KERYX BIOPHARMACEUTICALS INC
Form 10-Q
May 04, 2015
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

x **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the quarterly period ended March 31, 2015

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.)**

750 Lexington Avenue

New York, New York 10022

(Address including zip code of principal executive offices)

(212) 531-5965

(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 103,596,271 shares of the registrant s common stock, $0.001 par value, outstanding as of April 20, 2015.

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KERYX BIOPHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED MARCH 31, 2015

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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 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 written or oral 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);
- expectations for increases or decreases in expenses;
- expectations for pre-clinical and clinical development and regulatory progress, including our pending Marketing Authorization Application with the European Medicines Agency, manufacturing, regulatory approval, and commercialization (including market acceptance) of Auryxia or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations regarding our ability to successfully market Riona® through our Japanese partner, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd.;
- expectations regarding our ability to successfully develop Auryxia for the treatment of iron deficiency anemia in non-dialysis chronic kidney disease patients;
- expectations that the European Medicines Agency will concur with our interpretation of our registration studies in End Stage Renal Disease and non-dialysis dependent chronic kidney disease, supportive data, conduct of such studies, or any other part of our Marketing Authorization Application submission;

expectations for generating revenue or becoming profitable on a sustained basis;

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

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

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

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

expected losses; and

expectations for future capital requirements.

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

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.

Consolidated Balance Sheets as of March 31, 2015 and December 31, 2014

(in thousands, except share and per share amounts)

	March 31, 2015 (Unaudited)	December 31, 2014
Assets		
Current assets:		
Cash and cash equivalents	$ 168,836	$ 74,284
Short-term investment securities		11,508
Interest receivable		48
Inventory	27,242	7,830
Accounts receivable, net	1,283	834
Other current assets	3,388	4,092
Total current assets	200,749	98,596
Property, plant and equipment, net	1,455	1,532
Goodwill	3,208	3,208
Other assets, net	307	292
Total assets	$ 205,719	$ 103,628
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 33,069	$ 24,146
Accrued compensation and related liabilities	2,573	4,751
Deferred revenue	714	414
Total current liabilities	36,356	29,311
Deferred tax liability	722	700
Other liabilities	99	133
Total liabilities	37,177	30,144
Commitments and contingencies		

Stockholders equity:				
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)				
Common stock, $0.001 par value per share (130,000,000 shares authorized, 103,700,385 and 92,758,789 shares issued, 103,620,437 and 92,678,841 shares outstanding at March 31, 2015 and December 31, 2014, respectively)		104		93
Additional paid-in capital		747,392		624,606
Treasury stock, at cost, 79,948 shares at March 31, 2015 and December 31, 2014, respectively		(357)		(357)
Accumulated deficit		(578,597)		(550,858)
Total stockholders equity		168,542		73,484
Total liabilities and stockholders equity	$	205,719	$	103,628

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

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Operations

for the three months ended March 31, 2015 and 2014 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended March 31,	
	2015	**2014**
Revenues:		
Product revenue, net	$ 422	$
License revenue	753	10,000
Total Revenues	1,175	10,000
Operating expenses:		
Cost of goods sold	76	
License expenses	452	
Research and development	9,591	16,359
Selling, general and administrative	18,880	7,292
Total operating expenses	28,999	23,651
Operating loss	(27,824)	(13,651)
Interest and other income, net	107	121
Loss before income taxes	(27,717)	(13,530)
Income taxes	22	
Net loss	$ (27,739)	$ (13,530)
Basic and diluted net loss per common share	$ (0.28)	$ (0.15)
Weighted average shares used in computing basic and diluted net loss per common share	100,553,490	88,517,437

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

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Keryx Biopharmaceuticals, Inc.

Consolidated Statement of Stockholders Equity

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

(in thousands, except share amounts)

	Common stock		Additional paid-in	Treasury stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	deficit	Total
Balance at December 31, 2014	92,758,789	$ 93	$ 624,606	79,948	$ (357)	$ (550,858)	$ 73,484
Changes during the period:							
Issuance of common stock in public offering (net of offering costs of $8,216)	10,541,667	11	118,273				118,284
Issuance of restricted stock	399,000	*					*
Forfeiture of restricted stock	(17,696)	( )*					( )*
Issuance of common stock in connection with exercise of options	18,625	*	97				97
Compensation in respect of options and restricted stock granted to employees, directors and third-parties			4,416				4,416
Net loss						(27,739)	(27,739)
Balance at March 31, 2015	103,700,385	$ 104	$ 747,392	79,948	$ (357)	$ (578,597)	$ 168,542

* Amount less than one thousand dollars.

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

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Keryx Biopharmaceuticals, Inc.

Consolidated Statements of Cash Flows

for the three months ended March 31, 2015 and 2014 (Unaudited)

(in thousands)

	Three months ended March 31,	
	2015	**2014**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (27,739)	$ (13,530)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Stock compensation expense	4,321	2,552
Depreciation and amortization	138	32
Deferred income taxes	22	
Changes in assets and liabilities:		
Decrease (increase) in other current assets	704	(13)
Increase in accounts receivable, net	(449)	
Decrease (increase) in accrued interest receivable	48	(195)
Increase in inventory	(19,317)	
(Increase) decrease in other assets	(15)	64
Increase in accounts payable and accrued expenses	8,923	1,951
Decrease in accrued compensation and related liabilities	(2,178)	(910)
Increase in deferred revenue	300	
(Decrease) increase in other liabilities	(34)	3
Net cash used in operating activities	(35,276)	(10,046)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(61)	(221)
Investment in held-to-maturity short-term securities		(49,772)
Proceeds from maturity of held-to-maturity short-term securities	11,508	107
Net cash provided by (used in) investing activities	11,447	(49,886)
CASH FLOWS FROM FINANCING ACTIVITIES		
Gross proceeds from public offerings	126,500	115,057
Offering costs related to public offerings	(8,216)	(7,460)
Proceeds from exercise of options	97	1,896

Net cash provided by financing activities	118,381	109,493
NET INCREASE IN CASH AND CASH EQUIVALENTS	94,552	49,561
Cash and cash equivalents at beginning of period	74,284	55,696
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 168,836	$ 105,257

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

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Keryx Biopharmaceuticals, Inc.

Notes to Consolidated Financial Statements (unaudited)

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

NOTE 1 GENERAL

Basis of Presentation

We are a biopharmaceutical company focused on bringing innovative therapies to market for patients suffering from renal disease. Most of our biopharmaceutical development and substantially all of our administrative operations during the three months ended March 31, 2015 and 2014 were conducted in the United States of America.

