

KERYX BIOPHARMACEUTICALS INC

Form 10-Q

May 08, 2013

[Table of Contents](#)

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended March 31, 2013

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)

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**Delaware**  
(State or other jurisdiction of  
incorporation or organization)

**13-4087132**  
(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 ☒ 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 ☒ 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 ☒  
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 ☒

There were 81,718,058 shares of the registrant's common stock, \$0.001 par value, outstanding as of April 30, 2013.

**Table of Contents**

**KERYX BIOPHARMACEUTICALS, INC.**

**FORM 10-Q**

**FOR THE QUARTER ENDED MARCH 31, 2013**

**TABLE OF CONTENTS**

	<b>Page</b>
<b><u>SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS</u></b>	<b>3</b>
<b>PART I      <u>FINANCIAL INFORMATION</u></b>	<b>4</b>
Item 1 <u>Financial Statements</u>	4
<u>Consolidated Balance Sheets as of March 31, 2013 (unaudited) and December 31, 2012</u>	4
<u>Consolidated Statements of Operations for the three months ended March 31, 2013 and 2012 (unaudited)</u>	5
<u>Consolidated Statement of Stockholders' Equity for the three months ended March 31, 2013 (unaudited)</u>	6
<u>Consolidated Statements of Cash Flows for the three months ended March 31, 2013 and 2012 (unaudited)</u>	7
<u>Notes to Consolidated Financial Statements (unaudited)</u>	8
Item 2 <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	13
Item 3 <u>Quantitative and Qualitative Disclosures About Market Risk</u>	19
Item 4 <u>Controls and Procedures</u>	19
<b>PART II      <u>OTHER INFORMATION</u></b>	<b>20</b>
Item 1 <u>Legal Proceedings</u>	20
Item 1A <u>Risk Factors</u>	20
Item 6 <u>Exhibits</u>	33

**Table of Contents**

**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 and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions Risk Factors,

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

expectations for increases or decreases in expenses;

expectations for the pre-clinical and clinical development, manufacturing, regulatory approval, and commercialization (including market acceptance) of Zerenex<sup>TM</sup> (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;

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 our drug candidate;

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

expected losses;

expectations for future capital requirements; and

costs related to litigation.

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

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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.

**Table of Contents****PART I. FINANCIAL INFORMATION****ITEM 1. FINANCIAL STATEMENTS****Keryx Biopharmaceuticals, Inc.**

Consolidated Balance Sheets as of March 31, 2013 and December 31, 2012

(in thousands, except share and per share amounts)

	March 31, 2013 (Unaudited)	December 31, 2012
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 87,343	\$ 14,677
Other current assets	1,744	430
Total current assets	89,087	15,107
Property, plant and equipment, net	91	56
Goodwill	3,208	3,208
Other assets, net	163	198
Total assets	\$ 92,549	\$ 18,569
<b>Liabilities and stockholders' equity</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 8,454	\$ 7,212
Accrued compensation and related liabilities	202	827
Total current liabilities	8,656	8,039
Other liabilities	24	36
Total liabilities	8,680	8,075
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 (95,000,000 shares authorized, 81,798,006 and 72,002,949 shares issued, 81,718,058 and 71,923,001 shares outstanding at March 31, 2013 and December 31, 2012, respectively)	82	72
Additional paid-in capital	478,807	403,387
Treasury stock, at cost, 79,948 shares at March 31, 2013 and December 31, 2012, respectively	(357)	(357)
Accumulated deficit	(394,663)	(392,608)
Total stockholders' equity	83,869	10,494

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Total liabilities and stockholders' equity	\$	92,549	\$	18,569
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*The accompanying notes are an integral part of the consolidated financial statements.*

**Table of Contents****Keryx Biopharmaceuticals, Inc.**

## Consolidated Statements of Operations

for the three months ended March 31, 2013 and 2012 (Unaudited)

(in thousands, except share and per share amounts)

	<b>Three months ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
License revenue	\$ 7,000	\$
Operating expenses:		
Research and development:		
Non-cash compensation	191	278
Other research and development	6,239	7,122
Total research and development	6,430	7,400
General and administrative:		
Non-cash compensation	390	368
Other general and administrative	2,338	1,408
Total general and administrative	2,728	1,776
Total operating expenses	9,158	9,176
Operating loss	(2,158)	(9,176)
Interest and other income, net	103	62
Loss before income taxes	(2,055)	(9,114)
Income taxes		
Net loss	\$ (2,055)	\$ (9,114)
Basic and diluted net loss per common share	\$ (0.03)	\$ (0.13)
Weighted average shares used in computing basic and diluted net loss per common share	77,990,094	71,225,006

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





**Table of Contents****Keryx Biopharmaceuticals, Inc.**

## Consolidated Statement of Stockholders' Equity

for the three months ended March 31, 2013 (Unaudited)

(in thousands, except share amounts)

	Common stock		Additional	Treasury stock		Accumulated	Total
	Shares	Amount	paid-in Capital	Shares	Amount	deficit	
Balance at December 31, 2012	72,002,949	\$ 72	\$ 403,387	79,948	\$ (357)	\$ (392,608)	\$ 10,494
Changes during the period:							
Issuance of common stock in public offering (net of offering costs of \$5,637)	9,469,100	10	74,746				74,756
Issuance of restricted stock	291,020	*					*
Issuance of common stock in connection with exercise of options	34,937	*	93				93
Compensation in respect of options and restricted stock granted to employees, directors and third-parties			581				581
Net loss						(2,055)	(2,055)
Balance at March 31, 2013	81,798,006	\$ 82	\$ 478,807	79,948	\$ (357)	\$ (394,663)	\$ 83,869

\* Amount less than one thousand dollars.

