KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 08, 2012

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2012

OR

£ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE
SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware	13-4087132
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

750 Lexington Avenue

New York, New York 10022

(Address including zip code of principal executive offices)

(212) 531-5965

(Registrant's telephone number, including area code)

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No £

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes x No £

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See definition of “large accelerated filer,” “accelerated filer” and “smaller reporting company” in Rule 12b-2 of the Exchange Act.

Large accelerated filer £	Accelerated filer x
Non-accelerated filer £ (Do not check if smaller reporting company)	Smaller reporting company £

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes £ No x

There were 71,913,001 shares of the registrant’s common stock, $0.001 par value, outstanding as of July 31, 2012.

KERYX BIOPHARMACEUTICALS, INC.

FORM 10-Q

FOR THE QUARTER ENDED JUNE 30, 2012

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" 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 of Zerenex™ (ferric citrate) or any other products we may acquire or in-license;
- expectations for our ability to successfully adjust our strategy and reduce our operating expenses following the termination, on May 4, 2012, of the KRX-0401 (perifosine) license agreement;
- 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; and

- expectations for future capital requirements.

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.

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.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.
Consolidated Balance Sheets as of June 30, 2012 and December 31, 2011

(in thousands, except share and per share amounts)

	June 30, 2012 (Unaudited)	December 31, 2011
Assets		
Current assets:		
Cash and cash equivalents	$ 21,100	$ 35,252
Short-term investment securities	6,012	4,211
Interest receivable	38	7
Other current assets	190	534
Total current assets	27,340	40,004
Property, plant and equipment, net	51	67
Goodwill	3,208	3,208
Other assets, net	209	209
Total assets	$ 30,808	$ 43,488
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 8,865	$ 8,870
Accrued compensation and related liabilities	418	897
Total current liabilities	9,283	9,767
Contingent equity rights	—	2,639
Other liabilities	11	35
Total liabilities	9,294	12,441
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, 71,996,006 and 71,102,899 shares issued, 71,916,058 and 71,022,951 shares outstanding at June 30, 2012 and December 31, 2011, respectively)	72	71
Additional paid-in capital	402,304	401,220
Treasury stock, at cost, 79,948 shares at June 30, 2012 and December 31, 2011, respectively	(357)	(357)

Accumulated deficit	(380,505)	(369,887)
Total stockholders' equity	21,514	31,047
Total liabilities and stockholders' equity	$ 30,808	$ 43,488

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Operations
for the three and six months ended June 30, 2012 and 2011 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended		Six months ended	
	June 30,		June 30,	
	2012	2011	2012	2011
License revenue	$—	$5,000	$—	$5,000
Operating expenses:				
Research and development:				
Non-cash compensation	73	205	351	464
Other research and development	3,726	6,295	10,848	10,913
Total research and development	3,799	6,500	11,199	11,377
General and administrative:				
Non-cash compensation	365	314	733	628
Other general and administrative	1,535	1,404	2,943	2,688
Total general and administrative	1,900	1,718	3,676	3,316
Total operating expenses	5,699	8,218	14,875	14,693
Operating loss	(5,699)	(3,218)	(14,875)	(9,693)
Interest and other income, net	1,556	122	1,618	192
Loss before income taxes and extraordinary gain	(4,143)	(3,096)	(13,257)	(9,501)
Income taxes	—	—	—	—
Extraordinary gain	2,639	—	2,639	—
Net loss	$(1,504)	$(3,096)	$(10,618)	$(9,501)
Basic and diluted net loss per common share:				
Before extraordinary gain	$(0.06)	$(0.05)	$(0.19)	$(0.15)
Extraordinary gain	0.04	—	0.04	—
Basic and diluted net loss per common share	$(0.02)	$(0.05)	$(0.15)	$(0.15)
Weighted average shares used in computing basic and diluted net loss per common share	71,466,740	66,286,615	71,345,873	63,931,209

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

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Keryx Biopharmaceuticals, Inc.
Consolidated Statement of Stockholders' Equity
for the six months ended June 30, 2012 (Unaudited)

