securities		11,508
Net cash (used in) provided by investing activities	(2,040)	11,344

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	144	1,438
Net cash provided by financing activities	144	119,707
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(44,494)	57,005
Cash and cash equivalents at beginning of year	200,290	74,284
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 155,796	$ 131,289
Non-cash financing activities:		
Reclassification of derivative liability to equity	$ 51,404	$

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 approved in Europe as Fexeric. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our investigational medicine in Phase 3, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

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

On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets is imminent due to a production-related issue. We expect to make Auryxia available to patients when supply of Auryxia is back to adequate levels, which we anticipate will be during the fourth quarter of 2016. We have determined that a supply interruption is going to occur due to a production-related issue in converting active pharmaceutical ingredient, or API, to finished drug product at our contract manufacturer. This issue has resulted in variable production yields of finished drug product and, as a result, we have exhausted our reserve of finished drug product. At this time, current inventories of Auryxia are 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 and rebuild adequate supply. 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. 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 late in the third quarter of 2016 seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD.

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

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

Currently, our only product is Auryxia. In January 2015, we began to recognize 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 partners, JT and Torii. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

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

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of Auryxia. In 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 June 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 43% of our issued and outstanding common stock.

Most of our biopharmaceutical development and substantially all of our administrative operations during the three and six months ended June 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 six months ended June 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 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 June 30, 2016 and December 31, 2015, all of our cash and cash equivalents were held in either commercial bank accounts or money market funds.

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Inventory

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

Accounts Receivable, Net

We extend credit to our customers for U.S. Auryxia product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to certain of our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the condensed consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at June 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) collectability is reasonably assured, and (iv) the price is fixed or determinable. Until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue will be recognized based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers. Consistent with industry practice, once we 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 have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product sales from the sales to Customers and (ii) reasonably estimate our net product sales. We calculate gross product sales based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product sales by deducting from our gross product sales (a) trade allowances, such as invoice discounts for prompt payment and distributor fees, (b) estimated government and private payor rebates, chargebacks and discounts, such as Medicaid

reimbursements, (c) reserves for expected product returns, upon our ultimate transition to a sell-in revenue recognition model and (d) estimated costs of incentives offered to certain indirect customers, including patients.

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services, such as fees for certain data that Distributors provide to us. The payment terms for sales to Distributors generally include a prompt-pay discount for payment made 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.

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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 six months ended June 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 is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of June 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 six months ended June 30, 2016 and 2015 were offset by provisions for allowances and accruals as set forth in the tables below.

(in thousands)	Three months ended June 30, 2016	Percent of gross Auryxia product sales	Three months ended June 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 12,561		$ 3,097	
Less provision for product sales allowances and accruals				
Trade allowances	1,555	12%	348	11%
Rebates, chargebacks and discounts	2,543	20%	140	5%
Product returns				

Other incentives (1)	184	2%	851	27%
Total	4,282	34%	1,339	43%
Net U.S. Auryxia product sales	$ 8,279		$ 1,758	

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

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(in thousands)	Six months ended June 30, 2016	Percent of gross Auryxia product sales	Six months ended June 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 21,185		$ 4,061	
Less provision for product sales allowances and accruals				
Trade allowances	2,701	13%	448	11%
Rebates, chargebacks and discounts	4,221	20%	170	4%
Product returns				
Other incentives (1)	368	1%	1,263	31%
Total	7,290	34%	1,881	46%
Net U.S. Auryxia product sales	$ 13,895		$ 2,180	

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

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

(in thousands)	Three months ended June 30, 2016	Three months ended June 30, 2015	Six months ended June 30, 2016	Six months ended June 30, 2015
Net U.S. Auryxia sales recognized	$ 8,279	$ 1,758	$ 13,895	$ 2,180
Change in deferred product sales	(360)	815	(168)	1,529
	$ 7,919	$ 2,573	$ 13,727	$ 3,709

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

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

the written report and related information to us.

Cost of Goods Sold

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

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2016	2015	2016	2015
Cost of goods sold expensed	$ 5,099	$ 304	$ 6,170	$ 380
Change in finished goods inventory held by others	430	27	1,003	134
	$ 5,529	$ 331	$ 7,173	$ 514

Finished goods inventory held by others as of June 30, 2016 and 2015 represents the cost of goods sold that has been deferred to align with our deferral of net U.S. Auryxia product sales.

License Expenses

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

Research and Development Costs

Research and development costs are expensed as incurred. Pre-approval inventory expenditures are recorded as research and development expense as incurred. The capitalization of inventory for our product candidate(s) commence when it is probable that the product will be approved for commercial marketing. 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 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 June 30, 2016 and 2015, which are not included in the computation of net loss per share amounts, were 8,869,094 and 5,306,869, respectively. No warrants were outstanding during each of these periods.

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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 June 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 and held-to-maturity investments, when applicable, with multiple financial institutions that invest in investment-grade securities with average maturities of less than twelve months. See Note 3 Fair Value Measurements.

Our accounts receivable, net at June 30, 2016 and December 31, 2015 represent amounts due to the Company from customers. We perform ongoing credit evaluations of our customers and generally do not require collateral. The following table sets forth customers who represented 10% or more of our total accounts receivable, net as of June 30, 2016 and December 31, 2015:

	June 30, 2016	December 31, 2015
Fresenius Medical Care Rx	27%	15%
Davita Rx	20%	19%
McKesson Corporation	19%	23%
AmerisourceBergen Drug Corporation	16%	17%

Cardinal Health, Inc.	16%	24%

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 is imminent due to a production-related issue at this supplier of Auryxia. We expect to make Auryxia available to patients when supply of Auryxia is back to adequate levels, which we anticipate will be during the fourth quarter of 2016. 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.

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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. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets useful lives or the remaining lease term, whichever is shorter.

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

Recently Issued and Proposed Accounting Pronouncements

In May 2014, the 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.

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.