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

**Table of Contents****Keryx Biopharmaceuticals, Inc.**

## Consolidated Statements of Cash Flows

for the three months ended March 31, 2013 and 2012 (Unaudited)

(in thousands)

	<b>Three months ended March 31,</b>	
	<b>2013</b>	<b>2012</b>
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>		
Net loss	\$ (2,055)	\$ (9,114)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Stock compensation expense	581	646
Depreciation and amortization	10	10
Changes in assets and liabilities:		
(Increase) decrease in other current assets	(1,314)	10
Increase in accrued interest receivable		(60)
Decrease in other assets	35	
Increase in accounts payable and accrued expenses	1,242	689
Decrease in accrued compensation and related liabilities	(625)	(719)
Decrease in other liabilities	(12)	(11)
Net cash used in operating activities	(2,138)	(8,549)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>		
Purchases of property, plant and equipment	(45)	(2)
Investment in held-to-maturity short-term securities		(5,236)
Proceeds from maturity of held-to-maturity short-term securities		235
Net cash used in investing activities	(45)	(5,003)
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>		
Proceeds from public offering, net	74,756	
Proceeds from exercise of options	93	
Net cash provided by financing activities	74,849	
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>72,666</b>	<b>(13,552)</b>
Cash and cash equivalents at beginning of period	14,677	35,252
<b>CASH AND CASH EQUIVALENTS AT END OF PERIOD</b>	<b>\$ 87,343</b>	<b>\$ 21,700</b>

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

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**Table of Contents**

**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 the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of renal disease. Most of our biopharmaceutical development and substantially all of our administrative operations during the three months ended March 31, 2013 and 2012 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 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, 2012. The results of operations for the three months ended March 31, 2013, are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Except for 2009, we have incurred substantial operating losses since our inception, and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of March 31, 2013, we have an accumulated deficit of \$394.7 million.

Our major sources of cash have been proceeds from various public offerings of our common stock, private placements of equity securities, option and warrant exercises, interest income, and from the upfront and milestone payments from our Sublicense Agreement with Japan Tobacco Inc. ( JT ) and Torii Pharmaceutical Co., Ltd. ( Torii ) and miscellaneous payments from our other prior licensing activities. We have not yet commercialized any drug candidate and cannot be sure if we will ever be able to do so. Even if we commercialize a drug candidate, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidate alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate, if approved.

In January 2013, we announced successful top-line results from the long-term Phase 3 study of Zerenex for the treatment of hyperphosphatemia in patients with end-stage renal disease on dialysis. In this study, Zerenex met the study's primary and key secondary endpoints. This long-term study was the final component of our Phase 3 registration program, which was conducted pursuant to a special protocol assessment agreement with the U.S. Food and Drug Administration ( FDA ).

We received a non-refundable milestone payment of \$7.0 million in January 2013 for the achievement of the New Drug Application ( NDA ) filing milestone from JT and Torii. See Note 4 for additional information.

In January 2013, we raised approximately \$74.8 million, net of underwriting discounts and offering expenses of approximately \$5.6 million, in an underwritten public offering. See Note 3 for additional information.

## **Table of Contents**

We currently anticipate that our cash and cash equivalents at March 31, 2013 are sufficient to fund our anticipated operating cash requirements for approximately the next 21 to 24 months. 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 pre-launch/launch inventory, the timing and expenditures associated with submitting the NDA and Marketing Authorization Application ( MAA ) for Zerenex, the timing and expenditures associated with select pre-commercial/commercial activities related to Zerenex, and the timing, design and conduct of clinical trials for Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

In accordance with the licensing arrangement with JT and Torii, we may receive payments upon the achievement of pre-specified milestones. The next potential milestone is for the marketing approval of ferric citrate in Japan.

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol KERYX.

### ***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 were not invested in investment securities at March 31, 2013 and December 31, 2012. We classify our short-term and long-term debt securities as held-to-maturity. Held-to-maturity securities are those securities in which we have the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Available-for-sale investment securities are recorded at fair value (see Note 2 Fair Value Measurements). Other-than-temporary impairment charges are included in interest and other income, net, and unrealized gains (losses), if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity.

### ***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.

### ***Stock-Based Compensation***

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

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

## **Table of Contents**

### ***Income Taxes***

As of March 31, 2013, we have U.S. net operating loss carryforwards of approximately \$361.3 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 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. The options outstanding as of March 31, 2013 and 2012, which are not included in the computation of net loss per share amounts, were 3,882,100 and 3,908,500, respectively.

### ***Comprehensive Loss***

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

### ***Segment Reporting***

Following the discontinuation of the Services segment in December 2011, we have determined that 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, 2012, management concluded that there was no impairment of our goodwill. As of March 31, 2013, management determined that there were no 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;

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





**Table of Contents**

in fair value is determined to be other-than-temporary. We review our investments on an ongoing basis for indications of possible impairment. Once identified, the determination of whether the impairment is temporary or other-than-temporary requires significant judgment.

The following table provides the fair value measurements of applicable financial assets as of March 31, 2013:

(in thousands)	Financial assets at fair value as of March 31, 2013		
	Level 1	Level 2	Level 3
Money market funds (1)	\$ 61,697	\$	\$
Total	\$ 61,697	\$	\$

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

**NOTE 3 STOCKHOLDERS EQUITY****Common Stock**

On January 30, 2013, we announced the pricing of an underwritten public offering, whereby we sold 9,469,100 shares of our common stock at a price of \$8.49 per share for gross proceeds of approximately \$80.4 million. Net proceeds from this offering were approximately \$74.8 million, net of underwriting discounts and offering expenses of approximately \$5.6 million. The shares were sold under Registration Statements (Nos. 333-171517 and 333-186332) on Form S-3 and Form S-3MEF, respectively, and filed by us with the Securities and Exchange Commission.

