KERYX BIOPHARMACEUTICALS INC
Form 10-Q
November 06, 2014
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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended September 30, 2014

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 ¨	Accelerated filer x
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 91,940,297 shares of the registrant s common stock, $0.001 par value, outstanding as of October 31, 2014.

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KERYX BIOPHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED SEPTEMBER 30, 2014

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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 a 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:

- expectations for increases or decreases in expenses;
- expectations for the pre-clinical and clinical development, manufacturing, regulatory approval, and commercialization (including market acceptance) of Ferric Citrate or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Ferric Citrate;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell Ferric Citrate;

estimates of the sufficiency of our existing capital resources combined with future anticipated cash flows 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 September 30, 2014 and December 31, 2013

(in thousands, except share and per share amounts)

	September 30, 2014 (Unaudited)	December 31, 2013
Assets		
Current assets:		
Cash and cash equivalents	$ 84,132	$ 55,696
Short-term investment securities	34,101	
Interest receivable	151	
Inventory	918	
Other current assets	2,743	1,232
Total current assets	122,045	56,928
Property, plant and equipment, net	1,363	349
Goodwill	3,208	3,208
Other assets, net	292	281
Total assets	$ 126,908	$ 60,766
Liabilities and stockholders equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 25,138	$ 14,004
Accrued compensation and related liabilities	2,987	1,324
Total current liabilities	28,125	15,328
Other liabilities	75	38
Total liabilities	28,200	15,366
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, 92,053,199 and 82,723,145 shares issued, 91,973,251 and 82,643,197 shares outstanding at September 30, 2014 and December 31, 2013, respectively)	92	83
Additional paid-in capital	609,546	485,014
Treasury stock, at cost, 79,948 shares at September 30, 2014 and December 31, 2013, respectively	(357)	(357)
Accumulated deficit	(510,573)	(439,340)
Total stockholders equity	98,708	45,400
Total liabilities and stockholders equity	$ 126,908	$ 60,766

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 and nine months ended September 30, 2014 and 2013 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,	
	2014	**2013**	**2014**	**2013**
License revenue	$ 256	$	$ 10,256	$ 7,000
Operating expenses:				
License expenses	154		154	
Research and development	19,053	10,670	45,687	24,277
Selling, general and administrative	16,447	5,062	36,007	12,067
Total operating expenses	35,654	15,732	81,848	36,344
Operating loss	(35,398)	(15,732)	(71,592)	(29,344)
Interest and other income, net	109	81	359	280
Loss before income taxes	(35,289)	(15,651)	(71,233)	(29,064)
Income taxes				
Net loss	$ (35,289)	$ (15,651)	$ (71,233)	$ (29,064)
Basic and diluted net loss per common share	$ (0.38)	$ (0.19)	$ (0.79)	$ (0.36)
Weighted average shares used in computing basic and diluted net loss per common share	91,846,588	81,823,415	90,639,072	80,531,785

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 nine months ended September 30, 2014 (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, 2013	82,723,145	$ 83	$ 485,014	79,948	$ (357)	$ (439,340)	$ 45,400
Changes during the period:							
Issuance of common stock in public offering (net of offering costs of $7,525)	7,935,000	8	107,524				107,532
Issuance of restricted stock	890,558	1					1
Forfeiture of restricted stock	(49,905)	( )*					( )*
Issuance of common stock in connection with exercise of options	554,401	*	3,607				3,607
Compensation in respect of options and restricted stock granted to employees, directors and third-parties			13,401				13,401
Net loss						(71,233)	(71,233)
Balance at September 30, 2014	92,053,199	$ 92	$ 609,546	79,948	$ (357)	$ (510,573)	$ 98,708

* 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 nine months ended September 30, 2014 and 2013 (Unaudited)

(in thousands)

	Nine months ended September 30,	
	2014	**2013**
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$ (71,233)	$ (29,064)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Stock compensation expense	13,396	1,960
Depreciation and amortization	185	34
Changes in assets and liabilities:		
Increase in other current assets	(1,511)	(3,241)
Increase in accrued interest receivable	(151)	(156)
Increase in inventory	(912)	
Increase in security deposits	(116)	
Decrease (increase) in other assets	105	(23)
Increase in accounts payable and accrued expenses	11,134	8,651
Increase (decrease) in accrued compensation and related liabilities	1,663	(195)
Increase (decrease) in other liabilities	37	(36)
Net cash used in operating activities	(47,403)	(22,070)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(1,199)	(49)
Investment in held-to-maturity short-term securities	(49,725)	(24,403)
Proceeds from maturity of held-to-maturity short-term securities	15,624	24,403
Net cash used in investing activities	(35,300)	(49)
CASH FLOWS FROM FINANCING ACTIVITIES		
Gross proceeds from public offerings	115,057	80,393
Offering costs related to public offerings	(7,525)	(5,640)
Proceeds from exercise of options	3,607	427

Net cash provided by financing activities	111,139	75,180
NET INCREASE IN CASH AND CASH EQUIVALENTS	28,436	53,061
Cash and cash equivalents at beginning of period	55,696	14,677
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 84,132	$ 67,738

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 and nine months ended September 30, 2014 and 2013 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, 2013. The results of operations for the three and nine months ended September 30, 2014, 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, the breakdown of stock-based compensation is presented in Note 3 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 September 30, 2014, we have an accumulated deficit of $510.6 million.