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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 June 30, 2016 and December 31, 2015:

	Financial assets at fair value as of June 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)	$ 148,269	$	$	$ 193,886	$	$
Total assets	$ 148,269	$	$	$ 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. As of June 30, 2016 and December 31, 2015, the fair value of the Notes was $141.8 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.

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. During the three months ended June 30, 2016, the derivative liability was reclassified to equity as a result of the Notes no longer being convertible into cash.

NOTE 4 INVENTORY

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

(in thousands)	June 30, 2016	December 31, 2015
Raw materials	$ 616	$ 495
Work in process	35,978	40,124
Finished goods	1,843	1,031
Finished goods inventory held by others	1,234	231
Total inventory	$ 39,671	$ 41,881

During the three months ended June 30, 2016, we expensed $1.9 million of commercial inventory deemed no longer saleable as a result of a production-related issue converting API to finished drug product at our contract manufacturer, which was recorded in cost of goods sold.

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NOTE 5 STOCKHOLDERS EQUITY

2016 Annual Meeting of Stockholders

At our 2016 Annual Meeting of Stockholders held on May 25, 2016, our stockholders approved proposals to (i) amend our Certificate of Incorporation, as amended and restated and then currently in effect, to increase the number of authorized shares of our common stock from 130,000,000 shares to 180,000,000 shares and (ii) amend our 2013 Incentive Plan to, among other things, increase the number of shares of our common stock available for issuance thereunder from 9,500,000 shares to 18,000,000 shares.

Change in Stockholders Equity

Total stockholders equity decreased by $27.1 million during the six months ended June 30, 2016. This decrease was primarily attributable to our net loss of $85.6 million, partially offset by the reclassification of the derivative liability to equity of $51.4 million and $7.1 million related to stock-based compensation and stock option exercises.

NOTE 6 STOCK-BASED COMPENSATION EXPENSE

Equity Incentive Plans

As of June 30, 2016, a total of 7,102,521 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 six months ended June 30, 2016:

	Number of shares	Weighted-average exercise price
Outstanding at December 31, 2015	5,411,557	$ 10.96
Granted	4,348,450	4.40
Exercised	(48,042)	3.02
Forfeited	(365,648)	8.88
Expired	(477,223)	14.50
Outstanding at June 30, 2016	8,869,094	$ 7.87
Vested and expected to vest at June 30, 2016	8,135,948	$ 7.98
Exercisable at June 30, 2016	3,068,887	$ 10.19

Upon the exercise of stock options, we issue new shares of our common stock. As of June 30, 2016, 2,415,000 options issued to employees are unvested, performance-based options.

Restricted Stock

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

	Number of shares	Weighted average grant date fair value
Outstanding at December 31, 2015	1,344,747	$ 11.59
Granted	818,275	3.56
Vested	(290,733)	13.00
Forfeited	(137,986)	8.34
Outstanding at June 30, 2016	1,734,303	$ 7.82

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As of June 30, 2016, 560,000 shares of restricted stock issued to employees are unvested, performance-based shares.

Stock-Based Compensation Expense

We incurred $3.6 million and $4.1 million of stock-based compensation expense related to equity incentive grants during the three months ended June 30, 2016 and 2015, respectively, and $6.8 million and $8.4 million during the six months ended June 30, 2016 and 2015, respectively. The following table reflects stock-based compensation expense for the three- and six-month periods ended June 30, 2016 and 2015:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2016	2015	2016	2015
Cost of goods sold	$ 8	$ 2	$ 14	$ 3
Research and development	880	841	1,585	1,762
Selling, general and administrative	2,665	3,211	5,247	6,610
Total stock-based compensation expense	$ 3,553	$ 4,054	$ 6,846	$ 8,375

Stock-based compensation costs capitalized as part of inventory were immaterial for the three and six months ended June 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 June 30, 2016 and 2015 was $5.01 and $7.83, respectively, and during the six months ended June 30, 2016 and 2015 was $4.40 and $10.14, respectively. We used historical information to estimate forfeitures of stock options. As of June 30, 2016, there was $13.3 million and $8.9 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 2.5 years and 2.1 years, respectively. These amounts do not include 2,415,000 options outstanding as of June 30, 2016 and 560,000 shares of restricted stock outstanding as of June 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.

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 as of June 8, 2009, we entered into an Amended and Restated Sublicense Agreement, or Revised Agreement, with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the Sublicense Agreement.

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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 June 30, 2016 and 2015, we recorded $1.0 million and $0.8 million, respectively, in license revenue related to royalties earned on net sales of Riona in Japan. For the six months ended June 30, 2016 and 2015, we recorded $2.2 million and $1.5 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 June 30, 2016 and 2015, we recorded $0.6 million and $0.5 million, respectively, in license expenses related to royalties due to the licensor of ferric citrate relating to sales of Riona in Japan. For the six months ended June 30, 2016 and 2015, we recorded $1.3 million and $0.9 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 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.

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

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

(in thousands)	June 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 three and six months ended June 30, 2016 approximately $18.5 million and $34.2 million, respectively, of interest expense was recognized related to the Notes, all of which was attributable to the amortization of the debt discount. As of June 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 $141.8 million and $132.9 million, respectively.

NOTE 9 OTHER INCOME (EXPENSE), NET

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2016	2015	2016	2015
Interest income	$ 185	$ 114	$ 387	$ 221
Other income	9		12	
Fair value adjustment to derivative liability	(2,711)		(4,718)	
	$ (2,519)	$ 114	$ (4,319)	$ 221

NOTE 10 COMMITMENTS AND CONTINGENCIES

Commitments

As of June 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 matters referenced below, a liability is not probable or the amount cannot be reasonably estimated and, therefore, accruals have 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.