(in thousands, except share amounts)

	Common stock		Additional paid-in	Treasury stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	deficit	Total
Balance at December 31, 2011	71,102,899	$ 71	$ 401,220	79,948	$ (357)	$ (369,887)	$ 31,047
Changes during the period:							
Issuance of restricted stock	979,300	1	—	—	—	—	1
Forfeiture of restricted stock	(86,193)	(—)*	—	—	—	—	(—)*
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	1,084	—	—	—	1,084
Net loss	—	—	—	—	—	(10,618)	(10,618)
Balance at June 30, 2012	71,996,006	$ 72	$ 402,304	79,948	$ (357)	$ (380,505)	$ 21,514

* Amount less than one thousand dollars.

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows
for the six months ended June 30, 2012 and 2011 (Unaudited)

(in thousands)

	Six months ended June 30,	
	2012	2011
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(10,618)	$(9,501)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Stock compensation expense	1,084	1,092
Depreciation and amortization	19	21
Extraordinary gain	(2,639)	—
Changes in assets and liabilities:		
Decrease (increase) in other current assets	344	(168)
Increase in accrued interest receivable	(31)	(7)
Increase in security deposits	—	(51)
Increase in other assets	—	(21)
(Decrease) increase in accounts payable and accrued expenses	(5)	872
Decrease in accrued compensation and related liabilities	(479)	(316)
Decrease in other liabilities	(24)	(23)
Net cash used in operating activities	(12,349)	(8,102)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(3)	(34)
Investment in held-to-maturity short-term securities	(11,263)	(9,540)
Proceeds from maturity of held-to-maturity short-term securities	9,463	324
Net cash used in investing activities	(1,803)	(9,250)
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from public offering, net	—	30,809
Proceeds from exercise of options	—	1,340
Net cash provided by financing activities	—	32,149
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(14,152)	14,797
Cash and cash equivalents at beginning of period	35,252	28,412
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$21,100	$43,209

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

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 and six months ended June 30, 2012 and 2011 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, 2011. The results of operations for the three and six months ended June 30, 2012, 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 June 30, 2012, we have an accumulated deficit of $380.5 million.

Our major sources of cash have been proceeds from various private placements of equity securities, public offerings of our common stock, 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 October 2009, we filed a statement of claim with the Financial Institution Regulatory Authority, or FINRA, to commence an arbitration proceeding against an SEC registered broker-dealer, seeking damages arising from that broker-dealer's recommendations and purchases of auction rate securities for our cash management account. On May 7, 2012, we received the arbitrators' award, which required the broker-dealer to pay us compensatory damages in the amount of approximately $1.8 million. In June 2012, we received the award, which amounted to, after fees and legal expenses, approximately $1.5 million.

We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2012, exclusive of our anticipated milestone payments to be received, are sufficient to fund our anticipated operating cash requirements for approximately 15 to 18 months from June 30, 2012. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidate. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any drug candidate.

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

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 record our investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investment securities are recorded at fair value (see Note 2 – Fair Value Measurements). Other-than-temporary impairment charges are included in interest and other income, net, and unrealized gains (losses), if determined to be temporary, are included in accumulated other comprehensive income (loss) in stockholders' equity.

The following table summarizes our investment securities at June 30, 2012, and December 31, 2011:

(in thousands)	June 30, 2012	December 31, 2011
Short-term investments:		
Obligations of domestic governmental agencies (mature August 2012) (held-to-maturity)	$ 6,012	$ 4,011
Bank deposit (held-to-maturity)	—	200
Total short-term investment securities	$ 6,012	$ 4,211

Revenue Recognition

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

Income Taxes

As of June 30, 2012, we have U.S. net operating loss carryforwards of approximately $334.3 million which expire from 2019 through 2032. 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 and warrants, as their inclusion would be anti-dilutive. The options and warrants outstanding as of June 30, 2012 and 2011, which are not included in the computation of net loss per share amounts, were 3,777,292 and 7,188,628, respectively.