In September 2014, we announced that the U.S. Food and Drug Administration (FDA) approved Ferric Citrate (formerly known as Zerenex) for the control of serum phosphorus levels in patients with chronic kidney disease (CKD) on dialysis. The U.S. approval of Ferric Citrate was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Ferric Citrate effectively reduced serum phosphorus levels to well within the National Kidney Foundation Kidney Disease Outcomes Quality Initiative (KDOQI) guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Ferric Citrate s pharmacodynamic properties resulted in increased ferritin, iron and transferrin saturation (TSAT), whereas these parameters remained relatively constant in patients treated with active control (Renvela® and/or Phoslo®). The most common adverse events for Ferric Citrate treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough. Recently, we were informed by the FDA that approval of the brand name, Zerenex, had been rescinded. We are working with the

FDA to obtain an approved brand name on or prior to launch; however, a brand name is not a pre-requisite for the launch of an FDA-approved drug.

In addition, in March 2014, we submitted a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) seeking the approval of Ferric Citrate as a treatment for hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD (NDD-CKD). Also in March 2014, the EMA validated our MAA, confirming that the submission is sufficiently complete to begin the formal review process.

We have also completed a U.S.-based Phase 2 study of Ferric Citrate for the management of elevated serum phosphorus levels and iron deficiency anemia in subjects with Stage 3 to 5 NDD-CKD, and in September 2014 we initiated a pivotal Phase 3 study of Ferric Citrate for the treatment of iron deficiency anemia in patients with Stage 3 to 5 NDD-CKD.

In January 2014, we raised approximately $107.5 million, net of underwriting discounts and offering expenses of approximately $7.5 million, in an underwritten public offering. We have a shelf registration statement on Form S-3

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filed and declared effective by the SEC in August 2013, which provides for the offering of up to $150 million of common stock and warrants in the aggregate. Subsequent to the underwritten public offering completed in January 2014, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement. See Note 3 for additional information.

In January 2014, our Japanese partner, Japan Tobacco Inc. (JT) and Torii Pharmaceutical Co. Ltd. (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 Ferric Citrate associated with net sales of Riona® in Japan. See Note 4 for additional information.

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. We have not yet commercialized any drug, and though we expect commercial launch of our first product later this year, 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 revenues from our drug. We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate 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 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 and expenditures associated with commercial activities related to Ferric Citrate, and the timing, design and conduct of clinical trials for Ferric Citrate. As a result of these factors, we may need to seek significant additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Ferric Citrate, 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.

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.

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

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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 September 30, 2014, and December 31, 2013:

(in thousands)	September 30, 2014	December 31, 2013
Short-term investments (held to maturity):		
Obligations of domestic governmental agencies (mature between October 2014 and January 2015)	$ 34,101	$
Total short-term investment securities	$ 34,101	$

Inventory

Inventories are stated at the lower of cost or estimated realizable value. We capitalize inventory costs associated with a product after regulatory approval when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We received FDA approval for Ferric Citrate on September 5, 2014 and on that date began capitalizing inventory purchases of saleable product from approved suppliers. Until a supplier is approved, all product purchased from such supplier is included as a component of research and development expense. At September 30, 2014, we had approximately $0.9 million in inventory.

Revenue Recognition

We recognize license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification (the Codification). We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payments 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.

License Expenses

License expenses include royalty and other expenses due to the licensor of Ferric Citrate 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.

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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 September 30, 2014, we have U.S. net operating loss carryforwards of approximately $466.9 million which expire from 2019 through 2033. 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.

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 September 30, 2014 and 2013, which are not included in the computation of net loss per share amounts, were 5,109,047 and 4,042,600, 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, 2013, management concluded that there was no impairment of our goodwill. For the period ending September 30, 2014, 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 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;

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

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

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

The following table provides the fair value measurements of applicable financial assets as of September 30, 2014:

	Financial assets at fair value as of September 30, 2014		
(in thousands)	Level 1	Level 2	Level 3
Money market funds (1)	$ 72,909	$	$
Obligations of domestic governmental agencies (held-to-maturity) (2)	34,101		
Total	$ 107,010	$	$

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

(2) Amortized cost approximates fair value.

NOTE 3 STOCKHOLDERS EQUITY

Common Stock

On January 22, 2014, we announced the pricing of an underwritten public offering, whereby we sold 7,935,000 shares of our common stock at a price of $14.50 per share for gross proceeds of approximately $115.1 million. Net proceeds from this offering were approximately $107.5 million, net of underwriting discounts and offering expenses of approximately $7.5 million. The shares were sold under a Registration Statement (No. 333-190353) on Form S-3, filed by us with the SEC. This shelf registration statement on Form S-3, filed and declared effective by the SEC in August 2013, provides for the offering of up to $150 million of common stock and warrants in the aggregate. Subsequent to this underwritten public offering, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement.

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 303,731 shares at September 30, 2014.

Stock Options

The following table summarizes stock option activity for the nine months ended September 30, 2014:

	Number of shares	Weighted-average exercise price	Weighted-average contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2013	3,845,370	$ 5.75	6.2	$ 28,361,438
Granted	1,953,050	14.43		
Exercised	(554,401)	6.51		$ 4,870,250
Forfeited	(134,972)	10.29		
Expired				
Outstanding at September 30, 2014	5,109,047	$ 8.87	7.0	$ 27,074,455
Vested and expected to vest at September 30, 2014	5,026,185	$ 8.81	7.0	$ 26,916,174
Exercisable at September 30, 2014	2,635,552	$ 5.37	4.9	$ 22,349,631

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Upon the exercise of stock options, we issue new shares of our common stock. As of September 30, 2014, 140,000 options issued to employees are unvested, milestone-based options.