Two purported class action lawsuits have been filed against us and certain of our officers in the United States District Court for the Southern District of New York, one captioned Terrell Jackson v. Keryx Biopharmaceuticals, Inc., et al., No. 1:16-cv-06131 filed on August 2, 2016, and the other captioned Richard J. Erickson v. Keryx Biopharmaceuticals, Inc., et al. No. 1:16-cv-06218, filed on August 4, 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 and the Erickson complaint purports to be brought on behalf of stockholders who purchased our common stock between March 2, 2016 and July 29, 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 either of these lawsuits adverse to us or the other defendants, however, could have a material effect on our consolidated 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 approximately 5,000 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 is 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. Additionally, the safety profile of the drug candidate was consistent with previously reported clinical studies of ferric citrate. We believe the initial data support our plan to submit a supplemental new drug application, or sNDA, with the FDA late in the third quarter of 2016 seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD.

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

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

Currently, our only product is Auryxia. In January 2015, we began to recognize product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, license revenue from the sublicensing of rights to ferric citrate in Japan to our Japanese partners, JT and Torii. 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 notes, option and warrant exercises, interest income, and the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Even though we are commercializing Auryxia, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for Auryxia, successfully complete any post-approval regulatory obligations and successfully manufacture and commercialize Auryxia alone or in partnership. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from Auryxia.

During 2015, we completed two financings to secure capital needed to fund our commercialization efforts and to continue the clinical development of Auryxia. In 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 June 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 43% of our issued and outstanding common stock.

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

Supply Interruption of Auryxia

We have determined that a supply interruption of Auryxia is going to occur due to a production-related issue in converting active pharmaceutical ingredient, or API, to finished drug product at our contract manufacturer. This issue has resulted in variable production yields of finished drug product and, as a result, we have exhausted our reserve of finished drug product. At this time, current inventories of Auryxia are 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 and rebuild adequate supply. 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. We expect to make Auryxia available to patients when supply of Auryxia is back to adequate levels, which we anticipate will be during the fourth quarter of 2016. This supply interruption does not affect the supply of Riona manufactured and sold by JT in Japan.

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-downs of inventory that fails to meet specifications. Cost of goods sold also includes expenses due the licensor of Auryxia related to the manufacturing of product and product sales recognized during the period.

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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.

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

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GENERAL CORPORATE

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

CRITICAL ACCOUNTING POLICIES

The discussion and analysis of our financial condition and results of operations is based upon our 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) collectability is reasonably assured and (iv) the price is fixed or determinable. Until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue will be recognized based on the resale of Auryxia for the purposes of filling patient prescriptions, and not based on initial sales from us to our Customers. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Customers, we anticipate that our revenues will be recognized based on sales to our Customers. We currently defer Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue is recorded net of discounts, rebates, and chargebacks. We also defer the related cost of product sales and record such amounts as finished goods inventory held by others, which is included in inventory on our condensed consolidated balance sheets, until revenue related to such product sales is recognized.

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

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

Trade Allowances: We generally provide invoice discounts on Auryxia sales to our Distributors for prompt payment and pay fees for distribution services, such as fees for certain data that Distributors provide to us. The payment terms for sales to Distributors generally include a prompt-pay discount for payment made 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.

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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 six months ended June 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 is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of June 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.

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2016	2015	2016	2015
Net U.S. Auryxia sales recognized	$ 8,279	$ 1,758	$ 13,895	$ 2,180
Change in deferred product sales	(360)	815	(168)	1,529
	$ 7,919	$ 2,573	$ 13,727	$ 3,709

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

(in thousands)	Three months ended June 30, 2016	Three months ended June 30, 2015	Six months ended June 30, 2016	Six months ended June 30, 2015
Cost of goods sold expensed	$ 5,099	$ 304	$ 6,170	$ 380
Change in finished goods inventory held by others	430	27	1,002	134
	$ 5,529	$ 331	$ 7,172	$ 514

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

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

Stock-Based Compensation

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

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

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

Accruals for Clinical Research Organization and Clinical Site Costs

We make estimates of costs incurred in relation to external 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

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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 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 June 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.

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.

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RESULTS OF OPERATIONS

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

Net U.S. Auryxia Product Sales. For the three months ended June 30, 2016, we recognized $8.3 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $1.8 million for the three months ended June 30, 2015.

(in thousands)	Three months ended June 30, 2016	Percent of gross Auryxia product sales	Three months ended June 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 12,561		$ 3,097	
Less provision for product sales allowances and accruals				
Trade allowances	1,555	12%	348	11%
Rebates, chargebacks and discounts	2,543	20%	140	5%
Product returns				
Other incentives (1)	184	2%	851	27%
Total	4,282	34%	1,339	43%
Net U.S. Auryxia product sales	$ 8,279		$ 1,758	

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

We sell product to a limited number of major wholesalers, which we refer to as our Distributors, as well as certain pharmacies, which we refer to collectively as our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with our revenue recognition policy, until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue recognition is deferred until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product), and not based on sales from us to our Customers. At June 30, 2016, we have deferred revenues of $3.4 million, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and chargebacks. As a result of the supply interruption discussed above, we expect revenues for the remainder of 2016 to decline significantly as compared to the first six months of 2016.

License Revenue. For the three months ended June 30, 2016, we recognized $1.0 million in license revenue on royalty payments from sales of Riona in Japan as compared to $0.8 million for the three months ended June 30, 2015. This increase was due to increased sales by JT and Torii of Riona in Japan.

Cost of Goods Sold. For the three months ended June 30, 2016, we recognized $5.1 million in cost of goods sold related to product sales of Auryxia, as compared to $0.3 million for the three months ended June 30, 2015. The increase is attributable to increased sales of Auryxia, as well as approximately $2.4 million in product write-offs during the three months ended June 30, 2016, $1.9 million of which was related to the production-related issue discussed above.

License Expenses. For the three months ended June 30, 2016, we recognized $0.6 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.5 million for the three months ended June 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 $1.0 million, or 12%, to $7.0 million for the three months ended June 30, 2016, as compared to $8.0 million for the three months ended June 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 to remain relatively consistent on a quarterly basis throughout the remainder of 2016. In total, we expect 2016 research and development expenses to decline from 2015 following the completion of our pivotal Phase 3 study of ferric citrate for the treatment of IDA in patients with stage 3-5 NDD-CKD.