The accompanying unaudited consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (GAAP) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they may not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the consolidated financial statements have been included. Nevertheless, these unaudited consolidated financial statements should be read in conjunction with the audited consolidated financial statements contained in our Annual Report on Form 10-K for the year ended December 31, 2014. The results of operations for the three months ended March 31, 2015, are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Certain prior period amounts in the condensed consolidated financial statements have been altered to conform to the current quarter presentation. As of September 30, 2014, we removed the non-cash compensation disclosures from our consolidated statements of operations and, instead, present the amounts of non-cash compensation included in cost of goods sold, selling, general and administrative expenses and research and development expenses in the accompanying notes to the consolidated financial statements. See Note 4 Stockholders Equity.

Except for 2009, 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 March 31, 2015, we have an accumulated deficit of $578.6 million.

Our first product, Auryxia™ (ferric citrate), an oral, absorbable iron-based compound, received marketing approval from the U.S. Food and Drug Administration (FDA), in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis. Auryxia, which was launched in late December 2014, is being marketed in the U.S. through our specialty salesforce and commercial infrastructure. We currently have approximately 60 sales representatives in the field calling on approximately 5,000 target nephrologists.

Our Japanese partner, Japan Tobacco Inc. (JT) and Torii Pharmaceutical Co. Ltd. (Torii), received manufacturing and marketing approval of ferric citrate in January 2014 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 non-dialysis

dependent CKD (NDD-CKD). JT s subsidiary, Torii, launched the product under the brand name Riona® in May 2014. Under the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We owe a mid-single digit percentage of net sales royalty to the licensor of ferric citrate associated with net sales of Riona in Japan. See Note 5 for additional information.

We have also submitted, in March 2014, a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for the approval of Auryxia in patients with CKD, including dialysis and NDD-CKD. Also in March 2014, the EMA validated our MAA, confirming that the submission is sufficiently complete to begin the formal review process. The regulatory review of our MAA submission is ongoing.

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In September 2014, we announced the initiation of a pivotal Phase 3 study of Auryxia for the treatment of iron deficiency anemia (IDA) in patients with Stage 3-5 NDD-CKD. This study s primary endpoint is 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.

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

Our major sources of cash have been proceeds from various public and private offerings of our common stock, option and warrant exercises, interest income, and from the upfront and milestone payments from our Sublicense Agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. Prior to the launch of Auryxia in late December 2014, we have not commercialized any drug, and 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 January 2015, we raised approximately $118.3 million, net of underwriting discounts and offering expenses of approximately $8.2 million, in an underwritten public offering. 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. See Note 4 for additional information.

We currently expect that our existing capital resources combined with 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 the build-up of inventory and capacity expansion, the timing and expenditures associated with the regulatory review process for our EU MAA filing, and the timing, design and conduct of clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire.

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

Corporate

In January 2015, we announced the transitioning of the role of Chief Executive Officer from Ron Bentsur to Greg Madison. 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, bringing to Keryx a wealth of relevant expertise in both the phosphate binder and iron deficiency anemia markets. In March 2015, Mr. Madison was appointed to our Board of Directors. Mr. Madison assumed the Chief Executive Officer role following the resignation of Mr. Bentsur on April 30, 2015.

In February 2015, we announced a planned consolidation of our finance and accounting function into our Boston office and that our Chief Financial Officer, James Oliviero, will be leaving Keryx by October 2015. Mr. Oliviero has been with Keryx for twelve years and has served as the Chief Financial Officer since 2009. We have commenced a

search for a new Chief Financial Officer who will be based in our Boston office. Mr. Oliviero will continue to manage our finance and accounting team during the remainder of his tenure and will assist in the transition of his duties to the new Chief Financial Officer.

In April 2015, we announced the appointment of John F. Neylan, M.D., as our Chief Medical Officer.

In April 2015, we signed a new lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94 month term commencing May 1, 2015, at an average rent of approximately $123,600 per month. The new lease will replace our current subleased space in the same building, which term expires on December 31, 2015.

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Recently Issued Accounting Standards

In August 2014, the Financial Accounting Standards Board issued a new standard, Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. This new standard will explicitly require management to assess an entity s ability to continue as a going concern and to provide footnote disclosures in certain cases. Currently there is no guidance in GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern. The new standard applies to all entities and provides an explicit requirement that management assesses and discloses going concern uncertainties. Previous guidance in auditing standards required auditors to evaluate going concern. The new standard will be effective for all entities in the first annual period ending after December 15, 2016, which is December 31, 2016 for calendar year-end entities. Earlier application is permitted.

In May 2014, the Financial Accounting Standards Board issued 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, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard will have on our financial position and results of operations.

Cash and Cash Equivalents

We treat liquid investments with original maturities of three months or less when purchased as cash and cash equivalents.

Investment Securities

We classify our short-term debt securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Available-for-sale investment securities are recorded at fair value (see Note 2 Fair Value Measurements). Other-than-temporary impairment charges are included in interest and other income, net, and unrealized gains (losses), if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders equity.

The following table summarizes our investment securities at March 31, 2015, and December 31, 2014:

(in thousands)	**March 31, 2015**	**December 31, 2014**
Short-term investments (held to maturity):		
Obligations of domestic governmental agencies	$	$ 11,508
Total short-term investment securities	$	$ 11,508

Inventory

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of our inventories, which include 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 were included as a component of research and development expense.

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Accounts Receivable, net

We extend credit to our customers for product sales resulting in accounts receivable. Customer accounts are monitored for past due amounts. Past due accounts receivable, determined to be uncollectible, are written off against the allowance for doubtful accounts. Allowances for doubtful accounts are estimated based upon past due amounts, historical losses and existing economic factors, and are adjusted periodically. We offer cash discounts to our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at March 31, 2015 and December 31, 2014.

Revenue Recognition

Our commercial launch of Auryxia occurred in late December 2014. We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with GAAP, our revenue recognition policy requires that: (i) there is persuasive evidence that an arrangement exists between us and the Customer, (ii) delivery has occurred, (iii) collectability is reasonably assured and (iv) the price is fixed or determinable. 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 sales from us to such Customers. Consistent with industry practice, once we achieve sufficient history such that we can reliably estimate returns based on sales to our Customers, we anticipate that our revenues will be recognized based on sales to our Customers. We currently defer Auryxia revenue recognition until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue is recorded net of discounts, rebates, and chargebacks. We also defer the related cost of product sales and record such amounts as finished goods inventory held by others, which is included in inventory on our consolidated balance sheet, until revenue related to such product sales is recognized.

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product revenues from the sales to Customers and (ii) reasonably estimate our net product revenues. We calculate gross product revenues based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product revenues by deducting from our gross product revenues (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 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 revenues and accounts receivable at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various commercial and Medicare Part D private insurance providers, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We also contract with certain specialty pharmacies directly so that Auryxia will be eligible for purchase by these specialty pharmacies. We estimate the rebates, chargebacks and discounts we will provide to Third-party Payors and specialty pharmacies, and deduct these estimated amounts from our gross product revenues 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.

