KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 08, 2011

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2011

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 69,703,587 shares of the registrant's common stock, $0.001 par value, outstanding as of August 1, 2011.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2011

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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 KRX-0401 (perifosine) and ZerenexTM (ferric citrate) or any other products we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- 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.

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.
Consolidated Balance Sheets as of June 30, 2011 and December 31, 2010

(in thousands, except share and per share amounts)

	June 30, 2011 (Unaudited)	December 31, 2010
Assets		
Current assets:		
Cash and cash equivalents	$ 43,209	$ 28,412
Short-term investment securities	9,316	100
Interest receivable	7	—
Other current assets	368	200
Total current assets	52,900	28,712
Property, plant and equipment, net	70	57
Goodwill	3,208	3,208
Other assets, net	209	137
Total assets	$ 56,387	$ 32,114
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 6,239	$ 5,367
Accrued compensation and related liabilities	353	669
Deferred revenue	156	156
Total current liabilities	6,748	6,192
Contingent equity rights	2,639	2,639
Other liabilities	12	35
Total liabilities	9,399	8,866
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, 69,771,035 and 61,521,483 shares issued, 69,691,087 and 61,441,535 shares outstanding at June 30, 2011 and December 31, 2010, respectively)	70	62
Additional paid-in capital	398,540	365,307
Treasury stock, at cost, 79,948 shares at June 30, 2011 and December 31, 2010, respectively	(357)	(357)
Accumulated deficit	(351,265)	(341,764)
Total stockholders' equity	46,988	23,248
Total liabilities and stockholders' equity	$ 56,387	$ 32,114

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

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Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Operations
for the three months and six months ended June 30, 2011 and 2010 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
License revenue	$5,000	$—	$5,000	$—
Operating expenses:				
Research and development:				
Non-cash compensation	205	434	464	676
Other research and development	6,295	3,129	10,913	5,683
Total research and development	6,500	3,563	11,377	6,359
General and administrative:				
Non-cash compensation	314	261	628	668
Other general and administrative	1,404	1,356	2,688	2,254
Total general and administrative	1,718	1,617	3,316	2,922
Total operating expenses	8,218	5,180	14,693	9,281
Operating loss	(3,218)	(5,180)	(9,693)	(9,281)
Interest and other income, net	122	26	192	112
Loss before income taxes	(3,096)	(5,154)	(9,501)	(9,169)
Income taxes	—	—	—	—
Net loss	$(3,096)	$(5,154)	$(9,501)	$(9,169)
Basic and diluted net loss per common share	$(0.05)	$(0.09)	$(0.15)	$(0.16)
Weighted average shares used in computing basic and diluted net loss per common share	66,286,615	58,426,995	63,931,209	57,658,247

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statement of Stockholders' Equity
for the six months ended June 30, 2011 (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, 2010	61,521,483	$62	$ 365,307	79,948	$(357)	$ (341,764)	$23,248
Changes during the period:							
Issuance of common stock in public offering (net of offering costs of $2,191)	7,021,277	7	30,802	—	—	—	30,809
Issuance of restricted stock	206,450	—*	—	—	—	—	—*
Forfeiture of restricted stock	(9,325)	(—)*	—	—	—	—	(—)*
Issuance of common stock in connection with the exercise of options	1,031,150	1	1,339	—	—	—	1,340
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	1,092	—	—	—	1,092
Net loss	—	—	—	—	—	(9,501)	(9,501)
Balance at June 30, 2011	69,771,035	$70	$ 398,540	79,948	$(357)	$ (351,265)	$46,988

* 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, 2011 and 2010 (Unaudited)

(in thousands)