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 nine months ended September 30, 2014:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2013	1,420,930	$ 5.27	$ 18,401,044
Granted	890,558	14.14	
Vested	(897,284)	4.87	$ 14,308,137
Forfeited	(49,905)	8.14	
Outstanding at September 30, 2014	1,364,299	$ 11.22	$ 18,759,111

As of September 30, 2014, 55,000 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 Chief Executive Officer, which was amended on January 13, 2012, and further amended on September 11, 2013. The agreement, as amended, terminates on May 20, 2015, subject to certain early termination events. As of September 30, 2014, Mr. Bentsur has been granted a total of 750,000 shares of restricted stock based on the achievement of certain milestone awards described in his employment agreement. In addition, as of September 30, 2014, Mr. Bentsur has the opportunity to earn certain milestone awards as follows:

(1) 500,000 shares of fully vested common stock will be granted to Mr. Bentsur, upon the first to occur of (a) our first commercial sale of Ferric Citrate in the U.S. off an approved NDA, (b) our receipt of the first royalty upon the commercial sale of Ferric Citrate in the U.S. by a partner to whom we have sold exclusive or non-exclusive commercial rights, or (c) our complete outlicensing of the entire product rights of Ferric Citrate in the U.S.

(2) 100,000 shares of restricted stock will be granted to Mr. Bentsur upon each event of our outlicensing Ferric Citrate 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. Such restricted stock will vest in equal installments over each of the first three anniversaries of the date of grant, provided that Mr. Bentsur remains an employee during such vesting period.

Stock-Based Compensation

We incurred $8.2 million and $0.7 million of non-cash compensation expense related to equity incentive grants during the three months ended September 30, 2014 and 2013, respectively, and $13.4 million and $2.0 million during the nine months ended September 30, 2014 and 2013, respectively. The following table reflects stock-based compensation expense for the three- and nine-month periods ended September 30, 2014 and 2013:

Stock-Based Compensation (in thousands)	Three months ended September 30, 2014	2013	Nine months ended September 30, 2014	2013
Research and development	$ 5,008	$ 319	$ 6,078	$ 753
Selling, general and administrative	3,232	422	7,318	1,207
Total stock-based compensation expense	$ 8,240	$ 741	$ 13,396	$ 1,960

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The three and nine months ended September 30, 2014, included $4.6 million and $0.4 million of stock-based compensation in research and development and selling, general and administrative expense, respectively, related to the vesting of milestone-based stock options and restricted shares upon the FDA approval of Ferric Citrate.

Stock-based compensation costs capitalized as part of inventory were immaterial for the nine months ended September 30, 2014.

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 September 30,		Nine months ended September 30,	
	2014	2013	2014	2013
Risk-free interest rates	1.9%	1.1%	2.0%	0.6%
Dividend yield				
Volatility	101.3%	100.0%	103.5%	102.6%
Weighted-average expected term	6.0 years	4.0 years	6.0 years	3.8 years

The weighted average grant date fair value of options granted for the three months ended September 30, 2014 and 2013 was $12.07 and $6.74 per option, respectively, and for the nine months ended September 30, 2014 and 2013 was $11.64 and $3.62 per option. We used historical information to estimate forfeitures within the valuation model. As of September 30, 2014, there was $19.5 million and $11.8 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.5 years and 2.3 years, respectively. These amounts do not include, as of September 30, 2014, 140,000 options outstanding and 55,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones, such as drug launch and change in control. Stock-based compensation will be measured and recorded if and when it is probable that the milestone will occur.

NOTE 4 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 Ferric Citrate. To date, we have paid an aggregate of $9.6 million to Panion, including the $3.0 million milestone payment paid upon the FDA approval of Ferric Citrate, and Panion is eligible to receive one additional milestone payment of $2.0 million upon our successful achievement of EMA market approval, in addition to royalty payments based on a mid-single digit percentage of net sales of Ferric Citrate.

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 developed in the U.S. under the trade name Ferric Citrate. 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 nine months ended September 30, 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

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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. We record the associated mid-single digit percentage of net sales royalty expense due Panion, the licensor of Ferric Citrate, in the same period as the royalty revenue from JT and Torii is recorded.

NOTE 5 LEGAL PROCEEDINGS

On February 1, 2013, a lawsuit was filed against us and our chief executive officer on behalf of a putative class of all of our shareholders (other than the defendants) who acquired our shares between June 1, 2009 and April 1, 2012. Smith v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-0755-TPG (S.D.N.Y.). On February 26, 2013, a substantially similar lawsuit was filed against us and our chief executive officer as well as our chief financial officer. Park v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-1307-TPG (S.D.N.Y.). On June 10, 2013, the Court entered an Order consolidating the two lawsuits and appointing a lead plaintiff. The case was styled In re Keryx Biopharmaceuticals, Inc. Securities Litigation, Case No. 1:13-CV-0755-KBF (S.D.N.Y.). On July 10, 2013, the lead plaintiff filed a Consolidated Amended Complaint that, in substance, repeated the claims alleged in the consolidated lawsuits. The Consolidated Amended Complaint asserted claims against (i) us for alleged violations of Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act) and Rule 10b-5 promulgated thereunder and (ii) our chief executive officer for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. The claims in the Consolidated Amended Complaint were premised on general allegations that we and the individual defendant participated directly or indirectly in the preparation and/or issuance of purportedly false and misleading earnings reports, SEC filings, press releases, and other public statements, which allegedly caused our stock to trade at artificially inflated prices. On August 26, 2013, we filed a motion to dismiss the Consolidated Amended Complaint. On February 14, 2014, the Court entered an Opinion and Order granting the motion to dismiss. The Court entered Judgment for the Defendants on February 24, 2014. The lead plaintiff did not appeal the Judgment and this matter is now concluded.

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, 2013.