Comprehensive Loss

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

Segment Reporting

Following the discontinuation of the Diagnostic segment in September 2008 and 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. The negative outcome of our Phase 3 "X-PECT" (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) clinical trial evaluating perifosine (KRX-0401) + capecitabine (Xeloda) in patients with refractory advanced colorectal cancer, announced on April 2, 2012, triggered an impairment test. As of June 30, 2012, management concluded that there is no impairment of our goodwill.

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

The following table provides the fair value measurements of applicable financial assets as of June 30, 2012:

(in thousands)	Financial assets at fair value as of June 30, 2012 Level 1	Level 2	Level 3
Money market funds (1)	$ 13,331	$ —	$ —
Obligations of domestic governmental agencies (held-to-maturity) (2)	6,012	—	—
Total	$ 19,343	$ —	$ —

(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.

(2) Amortized cost approximates fair value.

NOTE 3 – STOCKHOLDERS' EQUITY

Common Stock

We currently have two shelf registration statements on Form S-3 filed and declared effective by the SEC, providing for the offering of up to $79 million of common stock and warrants in the aggregate. We may offer the securities under our shelf registration statements from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in our best interests and the best interests of our stockholders. We believe that these shelf registration statements provide us with the flexibility to efficiently raise additional capital to finance our operations as needed.

Equity Incentive Plans

Shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 991,619 shares at June 30, 2012.

Stock Options

The following table summarizes stock option activity for the six months ended June 30, 2012:

	Number of shares	Weighted-average exercise price	Weighted-average contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2011	3,517,000	$ 6.40	6.9	$2,139,130
Granted	516,500	2.35	10.0	
Exercised	—	—		$—
Forfeited	(236,208)	8.32		
Expired	(20,000)	10.17		
Outstanding at June 30, 2012	3,777,292	$ 5.70	6.4	$1,412,908
Vested and expected to vest at June 30, 2012	3,738,001	$ 5.73	6.4	$1,405,622
Exercisable at June 30, 2012	2,554,418	$ 6.68	5.5	$1,195,408

Upon the exercise of stock options, we issue new shares of our common stock. As of June 30, 2012, 95,000 options issued to employees and 50,000 options issued to consultants are unvested, milestone-based options.

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 six months ended June 30, 2012:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2011	621,581	$ 3.16	$1,572,600
Granted	979,300	1.92	
Vested	(263,258)	3.03	$183,902
Forfeited	(86,193)	2.30	
Outstanding at June 30, 2012	1,251,430	$ 2.28	$2,252,574

As of June 30, 2012, 550,000 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 June 30, 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 June 30, 2012, 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 $438,000 and $519,000 of non-cash compensation expense related to equity incentive grants during the three months ended June 30, 2012 and 2011, respectively, and $1,084,000 and $1,092,000 during the six months ended June 30, 2012 and 2011, 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.

	Three months ended June 30,				Six months ended June 30,			
Black-Scholes Option Valuation Assumptions	2012		2011		2012		2011	
Risk-free interest rates	0.6	%	1.1	%	0.6	%	1.4	%
Dividend yield	—		—		—		—	
Volatility	114.9	%	113.2	%	111.2	%	115.1	%
Weighted-average expected term	4.0 years		4.0 years		4.0 years		4.0 years	

The weighted average grant date fair value of options granted for the three months ended June 30, 2012 and 2011 was $1.35 and $3.28 per option, respectively, and for the six months ended June 30, 2012 and 2011 was $1.73 and $3.45 per option. We used historical information to estimate forfeitures within the valuation model. As of June 30, 2012, there was $2.0 million and $1.3 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 1.9 years and 1.8 years, respectively. These amounts do not include, as of June 30, 2012, 145,000 options outstanding and 700,000 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 April 2011, JT and Torii commenced a Phase 3 clinical program of ferric citrate in Japan. Under the terms of the license agreement with JT and Torii, we received a non-refundable milestone payment of $5.0 million in April 2011 for the achievement of the Phase 3 commencement milestone. As a result, we recorded license revenue of $5.0 million in accordance with our revenue recognition policy, which is included in the three and six months ended June 30, 2011.We may receive up to an additional $72.0 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.