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Product Returns: During the three months ended March 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 due to insufficient historical returns data. Once sufficient data exists, we will estimate the amount of Auryxia that will be returned and deduct these estimated amounts from our gross revenues at the time that revenues are recognized. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of March 31, 2015, we have experienced no 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 revenues at the time the revenues are recognized. Our vouchers offered to date will expire on December 31, 2015. 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 activity in each of the product revenue allowance and reserve categories described above for the three months ended March 31, 2015:

(in thousands)	Trade allowances	Rebates, chargebacks and discounts	Product returns	Other incentives (1)	Total
Balance at January 1, 2015	$ 136	$ 48	$	$ 275	$ 459
Provision related to current period and deferred sales	347	221		858	1,426
Credits/payments made for current period and deferred sales	(63)	(2)		(280)	(345)
Credits/payments made for prior period and deferred sales	(136)	(4)		(275)	(415)
Balance at March 31, 2015	$ 284	$ 263	$	$ 578	$ 1,125

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

The following table summarizes product revenue recognized and deferred during the three months ended March 31, 2015, and the year ended December 31, 2014:

(in thousands)	March 31, 2015	December 31, 2014

Product revenue recognized	$ 422	$
Deferred product revenue	714	414
	$ 1,136	$ 414

In conjunction with our recognition and deferral of product revenues, we expensed and capitalized the associated cost of goods, as follows, during the three months ended March 31, 2015, and the year ended December 31, 2014:

(in thousands)	**March 31, 2015**	**December 31, 2014**
Cost of goods sold expensed	$ 76	$
Finished goods inventory held by others	107	47
	$ 183	$ 47

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

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

Cost of Goods Sold

Cost of goods sold includes the cost of active pharmaceutical ingredient (API) for Auryxia on which product revenue was recognized during the period, as well as the associated costs for tableting, packaging, shipment, insurance and quality assurance. Cost of goods sold also includes the royalty expense due the licensor of Auryxia related to the product revenue recognized during the period.

License Expenses

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

Stock-Based Compensation

We recognize all share-based payments to employees and to non-employee directors for service on our board of directors as compensation expense in the consolidated financial statements based on the grant date fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. 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.

Income Taxes

As of March 31, 2015, we have U.S. net operating loss carryforwards of approximately $545.4 million which expire from 2019 through 2035. We have established a 100% valuation allowance against our net deferred tax assets due to our history of pre-tax losses and the likelihood that the deferred tax assets will not be realizable. Due to our historical equity transactions, the utilization of certain tax loss carryforwards may be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provisions.

For the three months ended March 31, 2015, we recognized $22,000 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. Indefinite-lived intangibles are non-monetary assets which are not amortized for book purposes since there is no foreseeable limit to the cash flows provided by them. The total deferred tax liability recognized on the balance sheet as of March 31, 2015 is $722,000.

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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 deferred tax liability.

We are not aware of any unrecorded tax liabilities which would materially impact our financial position or our results of operations.

Net Loss Per Share

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options, as their inclusion would be anti-dilutive for all periods presented. The options outstanding as of March 31, 2015 and 2014, which are not included in the computation of net loss per share amounts, were 6,257,851 and 4,360,925, respectively.

Comprehensive Loss

Comprehensive loss is the same as net loss for all periods presented.

Segment Reporting

We operate in only one reportable segment: the Products segment.

Impairment of 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. As of December 31, 2014, management concluded that there was no impairment of our goodwill. For the period ending March 31, 2015, management determined that there were no impairment indicators that would trigger a goodwill impairment analysis.

NOTE 2 FAIR VALUE MEASUREMENTS

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

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

	Financial assets at fair value as of March 31, 2015		
(in thousands)	Level 1	Level 2	Level 3
Money market funds (1)	$ 162,471	$	$
Total	$ 162,471	$	$

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

NOTE 3 INVENTORY

Upon approval of Auryxia on September 5, 2014 by the FDA, we began capitalizing our purchases of saleable inventory of Auryxia from suppliers. Inventories consist of the following at March 31, 2015 and December 31, 2014 (in thousands):

	March 31, 2015	December 31, 2014
Raw materials	$ 111	$ 111
Work in process	26,360	7,263
Finished goods	664	409
Finished goods inventory held by others	107	47
Total inventory	$ 27,242	$ 7,830

NOTE 4 STOCKHOLDERS EQUITY

Common Stock

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

Equity Incentive Plans

Total shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 3,973,425 shares at March 31, 2015.

Stock Options

The following table summarizes stock option activity for the three months ended March 31, 2015:

	Number of shares	Weighted-average exercise price	Weighted-average contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2014	5,132,426	$ 9.32	7.0	$ 26,916,823
Granted	1,189,150	14.42		
Exercised	(18,625)	5.19		$ 143,765
Forfeited	(24,017)	11.93		
Expired	(21,083)	11.33		
Outstanding at March 31, 2015	6,257,851	$ 10.29	7.3	$ 22,306,663
Vested and expected to vest at March 31, 2015	6,142,322	$ 10.22	7.3	$ 22,233,401
Exercisable at March 31, 2015	2,809,216	$ 5.87	5.0	$ 20,119,734

Upon the exercise of stock options, we issue new shares of our common stock. As of March 31, 2015, 125,000 options issued to employees are unvested, milestone-based options.

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Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under our incentive plans. The time-vesting restricted stock grants vest primarily over a period of three years. The following table summarizes restricted share activity for the three months ended March 31, 2015:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2014	926,947	$ 12.22	$ 13,116,300
Granted	399,000	14.28	
Vested	(138,489)	12.01	$ 1,821,032
Forfeited	(17,696)	8.59	
Outstanding at March 31, 2015	1,169,762	$ 13.00	$ 14,891,070

As of March 31, 2015, 80,000 shares of restricted stock issued to employees are unvested, milestone-based shares.

On September 14, 2009, we entered in an employment agreement with Ron Bentsur, our previous Chief Executive Officer, which was amended on January 13, 2012, and further amended on each of September 11, 2013 and April 30, 2015. The agreement, as amended, terminated on April 30, 2015. As of March 31, 2015, Mr. Bentsur had been granted a total of 1,250,000 shares of restricted stock based on the achievement of certain milestone awards described in his employment agreement. In accordance with the termination of Mr. Bentsur s employment, until July 30, 2015, Mr. Bentsur has the opportunity to earn milestone awards of 100,000 shares of restricted stock, vesting upon grant, upon each event of our outlicensing Auryxia in a foreign market, other than Japan, resulting in a greater than $10 million non-refundable cash payment to us with a gross deal value to us of at least $50 million.