**Equity Incentive Plans**

Shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 513,411 shares at March 31, 2013.

**Stock Options**

The following table summarizes stock option activity for the three months ended March 31, 2013:

	Number of shares	Weighted- average exercise price	Weighted- average contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2012	3,401,671	\$ 5.17	6.6	2,373,509
Granted	515,366	3.89		
Exercised	(34,937)	2.66		\$ 150,410
Forfeited				
Expired				
Outstanding at March 31, 2013	3,882,100	\$ 5.02	6.8	\$ 13,145,733
Vested and expected to vest at March 31, 2013	3,835,792	\$ 5.04	6.8	\$ 12,970,431

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Exercisable at March 31, 2013	2,449,776	\$	5.72	5.9	\$ 7,912,843
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Upon the exercise of stock options, we issue new shares of our common stock. As of March 31, 2013, 95,000 options issued to employees and 50,000 options issued to consultants are unvested, milestone-based options.

**Table of Contents****Restricted Stock**

Certain employees, directors and consultants have been awarded restricted stock under the 2004 Long-Term Incentive Plan and 2007 Incentive Plan. The time-vesting restricted stock grants vest primarily over a period of three to four years. The following table summarizes restricted share activity for the three months ended March 31, 2013:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2012	1,181,677	\$ 2.27	\$ 3,095,994
Granted	291,020	3.25	
Vested	(174,919)	2.66	\$ 850,857
Forfeited			
Outstanding at March 31, 2013	1,297,778	\$ 2.44	\$ 9,149,335

As of March 31, 2013, 590,000 and 150,000 shares of restricted stock issued to employees and consultants, respectively, 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. The agreement, as amended, terminates on May 20, 2014, subject to certain early termination events. As of December 31, 2012, Mr. Bentsur has been granted a total of 350,000 shares of restricted stock based on the achievement of certain milestone awards described in his employment agreement. In addition, as of March 31, 2013, Mr. Bentsur has the opportunity to earn certain milestone awards as follows:

(1) 400,000 shares of restricted stock will be granted to Mr. Bentsur upon the first to occur of (a) our filing of an accepted new drug application, or NDA, with the U.S. Food and Drug Administration, or FDA, for Zerenex, or (b) our outlicensing of Zerenex in the U.S. to a third party. 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. This milestone #1 may be achieved with respect to NDAs or qualifying outlicenses for multiple indications of the same product, but not for subsequent outlicenses of the product relating to an indication for which the milestone is met. Upon achievement of milestone #2 below with respect to a product, the restricted stock granted for one indication of the product under milestone #1 above will vest in full.

(2) 500,000 shares of restricted stock will be granted to Mr. Bentsur, upon the first to occur of (a) our first commercial sale of Zerenex in the U.S. off an approved NDA, (b) our receipt of the first royalty upon the commercial sale of Zerenex 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 Zerenex in the U.S. Such restricted stock will vest on the first anniversary of the date of grant provided that Mr. Bentsur remains an employee during such vesting period.

(3) 100,000 shares of restricted stock will be granted to Mr. Bentsur upon each event of our outlicensing Zerenex 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 \$581,000 and \$646,000 of non-cash compensation expense related to equity incentive grants during the three months ended March 31, 2013 and 2012, respectively. 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 and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future.

Black-Scholes Option Valuation Assumptions	Three months ended March 31,	
	2013	2012
Risk-free interest rates	0.6%	0.6%
Dividend yield		
Volatility	102.4%	110.0%
Weighted-average expected term	4.0 years	4.0 years

## **Table of Contents**

The weighted average grant date fair value of options granted for the three months ended March 31, 2013 and 2012 was \$2.73 and \$1.85 per option, respectively. We used historical information to estimate forfeitures within the valuation model. As of March 31, 2013, there was \$2.4 million and \$1.4 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.2 years and 2.2 years, respectively. These amounts do not include, as of March 31, 2013, 145,000 options outstanding and 740,000 shares of restricted stock outstanding which are milestone-based and vest upon certain corporate milestones, such as FDA approval of our drug candidates and change in control. Stock-based compensation will be measured and recorded if and when a milestone occurs.

### **NOTE 4 LICENSE AGREEMENTS**

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 Zerenex. 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 2013, JT and Torii filed its NDA with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of \$7.0 million in January 2013 for the achievement of the NDA filing milestone. As a result, we recorded license revenue of \$7.0 million in accordance with our revenue recognition policy, which is included in the three months ended March 31, 2013. We may receive up to an additional \$65.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, JT and Torii will make royalty payments to us on net sales of ferric citrate in Japan.

### **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.). We anticipate the court will consolidate the actions. Both complaints assert 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) the officers for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. Both complaints are premised on general allegations that we and the individual defendants 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. The plaintiffs seek an unspecified amount of damages. Motions to appoint Lead Plaintiff and Lead Plaintiff's Counsel were filed on April 2, 2013, and are presently pending. Following the appointment of Lead Plaintiff and Lead Plaintiff's Counsel, a Consolidated Amended Complaint will be filed that will serve as the operative complaint in this matter. We believe the claims made in the actions are without merit, and intend to defend the actions vigorously. We cannot, however, predict the outcome or effect, if any, of the lawsuit on our business.

## **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., its predecessor company 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, 2012.