On April 2, 2012, we reported that the Phase 3 "X-PECT" (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) clinical trial evaluating perifosine (KRX-0401) + capecitabine (Xeloda) in patients with refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine + placebo. On May 4, 2012, we executed a License Termination and Technology Transfer Agreement with Aeterna Zentaris GmbH (“Zentaris”), whereby the license agreement for KRX-0401 (perifosine) was terminated, and in exchange for the transfer of the U.S. Investigational New Drug Application, development data, intellectual property and contracts to Zentaris, we will receive a royalty on future net sales, if any, of perifosine in the U.S., Canada and Mexico. Zentaris has assumed all costs related to the Perifosine program going forward.

Due to the termination of the license for KRX-0401, we are no longer committed to pay to the former stockholders of ACCESS Oncology, Inc. certain contingent equity rights (up to 2,872,422 shares of our common stock). For the three and six months ended June 30, 2012, we recognized a non-cash extraordinary gain of $2.6 million relating to the write-off of the contingent equity rights liability.

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, 2011.

OVERVIEW

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. Zerenex is currently in Phase 3 clinical development in the United States, under a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, on dialysis. In addition, Zerenex (ferric citrate) is in Phase 3 clinical development in Japan by our Japanese partner, Japan Tobacco Inc., or JT, and Torii Pharmaceutical Co., Ltd., or Torii.

We also engage in business development activities that include seeking strategic relationships for our drug candidate, 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 and, therefore, have not generated any product sales from any drug candidate. We have generated, and expect to continue to generate, revenue from the licensing of rights to Zerenex in Japan to JT and Torii.

RECENT DEVELOPMENTS

Zerenex™ (ferric citrate)

On April 23, 2012, our Japanese partner for Zerenex (ferric citrate), JT and Torii, announced positive top-line results from a Phase 3 study of ferric citrate in Japan for the treatment of hyperphosphatemia in end-stage renal disease patients on hemodialysis. This study is part of an ongoing Phase 3 program for ferric citrate in Japan for the treatment of hyperphosphatemia. The Phase 3 study, conducted in Japan, was an open-label, randomized study evaluating the efficacy and safety of ferric citrate against an active control, sevelamer hydrochloride, over 12 weeks in hemodialysis patients with hyperphosphatemia. In the top-line results, which evaluated the change of serum phosphorus from baseline, the primary endpoint of efficacy met non-inferiority to sevelamer hydrochloride. Furthermore, there were no clinically significant findings on safety and tolerability of ferric citrate within the treatment period. JT and Torii stated that it is aiming to submit the marketing application for ferric citrate in Japan in their fiscal year ending March 31, 2013.

KRX-0401 (perifosine)

On April 2, 2012, we reported that the Phase 3 "X-PECT" (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) clinical trial evaluating perifosine (KRX-0401) + capecitabine (Xeloda) in patients with refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine + placebo. On May 4, 2012, we executed a License Termination and Technology Transfer Agreement with Aeterna Zentaris GmbH, or Zentaris, whereby the license agreement for KRX-0401 (perifosine) was terminated, and in exchange for the transfer of the U.S. Investigational New Drug Application, development data, intellectual property and contracts to Zentaris, we will receive a royalty on future net sales, if any, of perifosine in the U.S., Canada and Mexico. Zentaris has assumed all costs related to the Perifosine program going forward. Due to the termination of the license for KRX-0401, we are no longer committed to pay to the former stockholders of ACCESS Oncology, Inc. certain contingent equity rights (up to 2,872,422 shares of our common stock). For the three and six months ended June 30, 2012, we recognized a non-cash extraordinary gain of $2.6 million relating to the write-off of the contingent equity rights liability.

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 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, 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.

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.