OVERVIEW

We are a biopharmaceutical company focused on bringing innovative therapies to market for patients suffering from renal disease. We are developing Ferric Citrate, an oral, ferric iron-based compound. In September 2014, we announced that the U.S. Food and Drug Administration (FDA) approved Ferric Citrate (formerly known as Zerenex) for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. The U.S. approval of Ferric Citrate was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Ferric Citrate effectively reduced serum phosphorus levels to well within the National Kidney Foundation Kidney Disease Outcomes Quality Initiative, or KDOQI, guidelines range of 3.5 to 5.5 mg/dL. In addition to the effects on serum phosphorus levels, Ferric Citrate 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 Ferric Citrate treated patients were gastrointestinal-

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related, including diarrhea, nausea, constipation, vomiting and cough. Recently, we were informed by the FDA that approval of the brand name, Zerenex, had been rescinded. We are working with the FDA to obtain an approved brand name on or prior to launch; however, a brand name is not a pre-requisite for the launch of an FDA-approved drug.

In addition, in March 2014, we submitted a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, seeking the approval of Ferric Citrate as a treatment for hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD, or NDD-CKD. Also in March 2014, the EMA validated our MAA, confirming that the submission is sufficiently complete to begin the formal review process.

We have also completed a U.S.-based Phase 2 study of Ferric Citrate for the management of elevated serum phosphorus levels and iron deficiency anemia in subjects with Stage 3 to 5 NDD-CKD, and in September 2014, we initiated a pivotal Phase 3 study of Ferric Citrate for the treatment of iron deficiency anemia in patients with Stage 3 to 5 NDD-CKD.

Currently, our only drug product is Ferric Citrate. We may engage in business development activities that include seeking strategic relationships for Ferric Citrate, as well as evaluating other compounds and companies for in-licensing or acquisition. To date, we have not generated any product sales from Ferric Citrate or any other drug product. We expect commercial launch of Ferric Citrate later this year. We have generated, and expect to continue to generate, revenue from the sublicensing of rights to Ferric Citrate in Japan to our Japanese partner, JT and Torii.

RECENT DEVELOPMENTS

Ferric Citrate

In July 2014, we announced the publication of results from the long-term pivotal Phase 3 study of Ferric Citrate in the Journal of the American Society of Nephrology.

In July 2014, we completed the long-term, open-label extension, or OLE, study for Ferric Citrate in dialysis-dependent CKD patients. Patients who had participated in and successfully completed the long-term pivotal Phase 3 study were eligible for enrollment in the 48-week OLE study, providing for cumulative exposure to Ferric Citrate of up to two years. Patients in the OLE study (n=168) were titrated to achieve and maintain serum phosphorus levels within a range of 3.5 to 5.5 mg/dL, with a maximum daily dose of 12 grams per day of Ferric Citrate. The safety profile observed in the OLE study was consistent with that seen in the long-term pivotal Phase 3 study and there were no clinically meaningful changes in liver enzymes or aluminum levels over the course of the study. The full data from this study was submitted as an abstract to the American Society of Nephrology meeting.

In September 2014, we announced that the FDA approved Ferric Citrate for the control of serum phosphorus levels in patients with CKD on dialysis. The U.S. approval of Ferric Citrate was based on data from our Phase 3 registration program. In the Phase 3 clinical trials, Ferric Citrate 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, Ferric Citrate s pharmacodynamic properties resulted in increased ferritin, iron and TSAT; whereas these parameters remained relatively constant in patients treated with active control (Renvela® and/or Phoslo®). The most common adverse events for Ferric Citrate treated patients were gastrointestinal-related, including diarrhea, nausea, constipation, vomiting and cough. Recently, we were informed by the FDA that approval of the brand name, Zerenex, had been rescinded. We are working with the FDA to obtain an approved brand name on or prior to launch; however, a brand name is not a pre-requisite for the launch of an FDA-approved drug.

In September 2014, we announced the initiation of a pivotal Phase 3 study of Ferric Citrate for the treatment of iron deficiency anemia 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 in 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 Ferric Citrate arm vs. 15% in the placebo arm (p-value <0.001). Secondary endpoints in the Phase 3 study include change from baseline to end of Randomized Period for hemoglobin, ferritin, TSAT and serum phosphorus.

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In October 2014, we announced that the U.S. Patent and Trademark Office issued U.S. Patent No. 8,846,976. The patent, which expires in 2024, claims a method of treating hyperphosphatemia comprised of administering a therapeutically effective amount of an orally administrable form of Ferric Citrate to a subject, wherein the orally administrable form is prepared from a ferric citrate active pharmaceutical ingredient having an intrinsic dissolution rate of at least 1.88/mg/cm2/min. In addition, U.S. Patent No. 8,846,976 contains claims directed to the FDA approved dosing and daily administration of Ferric Citrate. This newly issued patent further enhances our key patent family, which includes U.S. Patent Nos. 7,767,851, 8,299,298, 8,338,642, 8,609,896, 8,754,257 and 8,754,258, which expire in 2024, and U.S. Patent No. 8,093,423, which expires in 2028, before patent term extension. Each of these patents contains composition and method of use claims covering Ferric Citrate.

In October 2014, following the regulatory approval of ferric citrate in Japan earlier this year, the Japan Patent office granted patent term extensions for patents #4964585 and #4173553, which extended the terms of these patents in Japan to November 2025 and November 2022, respectively.

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 activities related to Ferric Citrate, 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, pre-commercial/commercial, partnership and licensing activities. We have not yet commercialized any drug, and though we expect commercial launch of our first product later this year, 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 revenues from our drug.