### **OVERVIEW**

## Edgar Filing: KERYX BIOPHARMACEUTICALS INC - Form 10-Q

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of renal disease. We are developing Zerenex™ (ferric citrate), an oral, ferric iron-based compound that has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes. We have completed a U.S.-based Phase 3 clinical program for Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, on dialysis, conducted pursuant to a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA. The submissions of a New Drug Application, or NDA, with the FDA and Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, are pending.

Zerenex is also in Phase 2 development in the U.S. for the management of phosphorus and iron deficiency in anemic patients with Stages 3 to 5 non-dialysis dependent chronic kidney disease, or CKD.

## **Table of Contents**

We may engage in business development activities that include seeking strategic relationships for Zerenex, as well as evaluating compounds and companies for in-licensing or acquisition. To date, we have not received approval for the sale of any drug candidate in any market. Therefore, we have not generated any product sales from any drug candidate. We have generated, and expect to continue to generate, revenue from the sublicensing of rights to Zerenex in Japan to Japan Tobacco Inc., or JT, and Torii Pharmaceutical Co., Ltd., or Torii.

## **RECENT DEVELOPMENTS**

### ***Zerenex<sup>TM</sup> (ferric citrate)***

On January 28, 2013, we announced successful top-line results from our long-term Phase 3 study of Zerenex for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with ESRD on dialysis. In this study, Zerenex met the study's primary endpoint, demonstrating a highly statistically significant change in serum phosphorus versus placebo over the four-week Efficacy Assessment Period of the study. In addition, Zerenex met the key secondary endpoints of increasing ferritin and TSAT and reducing the use of IV iron and ESAs versus the active control group over the 52-week Safety Assessment Period of the study. This long-term Phase 3 study was the final component of our Phase 3 registration program, which was conducted pursuant to an SPA agreement with the FDA.

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

## **GENERAL CORPORATE**

We have devoted substantially all of our efforts to the identification, in-licensing, development and partnering of drug candidates. We have incurred negative cash flow from operations each year since our inception. We anticipate incurring negative cash flows from operating activities for the foreseeable future. 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, partnership and licensing activities.

Our license revenues currently 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 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.

We have not earned any revenues from the commercial sale of any drug candidate.

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, manufacturing, 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 general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, legal activities and facilities-related expenses.

## **Table of Contents**

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 show that Zerenex is effective in treating certain diseases or conditions, there is no guarantee that we will be able to record commercial sales of Zerenex in the future. In addition, we expect losses to continue as we continue to fund the development of Zerenex, including, but not limited to, new drug application submissions, building of inventory, 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 may need to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA or regulatory authorities of other countries, which would 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 March 31, 2013 and March 31, 2012**

*License Revenue.* License revenue for the three months ended March 31, 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 for the treatment of hyperphosphatemia in patients with CKD. There was no license revenue for the three months ended March 31, 2012. We do not expect our license revenue to have a material impact on our financial results for the remainder of 2013.

*Non-Cash Compensation Expense (Research and Development).* Non-cash compensation expense (research and development) related to equity incentive grants decreased by \$87,000 to \$191,000 for the three months ended March 31, 2013, as compared to \$278,000 for the three months ended March 31, 2012. The decrease in non-cash compensation expense in the three months ended March 31, 2013, as compared to March 31, 2012, was primarily related to a decrease in research and development personnel in 2013 as compared to the comparable quarter in 2012 and the recording of the fair value of equity awards granted to research and development personnel, which are expensed over the vesting periods of the individual awards.

*Other Research and Development Expenses.* Other research and development expenses decreased by \$883,000 to \$6,239,000 for the three months ended March 31, 2013, as compared to \$7,122,000 for the three months ended March 31, 2012. The decrease in other research and development expenses was due primarily to a \$3,774,000 decrease in research and development expenses related to KRX-0401 (perifosine) following the termination of the clinical development program and license agreement for KRX-0401 in May 2012, partially offset by a \$3,101,000 increase in research and development expenses related to our Zerenex program. We expect our other research and development expenses in 2013 to increase due to the build-up of pre-launch/launch inventory and the pending submissions of the NDA and MAA for Zerenex.



## **Table of Contents**

*Non-Cash Compensation Expense (General and Administrative).* Non-cash compensation expense (general and administrative) related to equity incentive grants increased by \$22,000 to \$390,000 for the three months ended March 31, 2013, as compared to \$368,000 for the three months ended March 31, 2012. The increase in non-cash compensation expense in the three months ended March 31, 2013, as compared to March 31, 2012, was primarily related to the recording of the fair value of equity awards granted to general and administrative personnel and directors, which are expensed over the vesting periods of the individual awards.

*Other General and Administrative Expenses.* Other general and administrative expenses increased by \$930,000 to \$2,338,000 for the three months ended March 31, 2013, as compared to \$1,408,000 for the three months ended March 31, 2012. The increase was primarily related to legal fees and pre-commercial activities related to Zerenex. We expect our other general and administrative costs in 2013 to increase in order to scale-up our operations and infrastructure to prepare to commercialize Zerenex, subject to our business development activities.

*Interest and Other Income, Net.* Interest and other income, net, increased by \$41,000 to \$103,000 for the three months ended March 31, 2013, as compared to \$62,000 for the three months ended March 31, 2012. The increase was due to a higher level of invested funds in our investment portfolio following our January 2013 public offering.

## **LIQUIDITY AND CAPITAL RESOURCES**

Our major sources of cash have been proceeds from various public offerings of our common stock, private placements of equity securities, 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 a drug candidate and cannot be sure if we will ever be able to do so. Even if we commercialize a drug candidate, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidate alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate.