	Six months ended June 30,	
	2011	2010
CASH FLOWS FROM OPERATING ACTIVITIES		
Net loss	$(9,501)	$(9,169)
Adjustments to reconcile net loss to cash flows used in operating activities:		
Stock compensation expense	1,092	1,344
Depreciation and amortization	21	33
Loss on sale of available-for-sale securities	—	82
Impairment of investment securities	—	32
Changes in assets and liabilities:		
(Increase) decrease in other current assets	(168)	297
(Increase) decrease in accrued interest receivable	(7)	65
Increase in security deposits	(51)	—
(Increase) decrease in other assets	(21)	2
Increase in accounts payable and accrued expenses	872	833
Decrease in accrued compensation and related liabilities	(316)	(492)
Decrease in other liabilities	(23)	(34)
Net cash used in operating activities	(8,102)	(7,007)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(34)	(6)
Investment in held-to-maturity short-term securities	(9,540)	(14,246)
Proceeds from maturity of held-to-maturity short-term securities	324	21,730
Proceeds from sale of available-for-sale long-term securities	—	1,620
Net cash (used in) provided by investing activities	(9,250)	9,098
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from public offering, net	30,809	—
Proceeds from exercise of warrants from public offering, net	—	1,618
Proceeds from exercise of options	1,340	1,543
Net cash provided by financing activities	32,149	3,161
NET INCREASE IN CASH AND CASH EQUIVALENTS	14,797	5,252
Cash and cash equivalents at beginning of period	28,412	16,386
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$43,209	$21,638

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

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Keryx Biopharmaceuticals, Inc.
Notes to Consolidated Financial Statements (unaudited)

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

NOTE 1 - GENERAL

Basis of Presentation

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of cancer and renal disease. Most of our biopharmaceutical development and substantially all of our administrative operations during the three and six months ended June 30, 2011 and 2010 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, 2010. The results of operations for the three and six months ended June 30, 2011, are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

Except for in 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, 2011, we have an accumulated deficit of $351.3 million.

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 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 of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, 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 candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates, if approved.

We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2011 are sufficient to fund our anticipated operating cash requirements for approximately 24 months from June 30, 2011. 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 candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

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

Recently Issued Accounting Standards

In June 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-05, "Comprehensive Income (Topic 220)." This newly issued accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders' equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this ASU do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This ASU is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011, which for us means January 1, 2012. As this accounting standard only requires enhanced disclosure, the adoption of this standard will not impact our financial position or results of operations.

Cash and Cash Equivalents

We treat liquid investments with original maturities of less than three months 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, 2011, and December 31, 2010:

(in thousands)	June 30, 2011	December 31, 2010
Short-term investments:		
Obligations of domestic governmental agencies (mature between December 2011 and April 2012) (held-to-maturity)	$ 9,116	$ -
Bank deposit (matures August 2011) (held-to-maturity)	200	100
Total short-term investment securities	$ 9,316	$ 100

Revenue Recognition

We recognize license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification, or 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, 2011, we have U.S. net operating loss carryforwards of approximately $310.0 million which expire from 2019 through 2031. 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, 2011 and 2010, which are not included in the computation of net loss per share amounts, were 7,188,628 and 10,026,616, respectively.

Comprehensive Loss

Comprehensive loss is composed of net loss and other comprehensive loss. Other comprehensive loss for the six months ended June 30, 2010, is comprised of a reduction of unrealized gains on our available-for-sale long-term investment securities that are excluded from net loss and reported separately in stockholders' equity. Comprehensive loss and its components are as follows:

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2011	2010	2011	2010
Net loss – as reported	$(3,096)	$(5,154)	$(9,501)	$(9,169)
Other comprehensive loss:				
Reduction of unrealized gain on available-for-sale long-term investment securities	—	—	—	(180)
Comprehensive loss	$(3,096)	$(5,154)	$(9,501)	$(9,349)

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.

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.

In May 2010, we sold our one remaining auction rate security investment for $1.6 million, representing a loss of $82,000. Auction rate securities were recorded at their fair value and classified as long-term investments. In prior quarters, we assessed the fair value of our auction rate securities portfolio. As a result of this valuation process, as described below, we reported an other comprehensive loss of $180,000 in the six months ended June 30, 2010, for a reduction of a temporary unrealized gain related to the estimated fair value of our last auction rate security, and reported an other-than-temporary impairment charge and a realized loss in interest and other income, net, as per the following table.