Our ongoing clinical trials are lengthy and expensive. Even if these trials show that our current, and any future, drug candidate is effective in treating certain diseases or conditions, there is no guarantee that we will be able to record commercial sales of any drug candidate in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. 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 candidate(s) following approval, if any, by the FDA, European Medicines Agency, or EMA, 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 June 30, 2012 and June 30, 2011

License Revenue. There was no license revenue for the three months ended June 30, 2012. License revenue for the three months ended June 30, 2011 was $5.0 million due to the recognition of a non-refundable milestone payment received in April 2011 from JT and Torii for their commencement of a Phase 3 clinical program in Japan. We do not expect our license revenue to have a material impact on our financial results for the remainder of 2012.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants decreased by $132,000 to $73,000 for the three months ended June 30, 2012, as compared to $205,000 for the three months ended June 30, 2011. The decrease in non-cash compensation expense in the three months ended June 30, 2012, as compared to June 30, 2011, was primarily related to a decline in the fair value of equity awards granted to a research and development consultant following the decline in the market price of our common stock in the three months ended June 30, 2012.

Other Research and Development Expenses. Other research and development expenses decreased by $2,569,000 to $3,726,000 for the three months ended June 30, 2012, as compared to $6,295,000 for the three months ended June 30, 2011. The decrease in other research and development expenses was due primarily to a $3,211,000 decrease in research and development expenses related to the completion in April 2012 of the KRX-0401 Phase 3 study in metastatic colorectal cancer and subsequent termination of the clinical development program and license agreement for KRX-0401 on May 4, 2012. The decrease was partially offset by a $728,000 increase in research and development expenses related to our Zerenex Phase 3 clinical program. We expect our other research and development expenses to decrease for the remainder of 2012 due to the termination of our clinical development program and license agreement for KRX-0401 and the expected completion of the Zerenex long-term Phase 3 study in the fourth quarter of 2012, partially offset by expenses associated with our potential filings of new drug applications for Zerenex.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense (general and administrative) related to equity incentive grants increased by $51,000 to $365,000 for the three months ended June 30, 2012, as compared to $314,000 for the three months ended June 30, 2011. The increase in non-cash compensation expense in the three months ended June 30, 2012, as compared to June 30, 2011, 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 $131,000 to $1,535,000 for the three months ended June 30, 2012, as compared to $1,404,000 for the three months ended June 30,

2011. The increase was due primarily to increased miscellaneous general and administrative expenses, including market research initiatives. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2012.

Interest and Other Income, Net. Interest and other income, net, increased by $1,434,000 to $1,556,000 for the three months ended June 30, 2012, as compared to $122,000 for the three months ended June 30, 2011. The increase was due to the award of $1.5 million in compensatory damages, net of fees and legal expenses, relating to the statement of claim we filed with FINRA against an SEC registered broker-dealer for damages arising from that broker-dealer's recommendations and purchases of auction rate securities for our cash management account.

Extraordinary Gain. For the three months ended June 30, 2012, we recorded a non-cash extraordinary gain of $2,639,000 relating to a write-off of the contingent equity rights liability following the termination of the license agreement for KRX-0401.

Six months ended June 30, 2012 and June 30, 2011

License Revenue. There was no license revenue for the six months ended June 30, 2012. License revenue for the six months ended June 30, 2011 was $5.0 million due to the recognition of a non-refundable milestone payment received in April 2011 from JT and Torii for their commencement of a Phase 3 clinical program in Japan. We do not expect our license revenue to have a material impact on our financial results for the remainder of 2012.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants decreased by $113,000 to $351,000 for the six months ended June 30, 2012, as compared to $464,000 for the six months ended June 30, 2011. The decrease in non-cash compensation expense in the six months ended June 30, 2012, as compared to June 30, 2011, was primarily related to 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 $65,000 to $10,848,000 for the six months ended June 30, 2012, as compared to $10,913,000 for the six months ended June 30, 2011. The decrease in other research and development expenses was due primarily to a $1,970,000 decrease in research and development expenses related to the completion in April 2012 of the KRX-0401 Phase 3 study in metastatic colorectal cancer and subsequent termination of the clinical development program and license agreement for KRX-0401 on May 4, 2012. The decrease was partially offset by a $1,847,000 increase in research and development expenses related to our Zerenex Phase 3 clinical program. We expect our other research and development costs to decrease for the remainder of 2012 due to the termination of our clinical development program and license agreement for KRX-0401 and the expected completion of the Zerenex long-term Phase 3 study in the fourth quarter of 2012, partially offset by expenses associated with our potential filings of new drug applications for Zerenex.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense (general and administrative) related to equity incentive grants increased by $105,000 to $733,000 for the six months ended June 30, 2012, as compared to $628,000 for the six months ended June 30, 2011. The increase in non-cash compensation expense in the six months ended June 30, 2012, as compared to June 30, 2011, 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 $255,000 to $2,943,000 for the six months ended June 30, 2012, as compared to $2,688,000 for the six months ended June 30, 2011. The increase was due primarily to increased miscellaneous general and administrative expenses, including market research initiatives. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2012.