On January 30, 2013, we announced the pricing of an underwritten public offering, whereby we sold 9,469,100 shares of our common stock at a price of \$8.49 per share for gross proceeds of approximately \$80.4 million. Net proceeds from this offering were approximately \$74.8 million, net of underwriting discounts and offering expenses of approximately \$5.6 million. The shares were sold under Registration Statements (Nos. 333-171517 and 333-186332) on Form S-3 and Form S-3MEF, respectively, and filed by us with the Securities and Exchange Commission.

As of March 31, 2013, we had \$87.3 million in cash and cash equivalents, an increase of \$72.6 million from December 31, 2012. We currently anticipate that our cash and cash equivalents at March 31, 2013 are sufficient to fund our anticipated operating cash requirements for approximately the next 21 to 24 months. 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 pre-launch/launch inventory, the timing and expenditures associated with submitting the NDA and MAA for Zerenex, the timing and expenditures associated with select pre-commercial/commercial activities related to Zerenex, and the timing, design and conduct of clinical trials for Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

In accordance with the licensing arrangement with JT and Torii, we may receive payments upon the achievement of pre-specified milestones. In January 2013, JT and Torii filed its NDA with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with CKD. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of \$7.0 million in January 2013 for the achievement of the NDA filing milestone. The next potential milestone is for the marketing approval of ferric citrate in Japan.

Net cash used in operating activities for the three months ended March 31, 2013 was \$2.1 million, as compared to \$8.5 million for the three months ended March 31, 2012. This decrease in net cash used in operating activities was primarily related to the \$7.0 million non-refundable milestone payment received from JT and Torii in January 2013.

**Table of Contents**

For the three months ended March 31, 2013, net cash used by investing activities was \$45,000, as compared to \$5.0 million used in investing activities for the three months ended March 31, 2012. The change was primarily due to the timing of our investments in, and maturities of, held-to-maturity short-term securities.

For the three months ended March 31, 2013, net cash provided by financing activities was \$74.8 million as compared to no net cash provided by financing activities for the three months ended March 31, 2012. The increase was primarily related to net proceeds of \$74.8 million received from the 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**

In March 2013, we signed an amendment to the lease on our corporate and executive office located in New York City extending its term through September 30, 2014.

As of March 31, 2013, we have the following operating lease obligations.

		Payment due by period			
	Total	Less than 1 year	1-3 years	3-5 years	More than 5 years
Operating lease	\$ 860,000	\$ 573,000	\$ 287,000	\$	\$

**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.

## **Table of Contents**

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, 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 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.

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

*Accounting for Pre-Approval Inventory Expenditures.* Pre-approval inventory expenditures are recorded as research and development expenses as incurred. The capitalization of inventory for our product candidate will commence when it is probable that our product will be approved for commercial marketing.

*Accounting Related to Goodwill.* As of March 31, 2013, 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.

## **Table of Contents**

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. As of March 31, 2013, management concluded that there is no impairment of our goodwill.

*Impairment of Long-Lived Assets.* We recognize an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the excess of the carrying value of the asset above its fair value.

*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.

## **ITEM 3. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We currently invest in government and investment-grade corporate debt in accordance with our investment policy, which we may change from time to time. The securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the fair value of our investment will probably decline. As of March 31, 2013, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including money market funds. Due to the short-term nature of these financial instruments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our portfolio of financial instruments.

## **ITEM 4. CONTROLS AND PROCEDURES**

### **Evaluation of Disclosure Controls and Procedures**

As of March 31, 2013, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of March 31, 2013, our disclosure controls and procedures were effective.

## **Table of Contents**

### **Internal Control Over Financial Reporting**

There were no changes in our internal control over financial reporting during the quarter ended March 31, 2013, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## **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.

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.). We anticipate the court will consolidate the actions. Both complaints assert 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) the officers for alleged violations of Sections 10(b) and 20(a) of the Exchange Act and Rule 10b-5. Both complaints are premised on general allegations that we and the individual defendants 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. The plaintiffs seek an unspecified amount of damages. Motions to appoint Lead Plaintiff and Lead Plaintiff's Counsel were filed on April 2, 2013, and are presently pending. Following the appointment of Lead Plaintiff and Lead Plaintiff's Counsel, a Consolidated Amended Complaint will be filed that will serve as the operative complaint in this matter. We believe the claims made in the actions are without merit, and intend to defend the actions vigorously. We cannot, however, predict the outcome or effect, if any, of the lawsuit on our business.

### **ITEM 1A. RISK FACTORS**

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition 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**

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

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred substantial operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of March 31, 2013, we had an accumulated deficit of \$394.7 million. As we continue our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidate.

We have not yet commercialized any drug candidate and cannot be sure that we will ever be able to do so. In April 2012 we announced that our Phase 3 trial for KRX-0401 (perifosine) for refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine and placebo. Following these results, in May 2012, we abandoned our development efforts and terminated our license relating to the KRX-0401 (perifosine) drug candidate, and re-focused our development efforts on our only remaining drug candidate, Zerenex. Even if we commercialize Zerenex, or a future drug candidate, 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 regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidate.

## **Table of Contents**

### **Risks associated with our product development efforts**

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

Whether or not and how quickly we complete 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 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 candidate. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

We have conducted two Phase 3 clinical trials initiated in May 2010 and September 2010 for Zerenex as a treatment of hyperphosphatemia in patients with end-stage renal disease pursuant to a SPA agreement with the FDA. Many companies which have been granted SPAs and/or the right to utilize Fast Track or accelerated approvals have ultimately failed to obtain final approval to market their drugs. Since we are seeking approval for Zerenex under a SPA, based on protocol designs negotiated with, and agreed to by, the FDA, we may be subject to enhanced scrutiny. Regardless of the success of our Phase 3 clinical trials, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Additionally, the regulatory approval of new therapies could invalidate our SPA agreement, or require us to conduct additional, expensive clinical trials to obtain regulatory approval.