Stock-Based Compensation

We incurred $4.3 million and $2.6 million of non-cash compensation expense related to equity incentive grants during the three months ended March 31, 2015 and 2014, respectively. The following table reflects stock-based compensation expense for the three month period ended March 31, 2015 and 2014:

Stock-Based Compensation (in thousands)	**Three months ended March 31, 2015**	**2014**
Cost of goods sold	$ 1	$
Research and development	921	804
Selling, general and administrative	3,399	1,748
Total stock-based compensation expense	$ 4,321	$ 2,552

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

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data, the expected vesting period and the full contractual term. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future.

Black-Scholes Option Valuation Assumptions	**Three months ended March 31,**	
	2015	**2014**
Risk-free interest rates	1.7%	2.0%
Dividend yield		
Volatility	91.6%	104.9%
Weighted-average expected term	6.0 years	6.0 years

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The weighted average grant date fair value of options granted for the three months ended March 31, 2015 and 2014 was $10.83 and $11.28 per option, respectively. We used historical information to estimate forfeitures within the valuation model. As of March 31, 2015, there was $30.1 million and $12.4 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 2.4 years and 2.3 years, respectively. These amounts do not include, as of March 31, 2015, 125,000 options outstanding and 80,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones, such as change in control. Stock-based compensation will be measured and recorded if and when it is probable that the milestone will occur.

NOTE 5 LICENSE AGREEMENTS

In November 2005, we entered into a license agreement with Panion & BF Biotech, Inc. (Panion). Under the license agreement, we acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of Auryxia. To date, we have paid an aggregate of $9.6 million of milestone payments to Panion, and Panion is eligible to receive one additional milestone payment of $2.0 million upon our successful achievement of European marketing approval, in addition to royalty payments based on a mid-single digit percentage of net sales of Auryxia. For the three months ended March 31, 2015, we recorded approximately $24,000 in cost of goods sold related to royalties payments due Panion relating to sales of Auryxia in the U.S.

In September 2007, we entered into a Sublicense Agreement with JT and Torii, JT s pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan, which is being marketed in the U.S. under the trade name Auryxia. JT and Torii are responsible for the future development and commercialization costs in Japan. Effective as of June 8, 2009, we entered into an Amended and Restated Sublicense Agreement (the Revised Agreement) with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the sublicense agreement.

In January 2014, JT and Torii received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, launched in May 2014 and being marketed in Japan by JT s subsidiary, Torii Pharmaceutical Co., Ltd., under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. As a result, we recorded license revenue of $10.0 million in accordance with our revenue recognition policy, which is included in the three months ended March 31, 2014. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona® in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. In accordance with our revenue recognition policy, royalty revenues are recognized in the quarter that JT and Torii provide their written report and related information to us regarding sales of Riona®, which generally will be one quarter following the quarter in which the underlying sales by JT and Torii occurred. For the three months ended March 31, 2015, we recorded $0.8 million 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 Auryxia, as license expenses in the same period as the royalty revenue from JT and Torii is recorded. For the three months ended March 31, 2015, we recorded $0.5 million in license expenses related to royalties due Panion relating to sales of Riona® in Japan.

NOTE 6 LEGAL PROCEEDINGS

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

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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 in Risk Factors. See also the Special Cautionary Notice Regarding Forward-Looking Statements set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management s discussion and analysis and the audited consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2014.

OVERVIEW

We are a biopharmaceutical company focused on bringing innovative therapies to market for patients with renal disease. Our first product, Auryxia (ferric citrate), an oral, absorbable iron-based compound, 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. The U.S. approval of Auryxia was based on data from our Phase 3 registration program, in which Auryxia effectively reduced serum phosphorus levels to well within the KDOQI guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Auryxia s pharmacodynamic properties resulted in increased ferritin, iron and transferrin saturation, or TSAT, whereas these parameters remained relatively constant in patients treated with active control (Renvela® and/or PhosLo®). The most common adverse events for Auryxia treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough.

We launched Auryxia in the U.S. in late December 2014. Auryxia is being marketed in the U.S. through our specialty salesforce and commercial infrastructure. We currently have approximately 60 sales representatives in the field calling on approximately 5,000 target nephrologists.

Our Japanese partner, Japan Tobacco Inc., or JT, and Torii Pharmaceutical Co. Ltd., or Torii, received manufacturing and marketing approval of ferric citrate in January 2014 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. JT s subsidiary, Torii, launched the product under the brand name Riona® in May 2014. Under the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona® in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones.

We have also submitted, in March 2014, a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, for the approval of Auryxia in patients with CKD, including dialysis and NDD-CKD. Also in March 2014, the EMA validated our MAA, confirming that the submission is sufficiently complete to begin the formal review process. The regulatory review of our MAA submission is ongoing.

In September 2014, we announced the initiation of a pivotal Phase 3 study of Auryxia for the treatment of iron deficiency anemia, or IDA, in patients with Stage 3-5 NDD-CKD. This study s primary endpoint is 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. In our completed 12-week Phase 2 study of Auryxia for the management of elevated serum phosphorus levels and iron deficiency in subjects with Stage 3 to 5 NDD-CKD, a post-hoc analysis of this endpoint demonstrated that the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any time point during the study was 40% in the Auryxia arm vs. 15% in the placebo arm (p-value <0.001). Secondary endpoints in the Phase 3 study include change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus.

Currently, our only product is Auryxia. We may engage in business development activities that include seeking strategic relationships for Auryxia, as well as evaluating other compounds and companies for in-licensing or acquisition. We have also generated, and expect to continue to generate, revenue from the sublicensing of rights to Auryxia in Japan to JT and Torii.

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RECENT DEVELOPMENTS

In January 2015, we announced the transitioning of the role of Chief Executive Officer from Ron Bentsur to Greg Madison. 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, bringing to Keryx a wealth of relevant expertise in both the phosphate binder and iron deficiency anemia markets. In March 2015, Mr. Madison was appointed to our Board of Directors. Mr. Madison assumed the Chief Executive Officer role following the resignation of Mr. Bentsur on April 30, 2015.

In February 2015, we announced a planned consolidation of our finance and accounting function into our Boston office and that our Chief Financial Officer, James Oliviero, will be leaving Keryx by October 2015. Mr. Oliviero has been with Keryx for twelve years and has served as the Chief Financial Officer since 2009. We have commenced a search for a new Chief Financial Officer who will be based in our Boston office. Mr. Oliviero will continue to manage our finance and accounting team during the remainder of his tenure and will assist in the transition of his duties to the new Chief Financial Officer.

In April 2015, we announced the appointment of John F. Neylan, M.D., as our Chief Medical Officer.

In April 2015, we signed a new lease agreement for approximately 27,300 square feet in Boston, Massachusetts, for a 94 month term commencing May 1, 2015, at an average rent of approximately $123,600 per month. The new lease will replace our current subleased space in the same building, which term expires on December 31, 2015.