Our license revenues consist of license fees and milestone payments arising from our agreement with JT and Torii. We recognize license revenue in accordance with the revenue recognition guidance of the Financial Accounting Standards Board, or FASB, Accounting Standards Codification, or 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 the 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. Based on our agreement with JT and Torii, and 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.

We have not earned any revenues from the commercial sale of any drug. We expect commercial launch of Ferric Citrate later this year.

Our license expenses consist of royalty and other expenses due to the licensor of Ferric Citrate 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.

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

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

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

For awards of options and restricted stock 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. This results in a change to the amount previously recorded in respect of the equity award grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

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

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

RESULTS OF OPERATIONS

Three months ended September 30, 2014 and September 30, 2013

License Revenue. For the three months ended September 30, 2014, we recognized $0.3 million in license revenue on royalty payments from sales of Riona® in Japan. There was no license revenue for the three months ended September 30, 2013. 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 upon the achievement of certain annual net sales milestones.

License Expenses. For the three months ended September 30, 2014, we recognized $0.2 million in license expenses related to royalties due to the licensor of Ferric Citrate relating to sales of Riona® in Japan. There were no license expenses for the three months ended September 30, 2013. 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.

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Research and Development Expenses. Research and development expenses increased by $8.4 million to $19.1 million for the three months ended September 30, 2014, as compared to $10.7 million for the three months ended September 30, 2013. Stock-based compensation expense increased by $4.7 million to $5.0 million for the three months ended September 30, 2014 as compared to $0.3 million for the three months ended September 30, 2013, primarily related to $4.6 million of stock-based compensation expense due to the vesting of milestone-based stock options and restricted shares upon the FDA approval of Ferric Citrate. The increase in research and development expenses was also due to a $3.8 million increase in research and development expenses related to our Ferric Citrate program, including costs associated with the manufacturing of pre-approval inventory. The three months ended September 30, 2014, also includes a $3.0 million one-time milestone payment to Panion, the licensor of Ferric Citrate, for our achievement of FDA approval of Ferric Citrate in September 2014. We expect our research and development expenses in the fourth quarter of 2014 to decrease as compared to the third quarter of 2014 due to the inclusion in the third quarter of milestone-based expenses for stock-based compensation and a one-time payment to Panion incurred upon FDA approval of Ferric Citrate, partially offset by the continuous build of inventory by additional suppliers not yet approved by the FDA and an increase in expenses associated with our pivotal Phase 3 study of Ferric Citrate in NDD-CKD patients that began in September.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $11.4 million to $16.5 million for the three months ended September 30, 2014, as compared to $5.1 million for the three months ended September 30, 2013. The increase was primarily related to a $6.2 million increase in pre-commercial/commercial activities and associated personnel costs in preparation for the commercialization of Ferric Citrate. Stock-based compensation expense increased by $2.8 million to $3.2 million for the three months ended September 30, 2014, as compared to $0.4 million for the three months ended September 30, 2013, primarily related to increased selling, general and administrative personnel and the recording of the fair value of equity awards granted, which are expensed over the vesting periods of the individual awards. We expect our selling, general and administrative costs to increase in the fourth quarter of 2014 related to commercial preparations and the launch of Ferric Citrate.

Interest and Other Income, Net. Interest and other income, net, increased by $28,000 to $109,000 for the three months ended September 30, 2014, as compared to $81,000 for the three months ended September 30, 2013. The increase was due to a higher level of invested funds in our investment portfolio following our January 2014 public offering.

Nine months ended September 30, 2014 and September 30, 2013

License Revenue. License revenue for the nine months ended September 30, 2014 was $10.3 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 and $0.3 million of royalty payments from sales of Riona® in Japan. License revenue for the nine months ended September 30, 2013 was $7.0 million due to the recognition of a non-refundable milestone payment received in January 2013 from JT and Torii following their filing of their NDA with the Japanese Ministry of Health, Labour and Welfare for marketing approval of Ferric Citrate 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 upon the achievement of certain annual net sales milestones.

License Expenses. For the nine months ended September 30, 2014, we recognized $0.2 million in license expenses related to royalties due to the licensor of Ferric Citrate relating to sales of Riona® in Japan. There were no license expenses for the nine months ended September 30, 2013. 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.

Research and Development Expenses. Research and development expenses increased by $21.4 million to $45.7 million for the nine months ended September 30, 2014, as compared to $24.3 million for the nine months ended September 30, 2013. The increase in research and development expenses was due primarily to a $15.9 million increase in research and development expenses related to our Ferric Citrate program, including costs associated with the manufacturing of pre-approval inventory and the submission of our MAA filing. The nine months ended September 30, 2014,

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also includes a $2.0 million one-time milestone payment to Panion, the licensor of Ferric Citrate, for JT and Torii s achievement of the Japanese marketing approval milestone in January 2014 and a $3.0 million one-time milestone payment to Panion for our achievement of FDA approval of Ferric Citrate in September 2014. Stock-based compensation expense increased by $5.3 million to $6.1 million for the nine months ended September 30, 2014, as compared to $0.8 million for the nine months ended September 30, 2013, primarily related to $4.6 million of stock-based compensation expense due to the vesting of milestone-based stock options and restricted shares upon the FDA approval of Ferric Citrate. We expect our research and development expenses in the fourth quarter of 2014 to decrease as compared to the third quarter of 2014 due to the inclusion in the third quarter of milestone-based expenses for stock-based compensation and a one-time payment to Panion incurred upon FDA approval of Ferric Citrate, partially offset by the continuous build of inventory by additional suppliers not yet approved by the FDA and an increase in expenses associated with our pivotal Phase 3 study of Ferric Citrate in NDD-CKD patients that began in September.