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Selling, General and Administrative Expenses. Selling, general and administrative expenses decreased by $0.6 million, or 3%, to $20.2 million for the three months ended June 30, 2016, as compared to $20.8 million for the three months ended June 30, 2015. The decrease was primarily due to a decrease in marketing expenses during the 2016 period as compared to the same period in 2015 in which we had higher marketing expenses to support the initial launch of Auryxia and a decrease in stock-based compensation, partially offset by an increase in personnel costs attributable to our expanded sales force. We expect our selling, general and administrative costs to remain relatively consistent on a quarterly basis throughout the remainder of 2016. In total, we expect 2016 selling, general and administrative expenses to increase slightly from 2015.

Other income (expense), net. Other income (expense), net for the three months ended June 30, 2016 was a $21.0 million expense as compared to $0.1 million in income for the three months ended June 30, 2015. This increase in expense was primarily the result of $18.5 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 $2.7 million of expense for the three months ended June 30, 2016 related to the increase in fair value of the portion of the Notes accounted for separately as a derivative liability from March 31, 2016 to June 30, 2016. See Note 8 Debt for additional details.

Income Taxes. For the three months ended June 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 $23,000 in income tax expense for the three months ended June 30, 2015. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP, since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. We continue to maintain a full valuation allowance against the entire amount of our net deferred tax assets.

Six months ended June 30, 2016 and June 30, 2015

Net U.S. Auryxia Product Sales. For the six months ended June 30, 2016, we recognized $13.9 million in product sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks, as compared with $2.2 million for the six months ended June 30, 2015.

(in thousands)	Six months ended June 30, 2016	Percent of gross Auryxia product sales	Six months ended June 30, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 21,185		$ 4,061	
Less provision for product sales allowances and accruals				
Trade allowances	2,701	13%	448	11%
Rebates, chargebacks and discounts	4,221	20%	170	4%
Product returns				
Other incentives (1)	368	1%	1,263	31%
Total	7,290	34%	1,881	46%

Net U.S. Auryxia product sales	$	13,895	$	2,180

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

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. At June 30, 2016, we have deferred revenues of $3.4 million, as compared to $3.5 million at December 31, 2015, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable allowances, discounts, incentives, rebates and chargebacks.

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License Revenue. For the six months ended June 30, 2016, we recognized $2.2 million in license revenue on royalty payments from sales of Riona in Japan as compared to $1.5 million for the six months ended June 30, 2015. This increase was due to increased sales by JT and Torii of Riona in Japan.

Cost of Goods Sold. For the six months ended June 30, 2016, we recognized $6.2 million in cost of goods sold related to product sales of Auryxia, as compared to $0.4 million for the six months ended June 30, 2015. The increase is attributable to increased sales of Auryxia, as well as approximately $2.7 million in product write-offs during the six months ended June 30, 2016, $1.9 million of which was related to the production-related issue discussed above.

License Expenses. For the six months ended June 30, 2016, we recognized $1.3 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona in Japan as compared to $0.9 million for the six months ended June 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 $3.0 million, or 17%, to $14.6 million for the six months ended June 30, 2016, as compared to $17.6 million for the six months ended June 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 $1.4 million, or 3.5%, to $41.0 million for the six months ended June 30, 2016, as compared to $39.6 million for the six months ended June 30, 2015. The increase was primarily due to an increase in personnel and related costs associated with the continued commercialization of Auryxia.

Other income (expense), net. Other income (expense), net for the six months ended June 30, 2016 was a $39.0 million expense as compared to $0.2 million in income for the six months ended June 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 six months ended June 30, 2016 related to the increase in fair value of the portion of the Notes accounted for separately as a derivative liability from March 31, 2016 to June 30, 2016. See Note 8 Debt for additional details.

Income Taxes. For the six months ended June 30, 2016, we recognized $40,000 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 $45,000 in income tax expense for the six months ended June 30, 2015. Indefinite-lived intangibles are non-monetary assets which are not amortized under GAAP, since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the valuation allowance against our deferred tax assets. We continue to maintain a full valuation allowance against the entire amount of our net deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various public and private offerings of our common stock, the issuance of convertible notes, option and warrant exercises, interest income, and from the upfront and milestone payments from our agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. The commercial launch of our product, Auryxia, occurred in late December 2014 and we began to recognize revenue

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from the sales of Auryxia in 2015. The imminent 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, our Japanese partner, JT and Torii, received manufacturing and marketing approval of Riona from the Japanese Ministry of Health, Labour and Welfare. We receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

As of June 30, 2016, we had $155.8 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 $44.5 million.

We currently expect that our existing capital resources and future anticipated cash flows will be sufficient to execute our current business objectives. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the magnitude of cash received from product sales, the timing and expenditures associated with the build-up of inventory and capacity expansion, and the timing, design and conduct of clinical trials for 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 Annual Report on Form 10-K for the year ended December 31, 2015 and the other risk factors contained therein and in our subsequent Quarterly Reports on Form 10-Q and other SEC filings.

Net cash used in operating activities for the six months ended June 30, 2016 was $42.6 million as compared to $74.0 million net cash used in operating activities of for the same period in 2015. This decrease in net cash used in operating activities was primarily related to commercial expenditures to support the launch of Auryxia in 2015, including the manufacturing of inventory, as well as an increase in total revenues in the first six months of 2016 as compared to 2015.

Net cash used in investing activities for the six months ended June 30, 2016 was $2.0 million as compared to $11.3 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.

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Net cash provided by financing activities for the six months ended June 30, 2016 was $0.1 million 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 June 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, we recorded a deferred lease incentive, and an associated receivable from our landlord, for the total amount to be paid by the landlord for improvements. The deferred lease incentive is being amortized as a partial offset to rent expense over the term of the lease. We began occupying the space in November 2015. Improvements made to our leased space have been recorded as fixed assets and will be amortized over the assets useful lives or the remaining lease term, whichever is shorter.

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

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 June 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.

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 June 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.

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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 June 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 June 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 June 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.

ITEM 1A. RISK FACTORS.

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition and/or operating results could be materially harmed. These factors could cause the trading price of

our common stock to decline, and you could lose all or part of your investment.