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 launch of Auryxia in late December 2014, we have not commercialized any drug, and 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. We may continue to incur substantial operating losses even after we begin to generate meaningful revenues from our drug.

CRITICAL ACCOUNTING POLICIES

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

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

policies include the following:

Revenue Recognition

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

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product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product). The deferred revenue is recorded net of discounts, rebates, and chargebacks. We also defer the related cost of product sales and record such amounts as finished goods inventory held by others, which is included in inventory on our consolidated balance sheet, until revenue related to such product sales is recognized.

We have written contracts with our Customers and delivery occurs when a Customer receives Auryxia. We evaluate the creditworthiness of each of our Customers to determine whether revenues can be recognized upon delivery, subject to satisfaction of the other requirements, or whether recognition is required to be delayed until receipt of payment. In order to conclude that the price is fixed or determinable, we must be able to (i) calculate our gross product revenues from the sales to Customers and (ii) reasonably estimate our net product revenues. We calculate gross product revenues based on the wholesale acquisition cost that we charge our Customers for Auryxia. We estimate our net product revenues by deducting from our gross product revenues (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 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 revenues and accounts receivable at the time such revenues are recognized.

Rebates, Chargebacks and Discounts: We contract with Medicaid, other government agencies and various commercial and Medicare Part D private insurance providers, or collectively, our Third-party Payors, so that Auryxia will be eligible for partial or full reimbursement from such Third-party Payors. We also contract with certain specialty pharmacies directly so that Auryxia will be eligible for purchase by these specialty pharmacies. We estimate the rebates, chargebacks and discounts we will provide to Third-party Payors and specialty pharmacies, and deduct these estimated amounts from our gross product revenues 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: During the three months ended March 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 due to insufficient historical returns data. Once sufficient data exists, we will estimate the amount of Auryxia that will be returned and deduct these estimated amounts from our gross revenues at the time that revenues are recognized. Our Customers have the right to return Auryxia during the 18-month period beginning six months prior to the labeled expiration date and ending twelve months after the labeled expiration date. Currently the expiration date for Auryxia is eighteen months after it has been converted into tablet form, which is the last step in the manufacturing process for Auryxia and generally occurs within a few months before Auryxia is delivered to Customers. As of March 31, 2015, we have experienced no 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 revenues at the time the revenues are recognized. Our vouchers offered to date will expire on December 31, 2015. We adjust our accruals for co-pay mitigation and voucher rebates based on our estimates regarding the portion of issued rebates that we estimate will not be redeemed.

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The following table summarizes activity in each of the product revenue allowance and reserve categories described above for the three months ended March 31, 2015:

(in thousands)	Trade allowances	Rebates, chargebacks and discounts	Product returns	Other incentives (1)	Total
Balance at January 1, 2015	$ 136	$ 48	$	$ 275	$ 459
Provision related to current period and deferred sales	347	221		858	1,426
Credits/payments made for current period and deferred sales	(63)	(2)		(280)	(345)
Credits/payments made for prior period and deferred sales	(136)	(4)		(275)	(415)
Balance at March 31, 2015	$ 284	$ 263	$	$ 578	$ 1,125

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

The following table summarizes product revenue recognized and deferred during the three months ended March 31, 2015, and the year ended December 31, 2014:

(in thousands)	March 31, 2015	December 31, 2014
Product revenue recognized	$ 422	$
Deferred product revenue	714	414
	$ 1,136	$ 414

In conjunction with our recognition and deferral of product revenues, we expensed and capitalized the associated cost of goods, as follows, during the three months ended March 31, 2015, and the year ended December 31, 2014:

(in thousands)	March 31, 2015	December 31, 2014
Cost of goods sold expensed	$ 76	$
Finished goods inventory held by others	107	47
	$ 183	$ 47

We recognize license revenue in accordance with the revenue recognition guidance of the Codification. 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 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

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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.

Accruals for Clinical Research Organization and Clinical Site Costs

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

Inventories are stated at the lower of cost or estimated realizable value. We determine the cost of our inventories, which include 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 were 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 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 our customers, generally 2% of the sales price, as an incentive for prompt payment. The estimate of cash discounts is recorded at the time of sale. We account for the cash discounts by reducing revenue and accounts receivable by the amount of the discounts we expect our customers to take. The accounts receivable are reported in the consolidated balance sheets, net of the allowances for doubtful accounts and cash discounts. There was no allowance for doubtful accounts at March 31, 2015 and December 31, 2014.

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Accounting Related to Goodwill

As of March 31, 2015, there was approximately $3.2 million of goodwill on our consolidated balance sheet. 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, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

Accounting For Income Taxes

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

For the three months ended March 31, 2015, we recognized $22,000 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. Indefinite-lived intangibles are non-monetary assets which are not amortized for book purposes since there is no foreseeable limit to the cash flows provided by them. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax liability were the primary factors considered by management when recording the deferred tax liability.

RECENTLY ISSUED ACCOUNTING STANDARDS

In August 2014, the Financial Accounting Standards Board issued a new standard, Accounting Standards Update No. 2014-15, Disclosure of Uncertainties about an Entity s Ability to Continue as a Going Concern. This new standard will explicitly require management to assess an entity s ability to continue as a going concern and to provide footnote disclosures in certain cases. Currently there is no guidance in GAAP about management s responsibility to evaluate whether there is substantial doubt about an entity s ability to continue as a going concern. The new standard applies to all entities and provides an explicit requirement that management assesses and discloses going concern uncertainties. Previous guidance in auditing standards required auditors to evaluate going concern. The new standard will be

effective for all entities in the first annual period ending after December 15, 2016, which is December 31, 2016 for calendar year-end entities. Earlier application is permitted.

In May 2014, the Financial Accounting Standards Board issued 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

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recognition in both interim and annual periods. The standard is effective for interim and annual periods beginning after December 15, 2016 and allows for adoption using a full retrospective method, or a modified retrospective method. We are currently assessing the method of adoption and the expected impact the new standard will have on our financial position and results of operations.

RESULTS OF OPERATIONS

Three months ended March 31, 2015 and March 31, 2014

Product Revenue, Net. For the three months ended March 31, 2015, we recognized $0.4 million in product revenue from sales of Auryxia, net of allowances, discounts, incentives, rebates and chargebacks. Our commercial launch of Auryxia occurred in late December 2014. There was no product revenue for three months ended March 31, 2014.