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2011	2010	2011	2010
Impairment of investment security	$—	$—	$—	$32
Net realized loss	—	82	—	82
	$—	$82	$—	$114

The valuation methods used to estimate the auction rate securities' fair value were (1) a discounted cash flow model, where the expected cash flows of the auction rate securities are discounted to the present using a yield that incorporates compensation for illiquidity, and (2) a market comparables method, where the auction rate securities are valued based on indications, from the secondary market, of what discounts buyers demand when purchasing similar auction rate securities. The valuation also included assessments of the underlying structure of each security, expected cash flows, discount rates, credit ratings, workout periods, and overall capital market liquidity. These assumptions, assessments and the interpretations of relevant market data are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value of our past investments in auction rate securities. In addition, the estimated fair value of the auction rate securities may differ from the values that would have been used had a ready market existed, and the differences could be material to our consolidated financial statements.

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. We believe that the impairment charges related to our auction rate securities investments were other-than-temporary. The primary factors we considered in classifying impairments related to these securities included the extent and time the fair value of each investment had been below cost and our ability to hold such investment to maturity.

The following table provides the fair value measurements of applicable financial assets as of June 30, 2011:

	Financial assets at fair value as of June 30, 2011		
(in thousands)	Level 1	Level 2	Level 3
Money market funds (1)	$ 24,701	$ —	$ —
Obligations of domestic governmental agencies (held-to-maturity) (2)	9,116	—	—
Bank deposits (held-to-maturity)	200	—	—
Total	$ 34,017	$ —	$ —

(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

On May 4, 2011, we announced the pricing of an underwritten registered offering of 7,021,277 shares of our common stock at a price of $4.70 per share for gross proceeds of approximately $33 million. Net proceeds from this offering were approximately $30.8 million, net of underwriting discounts and offering expenses of approximately $2.2 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-171517) that was previously filed and declared effective by the SEC on January 28, 2011.

We currently have two shelf registration statements on Form S-3, filed and declared effective by the SEC. Subsequent to the May 2011 offering, these shelf registration statements provide for the offering of up to approximately $79 million of common stock and warrants. 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 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 1,011,681 shares at June 30, 2011.

Stock Options

The following table summarizes stock option activity for the six months ended June 30, 2011:

	Number of shares	Weighted-average exercise price	Weighted-average contractual term (in years)	Aggregate intrinsic value
Outstanding at December 31, 2010	7,638,403	$ 7.05	3.2	$12,422,037
Granted	682,350	4.55	4.0	
Exercised	(1,031,150)	1.30		$3,945,193
Forfeited	(82,975)	4.24		
Expired	(18,000)	7.87		
Outstanding at June 30, 2011	7,188,628	$ 7.66	3.7	$9,590,201
Vested and expected to vest at June 30, 2011	7,141,790	$ 7.69	3.7	$9,529,158
Exercisable at June 30, 2011	5,737,741	$ 8.40	2.5	$7,768,012

Upon the exercise of stock options, we issue new shares of our common stock. As of June 30, 2011, 235,000 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, 2011:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2010	1,400,694	$ 1.63	$ 6,415,179
Granted	206,450	4.49	
Vested	(865,434)	1.14	$ 4,284,246
Forfeited	(9,325)	4.58	
Outstanding at June 30, 2011	732,385	$ 2.98	$ 3,464,181

On September 14, 2009, we entered in an employment agreement with Ron Bentsur, our Chief Executive Officer. The agreement terminates on May 20, 2012, provided, however, that Mr. Bentsur's opportunity to earn the milestone awards described below will be effective until May 20, 2014, subject to certain early termination events. As of June 30, 2011, 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, 2011, 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 for Zerenex or Perifosine, or (b) our outlicensing of Zerenex or Perifosine 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 or Perifosine in the U.S. off an approved NDA, (b) our receipt of the first royalty upon the commercial sale of Zerenex or Perifosine 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 or Perifosine 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 $519,000 and $695,000 of non-cash compensation expense related to equity incentive grants during the three months ended June 30, 2011 and 2010, respectively, and $1,092,000 and $1,344,000 during the six months ended June 30, 2011 and 2010, respectively. The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of our common stock. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. We have assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be paid for the foreseeable future.