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Risks related to our business and industry

We have a limited operating history and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred substantial operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of June 30, 2016, we had an accumulated deficit of $759.6 million. As we continue our research and development and initial commercial efforts, we will incur increasing losses. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug, Auryxia. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post approval regulatory obligations and successfully manufacture and commercialize our drug.

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

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

- the effectiveness of Auryxia as a treatment for adult patients with CKD on dialysis;
- the adoption of Auryxia by physicians, which depends on whether physicians view it as a safe and effective treatment to lower serum phosphorus levels in patients with CKD on dialysis;
- the effectiveness of the sales, managed markets and marketing efforts by us and our competitors;
- our ability to quickly and successfully identify and resolve the production-related issue that we announced in August 2016 and, as a result of the supply interruption, our ability to quickly and successfully identify and engage secondary suppliers of finished drug product and to timely receive FDA approval of any secondary suppliers of finished drug product;
- our ability to return our business to the level of sales that we had achieved prior to the supply interruption and to increase our sales further;
- the size of the treatable patient population;
- our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, Auryxia by providing third party payers with a strong value proposition based on the existing burden

of illness associated with CKD patients on dialysis and the benefits of Auryxia;

the occurrence of any side effects, adverse reactions or misuse, or any unfavorable publicity in these areas, associated with Auryxia;

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

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

- our ability to identify reliable suppliers and successfully manufacture Auryxia.

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

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

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

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

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

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

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

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

prevent us or any potential partner from selling Fexeric on a profitable basis in a particular country, they could prevent the commercial launch or continued sale of Fexeric in that country.

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

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

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

- sales of Auryxia may be impaired;
- regulatory approvals for Auryxia may be restricted or withdrawn;
- we may decide to, or be required to, send drug warnings or safety alerts to physicians, pharmacists and hospitals, or we may decide to conduct a product recall;
- reformulation of the product, additional nonclinical or clinical studies, changes in labeling or changes to or re-approvals of manufacturing facilities may be required;
- we may be precluded from pursuing additional development opportunities to enhance the clinical profile of Auryxia within its indicated populations, as well as be precluded from studying Auryxia in additional indications and populations or in new formulations; and
- government investigations or lawsuits, including class action suits, may be brought against us.

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

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

We rely on third parties to manufacture and analytically test our drug. If these third parties do not successfully manufacture and test our drug, our business will be harmed.

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and analytically test our drug for commercial distribution and use

in clinical trials. We may not be able to enter into future contract agreements with these third-parties on terms acceptable to us, if at all.

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

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of the development program for our drug, particularly given that some of the third parties we intend to employ in the manufacturing process are single source providers. These risks become more acute as we scale up for commercial quantities, where a reliable source of active pharmaceutical ingredient, or API, and a qualified contract manufacturer become critical to commercial success. For example, given the large quantity of materials required for Auryxia production and the large quantities of Auryxia that will be required for commercial success, the commercial viability of Auryxia will also depend on adequate supply of starting materials that meet quality, quantity and cost standards and the ability of our contract manufacturers to produce the API and finished drug product on a commercial scale. Failure to achieve this level of supply can jeopardize and prevent the successful commercialization of the product. Moreover, issues that may arise in our scale-up and technology transfer of Auryxia may lead to significant delays in our development and commercial timelines. For example, we announced in August 2016 that a production-related issue would cause an interruption in supply of Auryxia which will make us unable to supply finished drug product to patients and will negatively impact our revenues.

Our third-party manufacturers may not perform as required under the terms of our supply agreement or quality agreement, or may not remain in the contract manufacturing business for the time required by us to successfully manufacture and distribute our drug. In addition, our contract manufacturers will be subject to ongoing periodic and unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with cGMPs, as well as other governmental regulations and corresponding foreign standards. While we periodically audit our contractors for adherence to regulatory requirements, and are ultimately held responsible for their regulatory compliance, we cannot assure you that unforeseen changes at these contractors will not occur that could change their regulatory standing. The same issues apply to contract analytical services which we use for quality, impurity and release testing of our drug. We are required by law to establish adequate oversight and control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract, supplier qualification and periodic audits, but unforeseen circumstances could affect our third-party manufacturers compliance with applicable regulations and standards. As we continue to scale up production, we continue to develop analytical tools for Auryxia drug substance and drug product testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to obtain FDA approval. Moreover, even with effective analytical methods available, there is no assurance that we will be able to analyze all the raw materials and qualify all impurities to the satisfaction of the FDA, possibly requiring additional analytical studies, analytical method development, or preclinical studies, which could significantly delay our ability to receive regulatory approvals for our drug. Additionally, changes in the analytical specifications required by the FDA or other regulatory authority, such as United States Pharmacopeial Convention standards, from time to time, could delay our ability to receive regulatory approvals for our drug or our commercial efforts. Switching or engaging multiple third-party contractors to produce our drug substance or drug product may be difficult and time consuming because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance or drug product must meet established specifications at each manufacturing facility. It may be difficult and time consuming for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Auryxia, the loss of any of our drug substance or drug product manufacturers would result in significant additional costs and delays in our development program. Moreover, if we need to add or change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve any new manufacturers in advance, which will involve additional inspections to ensure compliance with FDA and foreign regulations and standards.

If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties, we may be unable to commercialize our products.

We do not possess all of the capabilities to fully commercialize our product on our own. From time to time, we may need to contract with additional third parties, or renew or revise contracts with existing third parties, to:

manufacture our drug;
assist us in developing, testing and obtaining regulatory approval for and commercializing our compound and technologies; and
market and distribute our drug.

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We can provide no assurance that we will be able to successfully enter into agreements with such third parties on terms that are acceptable to us, if at all. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our product independently, which could result in significant delays. Furthermore, such failure could result in the termination of license rights to our product. If these manufacturing, development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our product. We cannot predict the form or scope that any such collaboration might take, and we may pursue other strategic alternatives if terms or proposed collaborations are not attractive. To the extent that we rely on third parties to research, develop or commercialize our product, we are unable to control whether such product will be scientifically or commercially successful. Additionally, if these third parties fail to perform their obligations under our agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor and ensure the quality of such work, we may face delays in achieving the business or regulatory milestones required for commercialization of our current drug and any future drug candidate.