(in thousands)	Three months ended March 31, 2015	Percent of gross Auryxia product sales
Gross Auryxia product sales	$ 964	
Less provision for product sales allowances and accruals		
Trade allowances	100	10%
Rebates, chargebacks and discounts	30	3%
Product returns		
Other incentives (1)	412	43%
Total	542	56%
Net Auryxia product sales	$ 422	

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

We sell product to a limited number of major wholesalers, our Distributors, as well as certain pharmacies, or collectively, our Customers. Our Distributors resell the product to retail pharmacies for purposes of their reselling the product to fill patient prescriptions. In accordance with our revenue recognition policy, until we have the ability to reliably estimate returns of Auryxia from our Customers, revenue recognition is deferred until the earlier of the product being resold for purposes of filling patient prescriptions and the expiration of the right of return (twelve months after the expiration date of the product), and not based on sales from us to our Customers. At March 31, 2015, we have deferred revenue of $0.7 million, which represents Auryxia product shipped to our Customers, but not yet resold to fill patient prescriptions, net of applicable discounts and rebates. We expect Auryxia product revenue and patient prescriptions to increase in 2015 as we continue the commercialization of Auryxia.

Other incentives, which is currently our largest deduction from gross product revenues, includes costs associated with patient services programs, including a voucher program that provides a free month of drug to patients as we work to build formulary access for Auryxia. Going forward, we expect that voucher redemptions will represent a continuously decreasing percentage of our business. This will result in less impact to our gross to net deduction over time, but it will be partially offset by increases in rebates as more of our business will be contracted with Third-party Payors.

License Revenue. For the three months ended March 31, 2015, we recognized $0.8 million in license revenue on royalty payments from sales of Riona® in Japan. JT s subsidiary, Torii, launched Riona® in May 2014. License revenue for the three months ended March 31, 2014 was $10.0 million due to the recognition of a $10.0 million non-refundable milestone payment in January 2014 related to JT and Torii s achievement of marketing approval in Japan. We receive royalty payments based on a tiered double-digit percentage of net sales of Riona® in Japan escalating up to the mid-teens for sales made by Torii. We may also receive up to an additional $55 million of milestone payments upon the achievement of certain annual net sales milestones.

Cost of Goods Sold. For the three months ended March 31, 2015, we recognized $0.1 million in cost of goods sold related to product sales of Auryxia. Our commercial launch of Auryxia occurred in late December 2014. There was no cost of goods sold expense recorded for the three months ended March 31, 2014. Cost of goods sold includes the cost of API for Auryxia on which product revenue was recognized during the period, as well as the associated costs for tableting, packaging, shipment, insurance and quality assurance. Cost of goods sold also includes the royalty expense due the licensor of Auryxia related to the product revenue recognized during the period.

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License Expenses. For the three months ended March 31, 2015, we recognized $0.5 million in license expenses related to royalties due to the licensor of Auryxia relating to sales of Riona® in Japan. There were no license expenses for the three months ended March 31, 2014. We owe a mid-single digit percentage of net sales royalty to the licensor of Auryxia associated with net sales of Riona® in Japan.

Research and Development Expenses. Research and development expenses decreased by $6.8 million to $9.6 million for the three months ended March 31, 2015, as compared to $16.4 million for the three months ended March 31, 2014. The decrease in research and development expenses was due to a $2.9 million decrease in regulatory and clinical study expenses related to Auryxia and a $3.8 million decrease in expenses related to the manufacturing of Auryxia, which were expensed in the comparable period in 2014 and primarily capitalized as inventory following the approval of Auryxia in September 2014. The three months ended March 31, 2015 included $2.0 million of expenses for medical affairs activities, as the medical affairs group will increasingly be supporting additional research and development of Auryxia in the post-approval setting and, therefore, the associated costs are included in research and development expenses as of January 2015. The three months ended March 31, 2014, included a $2.0 million one-time milestone payment to the licensor of Auryxia for JT and Torii s achievement of the Japanese marketing approval milestone in January 2014. We expect our quarterly research and development expenses to remain at a comparable level for the remainder of 2015.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $11.6 million to $18.9 million for the three months ended March 31, 2015, as compared to $7.3 million for the three months ended March 31, 2014. The increase was primarily related to a $10.2 million increase in commercial activities and associated personnel costs related to the commercialization of Auryxia, which included a $1.7 million increase in associated stock-based compensation expense related to the recording of the fair value of equity awards granted, which are expensed over the vesting periods of the individual awards. We expect our quarterly selling, general and administrative costs for the remainder of 2015 to increase modestly as we continue the commercialization of Auryxia.

Interest and Other Income, Net. Interest and other income, net, decreased by $14,000 to $107,000 for the three months ended March 31, 2015, as compared to $121,000 for the three months ended March 31, 2014.

Income Taxes. For the three months ended March 31, 2015, we recognized $22,000 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. 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 deferred tax liability. There was no income tax expense for the three months ended March 31, 2014. We continue to maintain a full valuation allowance against our net deferred tax assets.

LIQUIDITY AND CAPITAL RESOURCES

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

revenues from our drug.

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.

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In January 2014, our Japanese partner, JT and Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, launched in May 2014 and being marketed in Japan by JT s subsidiary, Torii, under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and NDD-CKD. Under the license agreement with JT and Torii, we received a non-refundable payment of $10.0 million in February 2014 for the achievement of the marketing approval milestone. We also receive royalty payments based on a tiered double-digit percentage of net sales of Riona® in Japan escalating up to the mid-teens, as well as up to an additional $55.0 million upon the achievement of certain annual net sales milestones. We owe a mid-single digit percentage of net sales royalty to the licensor of Auryxia associated with net sales of Riona® in Japan.

As of March 31, 2015, we had $168.8 million in cash and cash equivalents, as compared to $85.8 million in cash, cash equivalents, short-term investments and interest receivable at December 31, 2014, representing an increase of $83.0 million. We currently expect that our existing capital resources combined with 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 the build-up of inventory and capacity expansion, the timing and expenditures associated with the regulatory review process for our EU MAA filing, and the timing, design and conduct of clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Auryxia, and to develop any drug candidates we may in-license or acquire.

Net cash used in operating activities for the three months ended March 31, 2015 was $35.3 million, as compared to $10.0 million for the three months ended March 31, 1014. This increase in net cash used in operating activities was primarily related to Auryxia commercial expenditures to support the launch, including the manufacturing of inventory.

For the three months ended March 31, 2015, net cash provided by investing activities was $11.4 million, primarily due to the maturity of held-to-maturity short-term securities, as compared to $49.9 million of net cash used in investing activities for the three months ended March 31, 2014, primarily related to the investment in held-to-maturity short-term securities.

For the three months ended March 31, 2015, net cash provided by financing activities was $118.4 million as compared to $109.5 million for the three months ended March 31, 2014. The increase was primarily related to $118.3 million of net proceeds received from our public offering of common stock in January 2015, as compared to $107.5 million of net proceeds received from our public offering of common stock in January 2014.

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

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We currently invest in government and investment-grade corporate debt

in accordance with our investment policy, which we may change from time to time. The securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of March 31, 2015, 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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ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of March 31, 2015, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2015, 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 quarter ended March 31, 2015, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Limitations on Effectiveness of Controls

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

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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

ITEM 1A. RISK FACTORS

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.