Interest and Other Income, Net. Interest and other income, net, increased by $1,426,000 to $1,618,000 for the six months ended June 30, 2012, as compared to $192,000 for the six months ended June 30, 2011. The increase was due to the award of $1.5 million in compensatory damages, net of fees and legal expenses, relating to the statement of claim we filed with FINRA against an SEC registered broker-dealer for damages arising from that broker-dealer’s recommendations and purchases of auction rate securities for our cash management account.

Extraordinary Gain. For the six months ended June 30, 2012, we recorded a non-cash extraordinary gain of $2,639,000 relating to a write-off of the contingent equity rights liability following the termination of the license agreement for KRX-0401.

LIQUIDITY AND CAPITAL RESOURCES

Our major sources of cash have been proceeds from various private placements of equity securities, option and warrant exercises, public offerings of our common stock, 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.

As June 30, 2012, we had $27.2 million in cash, cash equivalents, interest receivable, and investment securities, a decrease of $12.3 million from December 31, 2011. We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2012, exclusive of our anticipated milestone payments to be received, are sufficient to fund our anticipated operating cash requirements for approximately 15 to 18 months from June 30, 2012. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for our drug candidate. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any drug candidate.

We currently have two shelf registration statements on Form S-3, filed and declared effective by the SEC, providing for the offering of up to approximately $79 million of common stock and warrants in the aggregate.

- On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607), which the SEC declared effective on September 23, 2009, providing for the offering of up to $40 million of our common stock and warrants to purchase our common stock. There remains approximately $12 million of our common stock and warrants available for sale under this shelf registration statement. This registration statement will expire on September 23, 2012.

- On January 3, 2011, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-171517), which the SEC declared effective on January 28, 2011, providing for the offering of up to $100 million of our common stock and warrants to purchase our common stock. There remains approximately $67 million of our common stock and warrants available for sale under this shelf registration statement.

We may offer the securities under our shelf registration statements from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in our best interests and the best interests of our stockholders. We believe that these shelf registration statements provide us with the flexibility to efficiently raise additional capital to finance our operations as needed.

Cash used in operating activities for the six months ended June 30, 2012 was $12.3 million, as compared to $8.1 million for the six months ended June 30, 2011. This increase in net cash used in operating activities was primarily due to the $5.0 million non-refundable milestone payment received from JT and Torii in April 2011.

For the six months ended June 30, 2012, net cash used in investing activities was $1.8 million, as compared to $9.3 million for the six months ended June 30, 2011. This decrease was primarily due to the timing of our investments in, and maturities of, held-to-maturity short-term securities.

For the six months ended June 30, 2012, there was no net cash provided by financing activities, as compared to $32.1 million for the six months ended June 30, 2011. The decrease was primarily related to net proceeds of $30.8 million received from the underwritten registered offering in May 2011.

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.

CRITICAL ACCOUNTING POLICIES

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

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

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

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

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. We review and accrue CRO expenses and clinical trial study expenses based on work performed and rely upon estimates of those costs applicable to the stage of completion of a study. Accrued CRO costs are subject to revisions as such trials progress to completion. Revisions are charged to expense in the period in which the facts that give rise to the revision become known. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, 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 Related to Goodwill. As of June 30, 2012, there was approximately $3.2 million of goodwill on our consolidated balance sheet. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit’s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit’s goodwill is compared with the carrying amount of the unit’s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition that were used to determine the valuation of goodwill and intangibles. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment indicators.