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

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

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

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit our ability to generate revenue.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from:

government and health administration authorities;
private health insurers;
managed care programs; and
other third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved health care products, as well as the timing of coverage and reimbursement decisions by third-party payors. Third-party payors, including Medicare and Medicaid, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses

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of approved products for disease indications for which the FDA has not granted labeling approval. In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which for the first time established prescription drug coverage for Medicare beneficiaries, under Medicare Part D. Under this program, beneficiaries purchase insurance coverage from private insurance companies to cover the cost of their prescription drugs. Likewise, current and future legislative or regulatory efforts to control or reduce healthcare costs or reform government healthcare programs, such as the Patient Protection Affordable Care Act and the Health Care and Education Reconciliation Act of 2010, could result in lower prices or rejection of coverage and reimbursement for our drug. In addition, third-party insurance coverage may not be available to patients for our product. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our product, its market acceptance may be significantly reduced.

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

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

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

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

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

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

- state law equivalents of each of the above federal laws, such as anti-kickback and false claims laws which may apply to items or services reimbursed by any third-party payer, including commercial insurers, and state laws governing the privacy and security of health information in certain

circumstances, many of which differ from each other in significant ways and often are not preempted by federal laws, thus complicating compliance efforts;

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

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

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

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

If our competitors develop and market products that are less expensive, have a reduced pill burden, more effective or safer than our drug product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, our commercial opportunities may be reduced or eliminated.

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

Auryxia is competing in the United States with other FDA approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Genzyme Corporation (a wholly-owned subsidiary of Sanofi), or Genzyme, PhosLo® (calcium acetate), marketed by Fresenius Medical Care, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum and magnesium. Our strategy to compete against these existing treatments depends in part on physicians and patients accepting that Auryxia is differentiated in the marketplace versus these FDA approved phosphate binders. In addition, we may have to compete against existing treatments on price, which becomes more challenging as generic versions of these existing treatments come to market. There are several parties pursuing approval of pending Abbreviated New Drug Applications, or ANDAs, for generic Renvela® with the FDA. In addition, a generic formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the United States in October 2008. In addition, upon the expiration of its core patents, generic formulations of Fosrenol® may be launched. These generic formulations could have a further material effect on the pricing of phosphate binders.

Furthermore, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug product. Other companies have drug candidates

in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop drug products. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors.

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

As of August 1, 2016, we had 189 full and part-time employees. To successfully develop and commercialize our drug and any drug candidates we may in-license or acquire, we must be able to attract and retain highly skilled personnel. Our limited resources may hinder our efforts to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel our ability to continue to execute on our business plan could be materially impaired.

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

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

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

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

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

Risks associated with our product development efforts

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete our clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are currently conducting or planning clinical trials that seek to enroll patients with the same disease that we are studying. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials in a cost-effective or timely manner or at all. In addition, conducting multi-national studies adds another level of complexity and risk. As a result, we may be subject to events affecting countries outside the United States.

Negative or inconclusive results from the clinical trials we conduct, such as the recently completed Phase 3 study of Auryxia for the treatment of iron deficiency anemia in patients with NDD-CKD, or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials. For example, in May 2012, we abandoned our development efforts and terminated our license for KRX-0401 (perifosine) following negative results from the Phase 3 trial for KRX-0401. We may also opt to change the delivery method, formulation or dosage which could affect

efficacy results for the drug. Accordingly, we may not be able to complete our current or future clinical trials within an acceptable time frame, if at all.

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

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

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

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

Because all of our proprietary technologies are licensed or sublicensed to us by third parties, termination of these license rights would prevent us from developing and further commercializing Auryxia.

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

royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Auryxia) and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreement (including upon certain insolvency events), Panion could terminate the agreement, and we would lose the rights to Auryxia. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia. From time to time, we may have disagreements with our licensors or collaborators, or they and/or we may have disagreements with the original inventors, regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our current drug and any

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future drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug or drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drugs. Finally, our rights to develop and commercialize Auryxia, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Auryxia and the licenses and sublicenses we grant to others.

Our reliance on third parties, such as clinical research organizations, or CROs, may result in delays in completing, or a failure to complete, clinical trials if such CROs fail to perform under our agreements with them.

In the course of product development, we engage CROs and other vendors to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. If the CROs or applicable vendors fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory or timely manner, we may face significant delays in completing our clinical trials, submitting our regulatory filings, or approval, as well as the commercialization of one or more drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidate(s).

Other risks related to our business

Any acquisitions we make may require a significant amount of our available cash and may not be scientifically or commercially successful.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company s relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to the acquisition;
- the diversion of our management s attention from our core business; and
- the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

Health care reform measures could adversely affect our business.

The business prospects and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the pricing of healthcare

products and services in the United States or internationally, the reimportation of drugs into the United States from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third party payors. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services, or HHS, in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services, or CMS, issued a proposed regulation covering the calculation of Average Manufacturer Price, or AMP, which is the key variable in the calculation of these rebates.

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Furthermore, in the United States, health care reform legislation titled the Patient Protection and Affordable Care Act, or PPACA, was signed into law in March 2010. The impact of this legislation on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court s decision allows implementation of key provisions impacting drug and device manufacturers to go forward. This includes PPACA changes to the Medicare Part D Program (including closing the donut hole), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the Biologics Price Competition and Innovation Act and the Physician Payments Sunshine Act, both of which were enacted as part of the PPACA. Regulations to implement PPACA could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our product.