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 March 31, 2015, we had an accumulated deficit of $578.6 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.

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We are highly dependent on the commercial success of Auryxia in the U.S. for the foreseeable future; we may be unable to attain profitability and positive cash flow from operations.

In September 2014, the FDA approved Auryxia (formerly known as Zerenex) 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 size of the treatable patient population;
- the effectiveness of the sales, managed markets and marketing efforts by us and our competitors;
- 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;
- 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;
- 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.

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.

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 U.S. 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 in any of these circumstances:

- 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 may decide to conduct a product recall;
- reformulation of the product, additional nonclinical or clinical studies, changes in labeling or changes to or reapprovals of manufacturing facilities may be required;

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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 and 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 and. 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 Good Manufacturing Practice regulations, (or cGMPs), and other regulatory requirements, including requirements from federal, state and local environmental and safety regulatory agencies and foreign regulatory requirements, if applicable. Significant scale-up of manufacturing may result in unanticipated technical challenges and will require validation studies that are subject to FDA inspection. Scale-up/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 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/technology transfer of Auryxia can

lead to significant delays in our development and commercial timelines.

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

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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.

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

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Auryxia in the U.S. 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.

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. The 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 that is designed to ensure that 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, 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 U.S. 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. For example, an authorized generic of Renvela® was launched in the U.S. in April 2014 by Impax Laboratories, Inc., or Impax, under a settlement agreement with Genzyme whereby Genzyme agreed to grant Impax a license to sell a one-time allotment of a specified number of bottles of an authorized generic version of Renvela® tablets. Impax is also pursuing approval of its pending Abbreviated New Drug Application, or ANDA, for generic Renvela® with the FDA. In addition, a generic formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the U.S. 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 April 20, 2015, we had 156 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. Although we have employment agreements with Greg Madison, James Oliviero, Brian Adams and John Neylan, M.D., these agreements do not prevent them from terminating their employment with us.

In January 2015, we announced the transitioning of the role of Chief Executive Officer from Ron Bentsur to Greg Madison. 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, bringing to Keryx a wealth of relevant expertise in both the phosphate binder and iron deficiency anemia markets. In March 2015, Mr. Madison was appointed to our Board of Directors. Mr. Madison assumed the Chief Executive Officer role following the resignation of Mr. Bentsur on April 30, 2015.

In February 2015, we announced a planned consolidation of our finance and accounting function into our Boston office and that our Chief Financial Officer, James Oliviero, will be leaving Keryx by October 2015. Mr. Oliviero has been with Keryx for twelve years and has served as the Chief Financial Officer since 2009. We have commenced a search for a new Chief Financial Officer who will be based in our Boston office. Mr. Oliviero will continue to manage our finance and accounting team during the remainder of his tenure and will assist in the transition of his duties to the new Chief Financial Officer.

Risks associated with our product development efforts

If we do not receive regulatory approvals to market our drug product in a timely manner, or at all, our business will be materially harmed and our stock price may be adversely affected.

We are commercializing and continuing to develop Auryxia, an oral, absorbable iron-based compound. In May 2011, we announced positive Scientific Advice from the EMA for the development of Auryxia for the management and control of serum phosphorus in CKD patients undergoing dialysis, and in NDD-CKD patients. The Scientific Advice from the EMA indicates that our successful Phase 3 program in dialysis in the U.S., in conjunction with safety data generated from other clinical studies with Auryxia, will be considered sufficient to support a MAA to the EMA for the indication in CKD patients on dialysis. The Scientific Advice also provided us with a regulatory path forward in the NDD-CKD setting in Europe. As a result, we believe that since our Phase 3 program in dialysis, and Phase 2 study in NDD-CKD, in the U.S. were successful, we will not need to conduct any additional clinical trials to assess the safety or efficacy of Auryxia in order to obtain European approval in CKD, including the dialysis and NDD-CKD settings. Accordingly, in March 2014, we submitted a MAA with the EMA for both dialysis and NDD-CKD, which was validated by the EMA in March 2014. Scientific Advice is legally non-binding and is based on the current scientific knowledge, which may be subject to future changes. Many companies which have been provided with positive Scientific Advice by the EMA have ultimately failed to obtain approval of an MAA for their drugs. Additionally, even if the primary endpoint in a Phase 3, or other pivotal, clinical trial is achieved, the Scientific Advice does not guarantee approval. The EMA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power and analyses, patient demographics, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision, which may delay or prevent EMA approval of Auryxia.

Obtaining approval of an MAA by the EMA is highly uncertain and like many product candidates, we may fail to obtain the approval even though our MAA has been validated by the EMA. The MAA review processes are extensive, lengthy, expensive and uncertain, and the EMA may delay, limit or deny approval of Auryxia for many reasons, including:

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we may not be able to demonstrate to the satisfaction of the regulatory authority that Auryxia is safe and effective for any indication;

the data arising from the clinical trials, including the Phase 3 results for dialysis patients and our Phase 2 results for NDD-CKD, the development program or the MAA for Auryxia may not be satisfactory to the EMA;

the EMA may disagree with the number, design, size, conduct or implementation of our clinical trials or conclude that the data fails to meet statistical or clinical significance;

the EMA may not find the data from preclinical and clinical studies sufficient to demonstrate that Auryxia s clinical and other benefits outweigh its safety risks;

the EMA may disagree with our interpretation of data from preclinical studies or clinical trials, and may reject conclusions from preclinical studies or clinical trials, or determine that primary or secondary endpoints from clinical trials were not met, or reject safety conclusions from such studies;

the EMA may not accept data generated at one or more of our clinical trial sites;

the EMA may determine that we did not properly oversee our clinical trials or follow the regulatory authority s advice or recommendations in conducting our clinical trials;

an advisory committee, if convened by the EMA, may recommend against approval of our application or may recommend that the respective regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve Auryxia;

data and analyses submitted to the EMA in response to questions raised during the review processes may not be satisfactory to the regulatory authority, and this may lead to significant delays in the approval of Auryxia or to the rejection of the Auryxia MAA; and

the EMA may identify deficiencies in the chemistry, manufacturing and controls, or CMC, sections of our MAA, our manufacturing processes, facilities or analytical methods or those of our third party contract manufacturers, and this may lead to significant delays in the approval of Auryxia or to the rejection of the Auryxia MAA.

Additionally, our March 2014 MAA submission to the EMA was our first MAA filing in Europe. During the regulatory review process, regulatory agencies will typically ask questions of drug sponsors, such as the Day 120 questions which we received from the EMA for which we submitted our responses in January 2015. We will endeavor

to answer all such questions in a timely and complete fashion; however, we cannot assure you that our answers to such questions will be complete and to the satisfaction of the regulatory agencies. If certain questions asked have not been fully and satisfactorily answered by us, approval of our filings may be delayed, or the filings may be rejected.