Selling, General and Administrative Expenses. Selling, general and administrative expenses increased by $23.9 million to $36.0 million for the nine months ended September 30, 2014, as compared to $12.1 million for the nine months ended September 30, 2013. The increase was primarily related to an $11.7 million increase in pre-commercial/commercial activities and associated personnel costs in preparation for the commercialization of Ferric Citrate. Stock-based compensation expense increased by $6.1 million to $7.3 million for the nine months ended September 30, 2014, as compared to $1.2 million for the nine months ended September 30, 2013, primarily related to increased selling, general and administrative personnel and the recording of the fair value of equity awards granted, which are expensed over the vesting periods of the individual awards. We expect our selling, general and administrative costs to increase in the fourth quarter of 2014 related to commercial preparations and the launch of Ferric Citrate.

Interest and Other Income, Net. Interest and other income, net, increased by $79,000 to $359,000 for the nine months ended September 30, 2014, as compared to $280,000 for the nine months ended September 30, 2013. The increase was due to a higher level of invested funds in our investment portfolio following our January 2014 public offering.

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. We have not yet commercialized any drug, and though we expect commercial launch of our first product later this year, 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 revenues from our drug. We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate 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 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 and expenditures associated with commercial activities related to Ferric Citrate, and the timing, design and conduct of clinical trials for Ferric Citrate. As a result of these factors, we may need to seek significant additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Ferric Citrate, and to develop any drug candidates we may in-license or acquire.

On January 22, 2014, we announced the pricing of an underwritten public offering, whereby we sold 7,935,000 shares of our common stock at a price of $14.50 per share for gross proceeds of approximately $115.1 million. Net proceeds from this offering were approximately $107.5 million, net of underwriting discounts and offering expenses of approximately $7.5 million. The shares were sold under a Registration Statement (No. 333-190353) on Form S-3, filed by us with the SEC. This shelf registration statement on Form S-3, filed and declared effective by the SEC in August 2013, provides for the offering of up to $150 million of common stock and warrants in the aggregate. Subsequent to this underwritten public offering, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement.

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

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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 Ferric Citrate associated with net sales of Riona® in Japan.

As of September 30, 2014, we had $118.4 million in cash, cash equivalents, short-term investments and interest receivable, an increase of $62.7 million from December 31, 2013. We currently expect that our existing capital resources combined with future anticipated cash flows will be sufficient to operate 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 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 and expenditures associated with commercial activities related to Ferric Citrate, and the timing, design and conduct of clinical trials for Ferric Citrate. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Ferric Citrate, and to develop any drug candidates we may in-license or acquire.

Net cash used in operating activities for the nine months ended September 30, 2014 was $47.4 million, as compared to $22.1 million for the nine months ended September 30, 2013. This increase in net cash used in operating activities was primarily related to increased Ferric Citrate development and pre-commercial expenditures.

For the nine months ended September 30, 2014, net cash used in investing activities was $35.3 million, as compared to $49,000 for the nine months ended September 30, 2013. The increase in net cash used in investing activities was primarily due to our investments in held-to-maturity short-term securities following our public offering of common stock in January 2014.

For the nine months ended September 30, 2014, net cash provided by financing activities was $111.1 million as compared to $75.2 million for the nine months ended September 30, 2013. The increase was primarily related to $107.5 million of net proceeds received from our public offering of common stock in January 2014, as compared to $74.8 million of net proceeds received from our public offering of common stock in January 2013.

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.

OBLIGATIONS AND COMMITMENTS

As of September 30, 2014, we have the following operating lease obligations, which include our office leases in New York and Boston.

	Payment due by period (in thousands)				
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Contractual obligations					
Operating leases	$ 2,685	$ 1,521	$ 1,164	$	$
Total	$ 2,685	$ 1,521	$ 1,164	$	$

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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 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 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:

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 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.

Revenue Recognition. 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

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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.

We recognize other revenues at the time such fees and payments are earned.

Inventory. Inventories are stated at the lower of cost or estimated realizable value. We capitalize inventory costs associated with a product after regulatory approval when, based on management s judgment, future commercialization is considered probable and the future economic benefit is expected to be realized. We received FDA approval for Ferric Citrate on September 5, 2014 and on that date began capitalizing inventory purchases of saleable product from approved suppliers. Until a supplier is approved, all product purchased from such supplier is included as a component of research and development expense. At September 30, 2014, we had approximately $0.9 million in inventory.

Accounting Related to Goodwill. As of September 30, 2014, 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.

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

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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.

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 September 30, 2014, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including government debt and money market funds. The average duration of all of our held-to-maturity investments held as of September 30, 2014, was less than 12 months. 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of September 30, 2014, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of September 30, 2014, 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 September 30, 2014, 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, except as stated below.

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On February 1, 2013, a lawsuit was filed against us and our chief executive officer on behalf of a putative class of all of our shareholders (other than the defendants) who acquired our shares between June 1, 2009 and April 1, 2012. Smith v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-0755-TPG (S.D.N.Y.). On February 26, 2013, a substantially similar lawsuit was filed against us and our chief executive officer as well as our chief financial officer. Park v. Keryx Biopharmaceuticals, Inc., et al., Case No. 1:13-CV-1307-TPG (S.D.N.Y.). On June 10, 2013, the Court entered an Order consolidating the two lawsuits and appointing a lead plaintiff. The case was styled In re Keryx Biopharmaceuticals, Inc. Securities Litigation, Case No. 1:13-CV-0755-KBF (S.D.N.Y.). On July 10, 2013, the lead plaintiff filed a Consolidated Amended Complaint that, in substance, repeated the claims alleged in the consolidated lawsuits. The Consolidated Amended Complaint asserted claims against (i) us for alleged violations of Section 10(b) of the Securities Exchange Act of 1934 (Exchange Act) and Rule 10b-5 promulgated thereunder and (ii) our chief executive officer for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. The claims in the Consolidated Amended Complaint were premised on general allegations that we and the individual defendant participated directly or indirectly in the preparation and/or issuance of purportedly false and misleading earnings reports, SEC filings, press releases, and other public statements, which allegedly caused our stock to trade at artificially inflated prices. On August 26, 2013, we filed a motion to dismiss the Consolidated Amended Complaint. On February 14, 2014, the Court entered an Opinion and Order granting the motion to dismiss. The Court entered Judgment for the Defendants on February 24, 2014. The lead plaintiff did not appeal the Judgment and this matter is now concluded.