The negative outcome of our Phase 3 "X-PECT" (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) clinical trial evaluating perifosine (KRX-0401) + capecitabine (Xeloda) in patients with refractory advanced colorectal cancer, announced on April 2, 2012, triggered an impairment test. As of June 30, 2012, 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. Some of 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 June 30, 2012, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including government debt and money market funds. Due to the short-term nature of our investments, we believe there is no material exposure to interest rate risk, and/or credit risk, arising from our investments.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2012, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2012, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2012, 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.

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 June 30, 2012, we had an accumulated deficit of $380.5 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. 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 complete our development efforts, obtain regulatory approval for our drug candidate, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidate.

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. 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.

In May 2010 and in September 2010, we initiated two Phase 3 clinical trials for Zerenex (ferric citrate) as a treatment of hyperphosphatemia in patients with end-stage renal disease pursuant to a SPA 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 the FDA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint in a Phase 3 clinical trial is achieved, 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, 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 current Phase 3 program in the U.S., if successful, in conjunction with safety data generated from other clinical studies with Zerenex, is 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 if our current Phase 3 program in the U.S. is 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.

Additionally, we have never filed a NDA or similar application for approval in the U.S., or in any country, which may result in a delay in, or the rejection of, our filing of an NDA 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 filing, some questions may remain unanswered by the time we file our NDA, or may be difficult or impossible to answer to the satisfaction of the regulatory authorities. Unless the FDA, or similar regulatory authority in other countries, opts not to pursue these questions, submission of a NDA may be delayed or rejected.

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 will 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 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 has permitted us to continue with 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. Top-line results 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.

We may not be able to replicate in our Phase 3 clinical program for Zerenex, the efficacy and safety results for Zerenex observed in the previous Phase 3 and Phase 2 clinical trials and the Open-Label Extension, or OLE, clinical trial. The positive effects of Zerenex on intravenous iron and erythropoiesis-stimulating agent, or ESA, use observed in the OLE clinical trial may not be reproducible. Further, any negative effects of the potential absorption and/or accumulation of ferric iron or citrate could significantly limit the likelihood of obtaining regulatory approval for Zerenex.

Independent Data Safety Monitoring Boards, or DSMBs, are monitoring the safety of our Phase 3 clinical program for Zerenex (ferric citrate) and, in accordance with the protocol for the clinical trial, will periodically assess whether the Phase 3 trial should continue as planned. The DSMBs have the authority to recommend placing a trial on clinical hold, temporarily or permanently, or recommend termination of the clinical trial, based on an evaluation of safety and efficacy. The DSMBs are independent from us and we have no control or influence on their decisions. Although all previous meetings of the DSMBs have resulted in recommendations that we continue our Zerenex Phase 3 program, we can provide no assurance that future meetings of our DSMBs will result in a positive outcome.

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. If we experience delays in the testing or approval process 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 and/or auditing could potentially invalidate the results.

Because all of our proprietary technologies are licensed to us by third parties, termination of these license agreements would prevent us from developing our drug candidate.

We do not own our drug candidate. We have licensed the rights, patent or otherwise, to our drug candidate from a third party. The license agreement 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, our licensor could terminate the agreement, and we would lose the rights to our drug candidate. 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.

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 and state 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, compliance with FDA and foreign regulations, 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 planned clinical trials and development timelines, and could affect our ability to complete our clinical trials on a cost-effective or timely basis, if at all.

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 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 active pharmaceutical ingredient and drug product testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to complete our Phase 3 clinical program and/or 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 or analytical method development, which could significantly 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 product may be difficult because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance 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, we currently rely on one supplier to source the ferric citrate active pharmaceutical ingredient. The loss of this source of supply 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.

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 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 FDA approval to market our drug product, if it fails to achieve market acceptance, we may never record meaningful revenues.

Even if our product 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 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;

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.

If our competitors develop and market products that are less expensive, more effective or safer than our drug product, 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. 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. in 2014), and generic formulations of Fosrenol®, may be launched, which could have a material effect on the pricing of phosphate binders.