In May 2011, we announced positive Scientific Advice from the European Medicines Agency, or EMA, for the development of Zerenex for the management and control of serum phosphorus in ESRD patients undergoing dialysis, and in pre-dialysis chronic kidney disease, or CKD, patients. The Scientific Advice from the EMA indicates that our successful Phase 3 program in the U.S., in conjunction with safety data generated from other clinical studies with Zerenex, will be considered sufficient to support a European marketing authorization application, or MAA, to the EMA for the indication in ESRD patients on dialysis. As a result, we believe that since our Phase 3 program in the U.S. was successful, we will not need to conduct any additional clinical trials to assess the safety or efficacy of Zerenex in order to obtain European approval in the dialysis setting. The Scientific Advice also provided us with a regulatory path forward in the pre-dialysis CKD setting in Europe. 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 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 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, 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 Zerenex.

Additionally, we have never submitted an NDA or similar application for approval in the U.S., Europe, or in any country, which may result in a delay in, or the rejection of, our filing of an NDA, MAA or similar application. During the drug development process, regulatory agencies will typically ask questions of drug sponsors. While we endeavor to answer all such questions in a timely fashion, or in the NDA or MAA, some questions may remain unanswered by the time we submit our NDA and MAA, or may be difficult or impossible to answer to the satisfaction of the regulatory authorities. Unless the FDA, EMA, or similar regulatory authority in other countries, opts not to pursue these questions, filing of an NDA, MAA or similar application may be delayed or rejected. We also can provide no assurance that our Japanese partner, JT and Torii, will not encounter delays or rejections of their NDA or similar application filings with the Japanese regulatory authority.

**Table of Contents**

***Pre-clinical testing and clinical development are long, expensive and uncertain processes. If our drug candidate does not receive the necessary regulatory approvals, we will be unable to commercialize our drug candidate, Zerenex.***

We have not received, and may never receive, regulatory approval for the commercial sale of any drug candidate. We may need to conduct significant additional research and human testing before we can apply for product approval with the FDA 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 FDA, or regulatory authority of another country as applicable, may pose additional questions or request further toxicological, 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 FDA has not requested us to conduct a two-year carcinogenicity study in animals, there is no assurance that prior to, at the time of, or subsequent to the filing of an NDA that the FDA or some other regulatory authority will not ask us to conduct such a study. Consequently, it may take us many years to complete the testing of our drug candidate and failure can occur at any stage of this process. Negative or inconclusive results or medical events during a pre-clinical or clinical trial could cause us to delay or terminate our development efforts. Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies.

Safety signals detected during clinical studies and pre-clinical animal studies, such as the gastrointestinal bleeding and liver toxicities that have been seen in some high-dose, ferric citrate canine studies, may require us to perform additional safety studies or analyses, which could delay the development of the drug or lead to a decision to discontinue development of the drug. We have submitted to the FDA data from our short-term and long-term rat and canine pre-clinical studies for Zerenex. While the FDA has reviewed the data from these studies and we have conducted our Phase 3 clinical program, we can provide no assurance that the FDA will not raise any safety concerns in the future from these studies. Drug candidates in the later stages of clinical development may fail to show the desired traits of safety and efficacy despite positive results in earlier clinical testing. The risk remains that a pivotal program may generate efficacy data that will be insufficiently persuasive for the approval of the drug, or may raise safety concerns that may prevent approval of the drug. 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. Interpretation of the prior pre-clinical and clinical safety and efficacy data of our drug candidate may be flawed. There can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted, which in subsequent, larger studies might appear and prevent approval of such drug candidate. In addition, top-line results reported on completed clinical trials 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 us or a regulatory authority. For example, on January 28, 2013, we announced successful top-line results from our long-term Phase 3 study of Zerenex for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with ESRD on dialysis. In this study, Zerenex met the study's primary endpoint, demonstrating a highly statistically significant change in serum phosphorus versus placebo over the four-week Efficacy Assessment Period of the study. In addition, Zerenex met the key secondary endpoints of increasing ferritin and TSAT and reducing the use of IV iron and ESAs versus the active control group over the 52-week Safety Assessment Period of the study. We can provide no assurance that our findings and conclusions from our long-term Phase 3 study of Zerenex will not change following a more comprehensive review of the data by us or 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 Zerenex or any other drug candidate we develop. If we experience delays in the testing or approval process for our existing drug candidate or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidate may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the U.S. and abroad. 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.

## **Table of Contents**

***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 Zerenex.***

We do not own our drug candidate, Zerenex. We have licensed and sublicensed the rights, patent or otherwise, to Zerenex from a third party, Panion & BF Biotech, Inc., or Panion, who in turn licenses certain rights to Zerenex from one of the inventors of Zerenex. 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 on sales of product resulting from the licensed technologies 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, Panion could terminate the agreement, and we would lose the rights to Zerenex. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Zerenex, Panion could lose its license, which could impair or delay our ability to develop and commercialize Zerenex. 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, and any future, drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drug candidates. Finally, our rights to develop and commercialize Zerenex, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Zerenex and the licenses and sublicenses we grant to others.