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 September 30, 2014, we had an accumulated deficit of $510.6 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 revenues from our drug, Ferric Citrate. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain additional regulatory approvals for our drug, successfully complete any post approval regulatory obligations and successfully manufacture and commercialize our drug.

We are highly dependent on the commercial success of Ferric Citrate 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 Ferric Citrate (formerly known as Zerenex) for the control of serum phosphorus levels in patients with CKD on dialysis. The commercial success of Ferric Citrate will depend on a number of factors, including:

the effectiveness of Ferric Citrate 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 Ferric Citrate 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;

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our ability to both secure and maintain adequate reimbursement for, and optimize patient access to, Ferric Citrate 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 Ferric Citrate;

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

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 Ferric Citrate.

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

Ferric Citrate 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 Ferric Citrate 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 Ferric Citrate (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 Ferric Citrate or any products perceived to be similar to Ferric Citrate, or if any of the foregoing are perceived to have occurred, then in any of these circumstances:

sales of Ferric Citrate may be impaired;

regulatory approvals for Ferric Citrate 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;

we may be precluded from pursuing additional development opportunities to enhance the clinical profile of Ferric Citrate within its indicated populations, as well as be precluded from studying Ferric Citrate 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 Ferric Citrate, likely increase our expenses and impair our ability to successfully commercialize Ferric Citrate.

Furthermore, as we explore development opportunities to enhance the clinical profile of Ferric Citrate, any clinical trials conducted, if successful, may expand the patient populations treated with Ferric Citrate 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 Ferric Citrate will soon be 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 Ferric Citrate is associated with serious adverse effects, undermining our commercialization efforts.

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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 use in clinical trials and for future commercial distribution. 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, (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 (API) and a qualified contract manufacturer become critical to commercial success. For example, given the large quantity of materials required for Ferric Citrate production and the large quantities of Ferric Citrate that will be required for commercial success, the commercial viability of Ferric Citrate 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 Ferric Citrate 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 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 Ferric Citrate 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 Ferric Citrate, 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.

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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 Ferric Citrate.

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 Ferric Citrate 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 Ferric Citrate. 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, Ferric Citrate is our first commercial product, so our implementation of our compliance program in connection with commercialization activities is still relatively new.

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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 payments, gifts, the provision of samples and other remuneration made to physicians and other healthcare professionals and healthcare organizations.

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 Ferric Citrate, we assembled an experienced compliance team who compiled a program based on industry best practices that is designed to ensure that our commercialization of Ferric Citrate 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.

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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.

Ferric Citrate will compete 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), 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 Ferric Citrate 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. 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 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 material effect on the pricing of phosphate binders.

In addition, 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.

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 October 31, 2014, we had 92 full and part-time employees. To successfully develop and commercialize our drug, 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, in particular, Ron Bentsur, our Chief Executive Officer and Greg Madison, our Chief Operating Officer, our ability to continue to execute on our business plan could be materially impaired. Although we have employment agreements with Mr. Bentsur and Mr. Madison, such agreements do not prevent either of them from terminating their respective employment with us.

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Risks associated with our product development efforts

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

We are developing Ferric Citrate, an oral, ferric iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. In May 2011, we announced positive Scientific Advice from the European Medicines Agency, or EMA, for the development of Ferric Citrate for the management and control of serum phosphorus in CKD patients undergoing dialysis, and in non-dialysis dependent 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 Ferric Citrate, will be considered sufficient to support a European marketing authorization application, or 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 non-dialysis dependent CKD setting in Europe. As a result, we believe that since our Phase 3 program in dialysis, and Phase 2 study in non-dialysis dependent CKD, in the U.S. were successful, we will not need to conduct any additional clinical trials to assess the safety or efficacy of Ferric Citrate in order to obtain European approval in CKD, including the dialysis and non-dialysis dependent CKD, or 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 Ferric Citrate.

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 Ferric Citrate for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the respective regulatory authority that Ferric Citrate 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 non-dialysis dependent CKD, the development program or the MAA for Ferric Citrate 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 Ferric Citrate 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 Ferric Citrate;

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

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questions which we recently received from the EMA. 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 Ferric Citrate. Any failure or delay in completion of the development program or the EMA review processes would delay or foreclose commercialization of Ferric Citrate 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.

Negative or inconclusive results from the clinical trials we conduct, such as the ongoing Phase 3 study of Ferric Citrate 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, Ferric Citrate in Europe.

We have not received, and may never receive, regulatory approval for the commercial sale of Ferric Citrate 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 Ferric Citrate 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 recently received Day 120 questions from the EMA on our MAA. We are working on responses to the EMA s questions and intend to submit such responses in a timely manner, but we cannot assure you that we will 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.