Black-Scholes Option Valuation Assumptions	Three months ended June 30,		Six months ended June 30,	
	2011	2010	2011	2010
Risk-free interest rates	1.1 %	1.8 %	1.4 %	1.9 %
Dividend yield	—	—	—	—
Volatility	113.2 %	126.5 %	115.1 %	127.9 %
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, 2011 and 2010 was $3.28 and $3.39 per option, respectively, and for the six months ended June 30, 2011 and 2010 was $3.45 and $2.72 per option. We used historical information to estimate forfeitures within the valuation model. As of June 30, 2011,

there was $2.6 million and $1.9 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 2.4 years and 2.1 years, respectively. These amounts do not include, as of June 30, 2011, 285,000 options outstanding which are milestone-based and vest upon certain corporate milestones, such as FDA approval of our drug candidates, market capitalization targets, 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, our Japanese partner for Zerenex (ferric citrate), 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.

NOTE 5 – SEGMENT INFORMATION

We have two reportable segments: Services and Products. The Services business provides clinical trial management and site recruitment services to other biotechnology and pharmaceutical companies. The Products business focuses on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of cancer and renal disease, and also includes license revenue, other revenue and associated costs.

Segment information for the three and six month periods were as follows:

	Revenue			
	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2011	2010	2011	2010
Services	$ —	$ —	$ —	$ —
Products	5,000	—	5,000	—
Total	$ 5,000	$ —	$ 5,000	$ —

	Operating loss			
	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2011	2010	2011	2010
Services	$ —	$ —	$ —	$ —
Products	(3,218)	(5,180)	(9,693)	(9,281)
Total	$ (3,218)	$ (5,180)	$ (9,693)	$ (9,281)

A reconciliation of the totals reported for the operating segments to the consolidated loss is as follows:

	Net loss			
	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2011	2010	2011	2010
Operating loss of reportable segments	$ (3,218)	$ (5,180)	$ (9,693)	$ (9,281)
Interest and other income, net	122	26	192	112
Income taxes	—	—	—	—
Consolidated loss	$ (3,096)	$ (5,154)	$ (9,501)	$ (9,169)

	Assets (1)	
(in thousands)	June 30, 2011	December 31, 2010
Services	$ —	$ —
Products	3,855	3,602

Total assets of reportable segments	3,855	3,602
Cash, cash equivalents, interest receivable and investment securities	52,532	28,512
Consolidated total assets	$ 56,387	$ 32,114

(1) Assets for our reportable segments include fixed assets, goodwill, accounts receivable and prepaid expenses.

The carrying amount of goodwill by reportable segment as of June 30, 2011 and December 31, 2010 was as follows:

(in thousands)	Goodwill June 30, 2011	December 31, 2010
Services	$ —	$ —
Products	3,208	3,208
Total	$ 3,208	$ 3,208

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 Kery 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, 2010.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of cancer and renal disease. We are developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase, or PI3K, pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, all of which are pathways associated with programmed cell death, growth, differentiation and survival. KRX-0401 is currently in Phase 3 clinical development for both refractory advanced colorectal cancer and multiple myeloma, and in Phase 1 and Phase 2 clinical development for several other tumor types. Each of the KRX-0401 Phase 3 programs is being conducted under Special Protocol Assessment, or SPA, agreements with the Food and Drug Administration, or FDA, and with Fast-Track Designation.

We are also 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 an SPA, as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, on dialysis. In April 2011, our Japanese partner for Zerenex (ferric citrate), JT and Torii, commenced its Phase 3 clinical program for 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 from JT and Torii for the achievement of the Phase 3 commencement milestone.

We also actively engage in business development activities that include seeking strategic relationships for our product candidates, as well as evaluating compounds and companies for in-licensing or acquisition. To date, we have not

received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates. We have generated, and expect to continue to generate, revenue from the licensing of rights to Zerenex in Japan to JT and Torii.

The table below summarizes the status of our product pipeline.