Accordingly, we may not receive the regulatory approvals needed to market Auryxia. Any failure or delay in completion of the development program or the EMA review processes would delay or foreclose commercialization of Auryxia and severely harm our business and financial condition.

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 U.S.

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Negative or inconclusive results from the clinical trials we conduct, such as the ongoing 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. 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 drug does not receive the necessary regulatory approvals, we will be unable to commercialize our drug, Auryxia, in Europe.

We have not received, and may never receive, regulatory approval for the commercial sale of Auryxia by the EMA. We may need to conduct significant additional research and human testing before we receive product approval with the EMA or with regulatory authorities of other countries. 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 EMA or a regulatory authority of another country, as applicable, may pose additional questions or request further toxicological, drug-drug interaction, pre-clinical or clinical data or substantiation. For example, while Auryxia is a Generally Recognized as Safe, or GRAS, substance in the U.S., and the EMA has not requested that we conduct a two-year carcinogenicity study in animals, there is no assurance that the EMA or some other regulatory authority will not ask us to conduct such a study in order to obtain regulatory approval. In addition, the EMA has not requested us to conduct reproductive toxicity, genotoxicity and single-dose toxicity studies and we are referencing such studies from the published scientific literature in our regulatory submissions. However, we can provide no assurance that the EMA will not ask us to conduct additional studies. We provided our responses to the EMA s Day 120 questions in January 2015 and in April 2015 we requested a 2-month extension to provide adequate time to respond to the final questions from the EMA; however, we cannot assure you that we have answered, or will continue to answer, these questions to the EMA s satisfaction or that the EMA will not have additional questions as part of the MAA review. Consequently, it may take us many years to complete the testing of our drug and failure can occur at any stage of this process. 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 Auryxia 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. We have submitted to the EMA data from our short-term and long-term rat and canine pre-clinical studies for Auryxia. While the EMA has reviewed the data from these studies and we have conducted 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 EMA 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. Moreover, the risk remains that the safety and efficacy data from our pivotal Phase 3 program for dialysis dependent CKD patients may be insufficiently persuasive for the approval of the drug, or may raise safety concerns that may prevent approval of the drug, for the indication sought. 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 EMA or any other regulatory agency. 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. In addition, top-line results reported on completed clinical trials, such as those from our long-term open label extension, or OLE, study for Auryxia in dialysis-dependent CKD patients, are based on a preliminary analysis of then available data (both safety and efficacy) and there is the risk that such findings and conclusions could change following a more comprehensive review of the data by a regulatory authority. For example, in January 2013, we announced successful top-line results from our long-term Phase 3 study of Auryxia for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with ESRD on dialysis. Updated results from the study were presented in June 2013 at the World Congress of Nephrology. We can provide no assurance that our findings and conclusions from our long-term Phase 3 study of Auryxia or from our long-term OLE study for Auryxia in dialysis-dependent CKD patients will not change following a more comprehensive review of the data by a regulatory authority.

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Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving what appeared to be promising results in earlier trials. We experienced such a setback with our Phase 3 KRX-0401 (perifosine) results in April 2012, and we can provide no assurance that we will not experience such setbacks with Auryxia 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 commercializing Auryxia.

We do not own our drug, Auryxia. We have licensed and sublicensed the rights, patent or otherwise, to Auryxia from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Auryxia from one of the inventors of Auryxia. The license agreement with Panion requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Auryxia) and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreement (including upon certain insolvency events), Panion could terminate the agreement, and we would lose the rights to Auryxia. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Auryxia, Panion could lose its license, which could impair or delay our ability to develop and commercialize Auryxia. From time to time, we may have disagreements with our licensors or collaborators, or they and/or we may have disagreements with the original inventors, regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our current drug and any future drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug or drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drugs. Finally, our rights to develop and commercialize Auryxia, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Auryxia and the licenses and sublicenses we grant to others.

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.

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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.

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 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. However, 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.

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 U.S. 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 U.S. or internationally, the reimportation of drugs into the U.S. 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.

Furthermore, in the U.S., 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

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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.

We have expanded our insurance coverage to include the commercial sale of Auryxia; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also

may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

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

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

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

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

Risks related to our financial condition

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

We currently expect that our existing capital resources combined with 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 the build-up of inventory and capacity expansion, the timing and expenditures associated with the regulatory review process for our EU MAA filing, and the timing, design and conduct of clinical trials for Auryxia. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of 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;
- the timing and expenditures associated with the build-up of inventory and capacity expansion;
- the timing and expenditures associated with the regulatory review process for our EU MAA filing;

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 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.

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If our cash is insufficient to meet 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 U.S. 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.

Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. In addition, in jurisdictions outside the U.S. 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.

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

if at all.

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

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

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 U.S., 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.

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The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. 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 may also seek to utilize market exclusivities in other territories, such as in the EU.

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 U.S., 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.

Risks Related to Our Common Stock

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 could make it more difficult for us to raise funds through the sale of equity in the future.

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 financing to provide cash necessary to execute our current operations, including beyond the initial 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:

- 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 the past, we have been the subject of a putative stockholders securities class action alleging misstatements or omissions in relation to our clinical trials for KRX-0401 (perifosine), which we abandoned in May 2012 following negative Phase 3 results. 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., as amended, filed as Exhibit 3.1 to the Registrant s Annual Report on Form 10-Q for the quarter ended September 30, 2004, filed on August 12, 2004, and incorporated herein by reference.
	3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002, and incorporated herein by reference.
	3.3	Amendment Number 2 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 September 30, 2007, filed on August 9, 2007 and incorporated herein by reference.
	3.4	Amendment Number 3 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 and incorporated herein by reference.
10.1	!	Employment Agreement with Gregory P. Madison dated March 10, 2015.
	10.2	Employment Agreement with Brian Adams dated April 8, 2014.
	10.3	Employment Agreement with John F. Neylan, M.D. dated April 22, 2015.
	10.4	Third Amendment to Employment Agreement with Ron Bentsur dated April 30, 2015.
	31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 4, 2015.
	31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 4, 2015.
	32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 4, 2015.
	32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 4, 2015.
	101	Interactive data files pursuant to Rule 405 of Regulation S-T: (i) Consolidated Balance Sheets, (ii) Consolidated Statements of Operations, (iii) Consolidated Statements of Stockholders Equity, (iv) Consolidated Statements of Cash Flows, and (v) the Notes to Consolidated Financial Statements.

Indicates management contract or compensatory plan or arrangement.

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

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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: May 4, 2015

By: /s/ James F. Oliviero, CFA
Chief Financial Officer
Principal Financial and Accounting Officer

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EXHIBIT INDEX

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

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