***We rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not successfully manufacture and test our drug candidate, 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 candidate for use in clinical trials and for future sales. 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 and commercialize our drug candidate will depend on the ability of such third parties to manufacture our drug candidate on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices, or cGMP, and other regulatory requirements, including requirements from federal, state and local environmental and safety regulatory agencies and foreign regulatory requirements, if applicable. Prior to approval, we will need to complete validation studies that the FDA must review and approve. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional validation studies that the FDA must review and approve. Contract manufacturers often encounter difficulties in scaling up production, including problems involving raw material supplies, production yields, scaled-up product characteristics, quality control and assurance, shortage of qualified personnel, capacity constraints, changing priorities within the contract manufacturers, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. 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 candidate. These risks become more acute as we scale up for commercial quantities, where a reliable source of raw material supplies becomes critical to commercial success. For example, given the large quantity of materials required for ferric citrate production, as we approach commercialization for Zerenex we will need to ensure an adequate supply of starting materials that meet quality, quantity and cost standards. Failure to achieve this level of supply can jeopardize the successful commercialization of the product. Moreover, issues that may arise in our current transition to commercial batch sizes with our third party manufacturers of Zerenex can lead to delays in our development timelines.

Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidate. 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 cGMP, as well as other governmental regulations and



## **Table of Contents**

corresponding foreign standards. While we periodically audit our contractors for adherence to regulatory requirements, 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 testing of our drug candidate. We will not have control over, other than by contract and periodic oversight, third-party manufacturers' compliance with these regulations and standards. We are currently developing 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 tooling 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 file an NDA or receive regulatory approval for our drug candidate. 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 file an NDA or receive regulatory approval for our drug candidate. Switching or engaging multiple third-party contractors to produce our drug substance or drug product may be difficult 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 for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Zerenex, 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 testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

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

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

manufacture our product candidate;

assist us in developing, testing and obtaining regulatory approval for and commercializing our compound and technologies; and

market and distribute our drug product.

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 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. Accordingly, 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 regulatory milestones required for commercialization of our current, and any future, drug candidate.

If, in the future, the market conditions for raising capital deteriorate, we may be forced to rely predominantly or entirely on our ability to contract with third parties for our manufacturing, drug development and marketing. If we are unable to contract with such third parties, we may be forced to limit or suspend or terminate the development of our drug candidate or marketing of any approved product.

## **Table of Contents**

*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 to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. If the CROs 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, as well as 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**

*If we are unable to develop adequate sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to commercialize our product effectively.*

In the event our drug candidate is approved by the FDA, we may conduct our own sales and marketing effort to support the drug. We currently have limited experience in sales, marketing or distribution. To directly market and distribute any product, we must build and train a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build and train such a sales and marketing organization on our own or with the assistance of a contract sales organization. For some market opportunities, we may want or need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our product. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our product, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

From time to time we may consider offers or hold discussions with companies for partnerships or the acquisition of our company or any of our current or future products. Any accepted offer may preclude us from commercializing our product(s) effectively.

*Even if we obtain regulatory approval to market Zerenex, if it fails to achieve market acceptance, we may never record meaningful revenues.*

Even if Zerenex is approved for sale, it may not be commercially successful in the marketplace. Market acceptance of our drug product will depend on a number of factors, including:

perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidate, including, but not limited to, the perception of the long-term effects of the potential absorption and/or accumulation of ferric iron or citrate resulting from the use of Zerenex;

the marketing claims that the FDA will permit us to make in the labeling and advertising of Zerenex, including potential marketing claims related to the effect of Zerenex on iron storage parameters and on the need for, and use of, IV iron and ESAs;

the rates of adoption of our product by medical practitioners and the target populations for our product;

the potential advantages that our product offers over existing treatment methods;

the cost-effectiveness of our product relative to competing products, which may be exacerbated as existing treatments go off-patent;

the availability of government or third-party payor reimbursement for our product;

the side effects or unfavorable publicity concerning our product or similar products; and

the effectiveness of our sales, marketing and distribution efforts.

Because we expect sales of our product, if approved, to generate substantially all of our revenues in the long-term, the failure of our drug to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

## **Table of Contents**

***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.

Zerenex, if approved in the U.S., would have to compete 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-Aventis), PhosLo® (calcium acetate), marketed by Fresenius Medical Care, and Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, 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 Zerenex provides certain advantages, such as the absence of hypercalcemia as compared to PhosLo, reduced pill burden as compared to Renagel and the lack of lanthanum build-up and a preferred route of administration (non-chewable) as compared to Fosrenol. In addition, we compete against existing treatments on price, which becomes more challenging as generic versions of these existing treatments come to market. For example, 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 their core patents, generic formulations of Renagel® and Renvela® (expected in the U.S. beginning in March 2014), and generic formulations of Fosrenol®, may be launched, which 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. Some of these potential competing drugs are further advanced in development than our drug candidate and may be commercialized earlier. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors. Fresenius Medical Care and Vifor Pharma are collaborating on the development of an iron-based phosphate binder, PA21, which we believe to be a chewable tablet formulation. Recently, Fresenius Medical Care and Vifor Pharma announced positive data from a multi-national, Phase 3 study of PA21 in dialysis patients, and also announced the submission to the FDA of an NDA and the submission to the EMA of the first approval dossier for PA21. If approved by the FDA and/or EMA, PA21 could have a material effect on the market opportunities of Zerenex in the U.S. and Europe, respectively.

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

As of April 30, 2013, we had 25 full and part-time employees. To successfully develop our drug candidate, 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, our ability to continue to execute on our business plan could be materially impaired. Although we have an employment agreement with Mr. Bentsur, such agreement does not prevent him from terminating his employment with us.

***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.

## **Table of Contents**

Acquisitions involve a number of operational risks, including:

difficulty and expense of assimilating the operations, technology and personnel of the acquired business;

our inability to retain the management, key personnel and other employees of the acquired business;

our inability to maintain the acquired company's relationship with key third parties, such as alliance partners;

exposure to legal claims for activities of the acquired business prior to the acquisition;

the diversion of our management's attention from our core business; and

the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

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

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

government and health administration authorities;

private health insurers;

managed care programs; and

other third-party payors.