For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or MIPPA. The final rule delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, delayed by two years the implementation of oral-only end-stage renal disease related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2016. In April 2014, the United States Congress passed legislation known as Protecting Access to Medicare Act of 2014, which, among other things, delays by eight years the implementation of oral-only ESRD related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2025. If phosphate binders are included in the bundle beginning in 2025, or earlier, separate Medicare reimbursement will no longer be available for phosphate binders, as it is today under Medicare Part D. While it is too early to project the impact bundling may have on the phosphate binder industry, the impact could potentially cause dramatic price reductions for phosphate binders, which could significantly reduce the commercial potential of Auryxia.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and post-marketing clinical trials related to serious risks, labeling changes based on new safety information, and compliance with risk evaluation and mitigation strategies approved by the FDA. The FDA s exercise of this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA restrictions on the sale or distribution of approved products. On July 9, 2012, the Food and Drug Administration Safety and Innovation Act was enacted to, among other things, renew the drug user fee program, expand the FDA s inspection records access and require manufacturers to establish appropriate oversight and controls over their suppliers and the supply chain, including raw material suppliers and contract manufacturers, as a part of cGMP compliance. On November 27, 2013, the Drug Quality and Security Act, which includes the Drug Supply Chain Security Act, was signed into law to, among other things, build an electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States. Requirements for the tracing of products through the pharmaceutical distribution supply chain took effect on January 1, 2015 for manufacturers and building internal systems to ensure compliance with this law will require dedication of resources. In addition, this law requires engaging in transactions only with authorized trading partners and could limit our pool of available trading partners.

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

The use of our drug or future drug candidates in clinical trials, and the future sale of any approved drug and new technology, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug product or limit commercialization of any approved product.

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We have expanded our insurance coverage to include the commercial sale of Auryxia; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

- decreased demand for a product;
- injury to our reputation;
- our inability to continue to develop a drug candidate;
- withdrawal of clinical trial volunteers; and
- loss of revenues.

Consequently, a product liability claim or product recall may result in losses that could be material to our business.

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

In the ordinary course of our business, we collect and store sensitive data, including intellectual property, our proprietary business information and that of our suppliers and business partners, as well as personally identifiable information of Auryxia patients, clinical trial participants and employees. We also have outsourced elements of our information technology structure, and as a result, we are managing independent vendor relationships with third parties who may or could have access to our confidential information. Similarly, our business partners and other third party providers possess certain of our sensitive data. The secure maintenance of this information is critical to our operations and business strategy. Despite our security measures, our information technology and infrastructure may be vulnerable to attacks by hackers or breached due to employee error, malfeasance or other disruptions. We, our partners, vendors and other third party providers could be susceptible to third party attacks on our, and their, information security systems, which attacks are of ever increasing levels of sophistication and are made by groups and individuals with a wide range of motives and expertise, including criminal groups. Any such breach could compromise our, and their, networks and the information stored there could be accessed, publicly disclosed, lost or stolen. Any such access, disclosure or other loss of information could result in legal claims or proceedings, liability under laws that protect the privacy of personal information, disrupt our operations, and damage our reputation, any of which could adversely affect our business.

Risks related to our financial condition

Our existing capital resources may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

We currently expect that our existing capital resources and future anticipated cash flows will be sufficient to execute our business plan. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with commercial activities related to Auryxia and the magnitude of cash received from product sales, the timing and expenditures associated with resolving the recently announced supply interruption of Auryxia, the build-up of inventory and capacity expansion, and the timing, design and conduct of, and results from, clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond commercializing Auryxia, and to develop any drug candidates we may in-license or acquire.

Our forecast of the period of time through which our existing capital resources will be adequate to support our current operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include, but are not limited to, the following:

- the timing and expenditures associated with commercial activities related to Auryxia and the magnitude of cash received from product sales;

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- the timing and expenditures associated with the build-up of inventory and capacity expansion, including our ability to quickly and successfully identify and resolve the production-related issue that we announced in August 2016 and, as a result of the supply interruption, our ability to quickly and successfully identify and engage secondary suppliers of finished drug product and to timely receive FDA approval of any secondary suppliers of finished drug product;
- our ability to return our business to the level of sales that we had achieved prior to the supply interruption and to increase our sales further;
- the timing, design and conduct of, and results from, clinical trials for Auryxia;
- the timing of expenses associated with manufacturing and product development of Auryxia and those proprietary drug candidates that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the timing and expenditures associated with commercial activities related to launching Fexeric in Europe, either by us or through a commercialization partner;
- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under our licensing arrangement;
- the timing and expenses associated with capital expenditures to expand our manufacturing capabilities;
- the timing and expenses associated with building our own commercial infrastructure to manufacture, market and sell our drug and those that may be in-licensed, partnered or acquired; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights or defending against claims of infringement initiated by third parties in respect of their intellectual property rights.

If our cash is insufficient to meet our future operating requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us, or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

Risks related to our intellectual property and third-party contracts

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

Our commercial success will depend in part on our ability, and the ability of our licensors, to obtain and maintain patent protection on our drug product and technologies, and to successfully defend these patents against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug product and technologies which may have an adverse effect on our business. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that any related patent may expire prior to, or remain in existence for only a short period following, commercialization, thus reducing any advantage of the patent. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage. As many of the

patents we use are licensed or sublicensed from third parties, we may not be able to enforce such licensed patents against third party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

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Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the United States. In addition, in jurisdictions outside the United States where we own or license patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

We also rely on trade secrets and know-how to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, licensees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to our drug product and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

The intellectual property that we own or have licensed relating to our drug, Auryxia, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Auryxia.