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, PA-21, 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 PA-21 in dialysis patients. If approved by the FDA and/or EMA, PA-21 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 August 1, 2012, we had 24 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.

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, 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 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 on March 23, 2010. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court’s decision allows implementation of key provisions impacting drug and device manufacturers to go forward. This includes PPACA changes to the Medicare Part D Program (including closing the “donut hole”), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the Biologics Price Competition and Innovation Act and the Physician Payments Sunshine Act, both of which were enacted as part of the PPACA. Regulations to implement PPACA could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our product.

For example, in July 2010, CMS released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare Improvements for Patients and Providers Act, or

MIPPA. The final rule delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014. If phosphate binders are included in the bundle beginning in 2014, 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.

Finally, 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.

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.

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 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 24 full and part-time employees as of August 1, 2012. 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, cash equivalents and investment securities as of June 30, 2012 are sufficient to fund our anticipated operating cash requirements for approximately 15 to 18 months from June 30, 2012. 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, design and conduct of, and results from, clinical trials for our drug candidate;

the timing of expenses associated with manufacturing and product development of the proprietary drug candidate within our portfolio and those that may be in-licensed, partnered or acquired;

the timing of the in-licensing, partnering and acquisition of new product opportunities;

the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;

our ability to achieve our milestones under our licensing arrangement; and

the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

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 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. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

We rely on trade secrets 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, 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 product 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:

Our composition of matter patent covering Zerenex expires in the second half of 2017 and we cannot assure you that we can obtain an extension to 2022 (the maximum term of extension under the patent term restoration program). 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. Upon expiration of our composition of matter patent for Zerenex, 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 method of use patents.

Our method of use patents only protect the product when used or sold for the specified method. However, this type of patent does 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 method, or for which there is a substantial use in commerce outside our patented method.

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 the Phase 3 clinical program for Zerenex is ongoing, and 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 extensions are obtained.

Proof of direct infringement by a competitor for method of use patents can prove difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, proof that a competitor contributes to or induces infringement of a patented method of use by another can also prove difficult because an off-label use of a product could prohibit a finding of contributory infringement and inducement of infringement requires proof of intent by the competitor.

Moreover, physicians may prescribe such 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, the limited 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 or other provisions of the FDCA 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.

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 our drug product or 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 our drug product or technologies could subject us to monetary liability and require our licensor or us to obtain a license to continue to use our drug product or 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.

We currently have two shelf registration statements on Form S-3, filed and declared effective by the SEC, providing for the offering of up to approximately $79 million of common stock and warrants in the aggregate.

On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607), which the SEC declared effective on September 23, 2009, providing for the offering of up to $40 million of our common stock and warrants to purchase our common stock. There remains approximately $12 million of our common stock and warrants available for sale under this shelf registration statement. This registration statement will expire on September 23, 2012.

On January 3, 2011, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-171517), which the SEC declared effective on January 28, 2011, providing for the offering of up to $100 million of our common stock and warrants to purchase our common stock. There remains approximately $67 million of our common stock and warrants available for sale under this shelf registration statement.

Future sales pursuant to these registration statements could depress the market for our common stock.

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

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

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

developments concerning our drug candidate, including the safety and efficacy results from clinical trials, such as the results from the Phase 3 long-term study for Zerenex;

announcements of technological innovations by us or our competitors;

introductions or announcements of new products by us or our competitors;

announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

changes in financial estimates by securities analysts;

actual or anticipated variations in quarterly operating results;

expiration or termination of licenses, research contracts or other collaboration agreements, including the recent termination of the license for KRX-0401;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

changes in the market valuations of similar companies;

negative comments and sentiment in the media; and

additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. 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 August 8, 2012.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2012.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2012.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2012.

SIGNATURES

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

KERYX BIOPHARMACEUTICALS, INC.

Date: August 8, 2012 By: /s/ James F. Oliviero, CFA
Chief Financial Officer
Principal Financial and Accounting Officer

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 August 8, 2012.
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