Significant uncertainty exists as to the 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 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 approved. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our product, its market acceptance may be 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

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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

## **Table of Contents**

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, delays 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. If phosphate binders are included in the bundle beginning in 2016, 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.

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 clinical trials, labeling changes based on new safety information, and compliance with risk evaluations 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.

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

The use of our drug candidate in clinical trials, and the future sale of any approved drug candidate 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.

***In connection with the clinical trial management and site recruitment services we previously provided, we may be exposed to liability that could have a material adverse effect on our financial condition and results of operations.***

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Online Collaborative Oncology Group, Inc., or OCOG, a subsidiary we acquired through our acquisition of ACCESS Oncology, Inc. in 2004, previously provided clinical trial management and site recruitment services to us as well as other biotechnology and pharmaceutical companies. OCOG entered into its last third-party service contract in 2005 and its business was discontinued as of December 2011. In conducting the activities of OCOG, any failure on our



## **Table of Contents**

part to comply with applicable governmental regulations or contractual obligations could expose us to liability to our clients and could have a material adverse effect on us. We also could be held liable for errors or omissions in connection with the services we performed. In addition, the wrongful or erroneous delivery of health care information or services may expose us to liability. If we were required to pay damages or bear the costs of defending any such claims, the losses could be material.

***Our corporate compliance efforts cannot guarantee that we are in compliance with all potentially applicable regulations.***

The development, manufacturing, pricing, sale, marketing, and reimbursement of our product(s), together with our general operations, are subject to extensive regulation by federal, state and other authorities within the U.S. and numerous entities outside of the U.S. We are a relatively small company with 25 full and part-time employees as of April 30, 2013. We also have significantly fewer employees than many other companies that have a product candidate in clinical development, and we rely heavily on third parties to conduct many important functions. While we believe that our corporate compliance program is sufficient to ensure compliance with applicable regulations, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, issuance of an enforcement or warning letter, restrictions on our product or manufacturing processes, withdrawal of product(s) from the market, significant fines, or other sanctions or litigation.

## **Risks related to our financial condition**

***Our cash, cash equivalents and investment securities may not be adequate to finance our operating cash requirements for the length of time that we have estimated.***

We currently anticipate that our cash and cash equivalents at March 31, 2013 are sufficient to fund our anticipated operating cash requirements for approximately the next 21 to 24 months. 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 pre-launch/launch inventory, the timing and expenditures associated with submitting the NDA and MAA for Zerenex, the timing and expenditures associated with select pre-commercial/commercial activities related to Zerenex, and the timing, design and conduct of clinical trials for Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

Our forecast of the period of time through which our cash, cash equivalents and investment securities 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 pre-launch/launch inventory;

the timing and expenditures associated with submitting the NDA and MAA filings for Zerenex;

the timing and expenditures associated with select pre-commercial/commercial activities related to Zerenex;

the timing, design and conduct of, and results from, clinical trials for Zerenex;

the timing of expenses associated with manufacturing and product development of Zerenex 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;

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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 candidate 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 costs related to litigation.

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## **Table of Contents**

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.

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 candidate, Zerenex, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Zerenex.***

The patent rights that we own or have licensed relating to Zerenex are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market Zerenex. 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 Zerenex in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We cannot assure you that we can obtain any extension of the term of this patent for delays caused by FDA regulatory review (the maximum amount of term of extension available under the Patent Term Extension provisions of 35

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**Table of Contents**

U.S.C. § 156 would extend the term of this patent to February 2022). Upon expiration of U.S. Patent No. 5,753,706, competitors who obtain the requisite regulatory approval can offer products with the same composition as our product, so long as the competitors do not infringe any other patents that we may hold, such as other composition of matter patents and/or method of use patents. We have 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 Zerenex), 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 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.

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.

Because any potential date for regulatory approval is currently unknown, it is possible that the life of these patents following regulatory approval will be minimal, even if the above-discussed Patent Term Extension is obtained.

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 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 of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Zerenex if we obtain regulatory approval, increase the risk that a generic version of Zerenex could enter the market to compete with Zerenex, limit our development and commercialization of Zerenex, 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 Zerenex. 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 orphan drug regulations, 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 new formulation exclusivity, to provide market exclusivity for a drug candidate. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. 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. We may also seek to utilize market exclusivities in other territories, such as in the EU. We cannot assure that our drug candidate, Zerenex (ferric citrate), or any drug candidates we may acquire or in-license, will obtain such orphan drug designation, 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.



## **Table of Contents**

***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 Zerenex or any other technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensor or us that seeks damages or an injunction of our commercial activities relating to Zerenex or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Zerenex or such technologies, and/or require our licensor or us to obtain a license to continue to use Zerenex 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.

Future issuances of common stock could further 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 candidate, 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;

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;

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.

## **Table of Contents**

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., 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 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.
- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 8, 2013.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 8, 2013.
- 32.1 Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 8, 2013.
- 32.2 Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated May 8, 2013.
- 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 Comprehensive Loss, (iv) Consolidated Statements of Stockholders' Equity, (v) Consolidated Statements of Cash Flows, and (vi) the Notes to Consolidated Financial Statements.



**Table of Contents**

**SIGNATURES**

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

KERYX BIOPHARMACEUTICALS, INC.

Date: May 8, 2013

By: /s/ James F. Oliviero, CFA

Chief Financial Officer

Principal Financial and Accounting Officer

**Table of Contents**

**EXHIBIT INDEX**

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

- 31.1 Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 8, 2013.
- 31.2 Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated May 8, 2013.
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