The patent rights that we own or have licensed relating to Auryxia are limited in ways that may affect our ability to exclude third parties from competing against us. In particular:

- Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are key, non-interchangeable components of the pharmaceutical product. The first composition of matter and method patent relating to Auryxia in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We licensed additional composition of matter and method of use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient, or API, of Auryxia), pharmaceutical compositions that include the API, pharmaceutical compositions having ferric citrate in an amount effective to reduce serum phosphate levels, and methods of treating hyperphosphatemia and metabolic acidosis.
- Our method of use patents, including U.S. Patent Nos. 7,767,851, 8,299,298 and 8,338,642 and (which expire in 2024), and U.S. Patent No. 8,093,423 (which expires in 2026) only protect the product when used or sold for the claimed methods. However, these types of patents do not limit a competitor from making and marketing a product that is identical to our product that is labeled for an indication that is outside of our patented methods.
- We have filed applications under the Patent Term Extension provisions of 35 U.S.C. § 156 on the above mentioned patents for delays caused by FDA regulatory review. If granted, we can utilize the patent term extension on one of these patents, however, we cannot assure you that we can obtain any extension of the term of these patents. If obtained, the maximum term of extension available under 35 U.S.C. § 156 would extend the term of the chosen patent by no more than five years. Upon expiration of these patents, competitors who obtain the requisite regulatory approval may potentially offer products with the same composition and/or method of use as our product, so long as the competitors do not infringe any other patents that we may hold.
- Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our product(s) or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our product.

Obtaining proof of direct infringement by a competitor for a method of use patent requires us to demonstrate that the competitors make and market a product for the patented use(s). Alternatively, we can prove that our competitors

induce or contribute to others in engaging in direct infringement. Proving that a competitor contributes to, or induces, infringement of a patented method by another has additional proof requirements. For example, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Auryxia, increase the risk that a generic version of Auryxia could enter the market to compete with Auryxia, limit our development and commercialization of Auryxia, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Auryxia. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

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

In addition, any limitations of our patent protection described above may adversely affect the value of our drug product and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

In addition to patent protection, we may utilize, if granted by the FDA, pediatric exclusivity or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, such as new chemical entity exclusivity, or NCE, or new formulation exclusivity, to provide market exclusivity for a drug candidate.

In the United States, the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity may provide an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired.

The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a New Chemical Entity, or NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full ANDA; however, an applicant submitting a full ANDA would be required to conduct sufficient studies to demonstrate that their generic product is bioequivalent to Auryxia.

We cannot assure that Auryxia or any drug candidates we may acquire or in-license, will obtain such pediatric exclusivity, NCE exclusivity or any other market exclusivity in the United States, EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection. We also cannot assure that Auryxia or any drug candidates we may acquire or in-license will obtain patent term extension.

Litigation or third-party claims could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our product.

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. In addition, third parties may have or may obtain patents in the future and claim that Auryxia or any other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management s attention may be diverted from operating our business. In addition, any legal action against our licensor or us that seeks damages or an injunction of our commercial

activities relating to Auryxia or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Auryxia or such technologies, and/or require our licensor or us to obtain a license to continue to use Auryxia or other technologies. We cannot predict whether our licensor or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

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Risks related to our common stock

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

As of June 30, 2016, Baupost beneficially owns approximately 24% of our issued and outstanding common stock. If all of the Notes were converted into shares of our common stock, Baupost would beneficially own approximately 43% of our issued and outstanding common stock. Baupost, through its equity interests, may have significant influence over matters submitted to our stockholders for approval and other corporate actions, such as:

- election of directors;
- timing and manner of dividend distributions;
- approval of contracts between us and Baupost or its respective affiliates, which could involve conflicts of interest;
- open market purchase programs or other purchases of our common shares;
- delay, defer or prevent a change in who controls us;
- discourage bids for our shares at a premium over the market price; and
- adversely affect the market price of our common shares.

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

Future sales or other issuances of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or make it more difficult for us to raise funds through the sale of equity in the future.

In October 2015, we raised $125 million through the private placement of Convertible Senior Notes, due 2020, with funds managed by The Baupost Group, L.L.C. The zero-coupon notes will mature in October 2020 unless converted into shares of our common stock in accordance with their terms prior to such date. Keryx does not have the right to

redeem the notes prior to maturity. The conversion price of the notes shall be equal to the closing price of Keryx s common stock on the day prior to closing, October 14, 2015, or $3.74 per share, subject to certain adjustments under the terms of the notes.

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

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

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If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders holdings may be significantly diluted. In addition, stockholders holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

Our stock price can be volatile, which increases the risk of litigation, and may result in a significant decline in the value of your investment.

The trading price of our common stock is likely to be highly volatile and subject to wide fluctuations in price in response to various factors, many of which are beyond our control. These factors include:

- our ability to resolve the recently announced supply interruption of Auryxia;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments involving us or our competitors;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in quarterly or annual operating results;
- developments relating to the marketing, safety and efficacy of our drug product, and regulatory filings and approvals for us or our competitors;
- expectations regarding our financial condition;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- expectations or investor speculation regarding the strength of our intellectual property position, or the availability of other forms of regulatory exclusivity;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies;
- negative comments and sentiment in the media; and
- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company s securities, securities class-action litigation has often been instituted against that company. For example, in August 2016, two purported class action lawsuits were filed against us and certain of our executive officers alleging false and/or misleading statements concerning the company and its business operations and future prospects in light of the recent announcement of the supply interruption of Auryxia. Any litigation instituted against us could cause us to incur substantial costs to defend such claims and divert management s attention and resources, which could seriously harm our business.

Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the

approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

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ITEM 6. EXHIBITS

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

3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated December 17, 2003, and the Amendment thereto, dated June 18, 2004, filed as Exhibit 3.1 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007, filed as Exhibit 3.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated June 18, 2013, filed as Exhibit 3.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed on August 2, 2013 (File No. 000-30929), and incorporated herein by reference.
3.4	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated May 25, 2016.
10.1	Keryx Biopharmaceuticals, Inc. Amended and Restated 2013 Incentive Plan, filed as Exhibit 10.1 to the Registrant s Current Report on Form 8-K, filed on May 27, 2016 (File No. 000-30929), and incorporated herein by reference.
10.2	Keryx Biopharmaceuticals, Inc. Fourth Amended and Restated Directors Equity Compensation Plan, filed as Exhibit 10.2 to the Registrant s Current Report on Form 8-K, filed on May 27, 2016 (File No. 000-30929), and incorporated herein by reference.
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 August 5, 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 August 5, 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 August 5, 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 August 5, 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.

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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: August 5, 2016

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

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