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Safety signals detected during clinical studies and pre-clinical animal studies, such as the gastrointestinal bleeding and liver toxicities that have been seen in some high-dose Ferric Citrate canine studies, may require us to perform additional safety studies or analyses, which could delay the development of the drug or lead to a decision to discontinue development of the drug. We have submitted to the EMA data from our short-term and long-term rat and canine pre-clinical studies for Ferric Citrate. 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 non-dialysis dependent 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 Ferric Citrate 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 Ferric Citrate 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 Ferric Citrate or from our long-term OLE study for Ferric Citrate in dialysis-dependent CKD patients will not change following a more comprehensive review of the data by a regulatory authority.

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 Ferric Citrate or any other drug candidate we develop. If we experience delays in the testing or approval process for our existing drug or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we engage, from time to time, clinical research organizations with experience in conducting regulatory trials, errors in the conduct, monitoring, data capture and analysis, and/or auditing could potentially invalidate the results.

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

We do not own our drug, Ferric Citrate. We have licensed and sublicensed the rights, patent or otherwise, to Ferric Citrate from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Ferric Citrate from one of the inventors of Ferric Citrate. 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 Ferric Citrate) 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 Ferric Citrate. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Ferric Citrate, Panion could lose its license, which could impair or delay our ability to develop and commercialize Ferric Citrate. 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

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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 Ferric Citrate, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Ferric Citrate and the licenses and sublicenses we grant to others.

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

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

Other Risks Related to Our Business

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

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

Acquisitions involve a number of operational risks, including:

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

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 Ferric Citrate 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. 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

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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 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, 2024. If phosphate binders are included in the bundle beginning in 2024, 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 Ferric Citrate.

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. Finally, 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.

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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 candidate or limit commercialization of any approved product.

We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; 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.

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 Ferric Citrate 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 operate 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 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 and expenditures associated with pre-commercial/commercial activities related to Ferric Citrate, and the timing, design and conduct of clinical trials for Ferric Citrate. As a result of these factors, we may need to seek additional financings to provide the cash necessary to execute our current operations, including beyond the initial commercialization of Ferric Citrate, and to develop any drug candidates we may in-license or acquire.

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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 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 and expenditures associated with pre-commercial/commercial activities related to Ferric Citrate;
- the timing, design and conduct of, and results from, clinical trials for Ferric Citrate;
- the timing of expenses associated with manufacturing and product development of Ferric Citrate 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;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the timing and magnitude of cash received from product sales.

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 before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage. As many of the patents we use are licensed or sublicensed from third parties, we may not be able to enforce such licensed patents against third party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

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Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. In addition, in jurisdictions outside the U.S. where we have 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, Ferric Citrate, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Ferric Citrate.

The patent rights that we own or have licensed relating to Ferric Citrate 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 Ferric Citrate in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We license additional composition of matter and use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient, or API, of Ferric Citrate), 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 methods 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 2028) 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, or for which there is a substantial use in commerce 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 can be difficult because the competitors making and marketing a product may not engage in the patented use. Additionally, obtaining proof that a competitor contributes to, or induces, infringement of a patented method by another can be difficult because, for example, an off-label use of a product could prohibit a finding of contributory infringement. In addition, 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

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of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Ferric Citrate, increase the risk that a generic version of Ferric Citrate could enter the market to compete with Ferric Citrate, limit our development and commercialization of Ferric Citrate, 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 Ferric Citrate. 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 or prosecute.

In addition, any limitations of our patent protection described above may adversely affect the value of our product candidate 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 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 provides an additional six months which are added to the term of data protection as well as to the term of a relevant patent, to the extent these protections have not already expired.

The FDCA provides a five-year period of non-patent marketing exclusivity within the 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 abbreviated new drug application, or 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 Ferric Citrate.

We may also seek to utilize market exclusivities in other territories, such as in the EU.

We cannot assure that our drug, Ferric Citrate, or any drug candidates we may acquire or in-license, will obtain such pediatric exclusivity, new chemical entity 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.

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 Ferric Citrate 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

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our commercial activities relating to Ferric Citrate or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Ferric Citrate or such technologies, and/or require our licensor or us to obtain a license to continue to use Ferric Citrate 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 August 2, 2013, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-190353), which the SEC declared effective on August 16, 2013, providing for the offering of up to $150 million of our common stock and warrants to purchase our common stock. Subsequent to the underwritten public offering that was completed on January 23, 2014, there remains approximately $34.9 million of our common stock and warrants available for sale on this shelf registration statement.

We may need to seek additional financing to provide cash necessary to execute our current operations, including beyond the initial commercialization of Ferric Citrate, 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.

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:

- developments concerning our drug or future drug candidates, including the safety and efficacy results from clinical trials and regulatory filings and approvals;
- 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 or inability to meet consensus analyst product sales estimates;

actual or anticipated variations in quarterly or annual operating results;

expectations regarding our financial condition;

expiration or termination of licenses, research contracts or other collaboration agreements;

developments relating to our intellectual property and those of our competitors, including but not limited to, the commercialization of generic products;

expectations or investor speculation regarding the strength of our intellectual property position, or the availability 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.

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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. Such litigation, if 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.

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*	Manufacturing Services Agreement, dated January 17, 2014, by and between Keryx Biopharmaceuticals, Inc. and Norwich Pharmaceuticals, Inc.
10.2*	First Addendum to Manufacturing Services Agreement, dated October 24, 2014, by and between Keryx Biopharmaceuticals, Inc. and Norwich Pharmaceuticals, Inc.
31.1	

Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 6, 2014.

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31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 6, 2014.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 6, 2014.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated November 6, 2014.
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.

* Portions of this exhibit have been omitted pursuant to a request for confidential treatment filed separately with the Securities and Exchange Commission.

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SIGNATURES

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

KERYX BIOPHARMACEUTICALS, INC.

Date: November 6, 2014

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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