Product candidate	Target indication	Development status
KRX-0401 (perifosine)	Colorectal cancer	Phase 3 trial ongoing, under SPA
	Multiple myeloma	Phase 3 trial ongoing, under SPA
	Several other forms of cancer	Phase 1 & 2 trials ongoing
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	U.S. Phase 3 program ongoing, under SPA
		Japan Phase 3 program ongoing by sublicensee (JT and Torii)

RECENT DEVELOPMENTS

KRX-0401 (perifosine)

On July 27, 2011, we announced the completion of patient enrollment in our Phase 3 registration trial of KRX-0401 (perifosine) for the treatment of refractory, advanced colorectal cancer. This Phase 3 trial, with over 430 randomized patients, is being conducted pursuant to an SPA with the FDA and with Fast-Track Designation. The Phase 3 trial, entitled the "X-PECT" (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) trial, is a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine + capecitabine vs. placebo + capecitabine in over 430 patients with refractory advanced colorectal cancer. Patients must have failed available therapy including 5-fluorouracil (5-FU), oxaliplatin (Eloxatin®), irinotecan, bevacizumab (Avastin®) and, if KRAS wild-type, failed therapy with prior cetuximab (Erbitux®) and/or panitumumab (Vectibix®). The primary endpoint is overall survival, with secondary endpoints including overall response rate (complete + partial responses), progression-free survival and safety. Approximately 360 events of death will trigger the un-blinding of the study.

Zerenex (ferric citrate)

On April 28, 2011, we reported the final dataset from the Phase 3 short-term clinical trial of Zerenex for the treatment of hyperphosphatemia in end-stage renal disease patients on dialysis. Top-line results from this Phase 3 short-term study were announced in November 2010. The final dataset was presented at the National Kidney Foundation Spring Clinical Meetings held in Las Vegas, Nevada, in an oral presentation. In this study, conducted pursuant to a SPA with the FDA, Zerenex met the study’s primary endpoint, described below, demonstrating a highly statistically significant dose response. In addition, key secondary endpoints were also met.

The Phase 3 short-term study was a multicenter, randomized, open-label trial with a two-week washout period, following which patients were randomized 1:1:1 to receive a fixed dose of Zerenex of either 1 gram, 6 grams or 8 grams per day for a treatment period of 28 days. Zerenex was administered using a 1 gram oral caplet formulation, and the fixed-dose arms of 1 gram, 6 grams and 8 grams per day represented 1, 6 and 8 pills per day, respectively. One hundred fifty-one dialysis patients were enrolled into the study. The Intent-to-Treat, or ITT, group included 146 patients, representing all patients who took at least one dose of Zerenex and provided a Baseline (at the end of washout) and at least one post-Baseline efficacy assessment. Efficacy assessments were taken weekly starting at Baseline and subsequently at days 7, 14, 21 and 28. The primary endpoint of the study was to determine whether there was a dose response in the change in serum phosphorus from Baseline to Day 28 in the ITT group, using a regression analysis to evaluate this objective.

The study met the primary endpoint, with the regression analysis indicating a highly statistically significant dose response ($p<0.0001$). Additional efficacy results are as follows:

Mean Serum Phosphorus (mg/dL)	1g/Day		6g/Day		8g/Day	
ITT (n=146)	(n=50)		(n=51)		(n=45)	
Baseline (End of Washout)	7.3		7.6		7.5	
Day 28 (End of Treatment)	7.4		5.6		5.3	
Change from Baseline at Day 28	0.1		-2.0		-2.2	
P-Value			<0.0001		<0.0001	
% Change from Baseline at Day 28	0.5	%	-25.7	%	-29.6	%

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In addition, a statistically significant dose response increase in serum bicarbonate was observed in the study, indicating the potential ability of Zerenex to address metabolic acidosis. Metabolic acidosis is a condition that occurs in many dialysis patients when the kidneys do not remove sufficient acid from the body, leading to low blood pH. The consequences of metabolic acidosis can be severe. The inability to manage metabolic acidosis is believed to be a drawback for some of the currently marketed phosphate binders.

Importantly, no clinically meaningful change in serum calcium was observed in the study. Additionally, a statistically significant dose response reduction in calcium-phosphorus product was also observed in the study. Elevated levels of serum calcium (hypercalcemia) and high levels of calcium-phosphorus product, both of which are believed to be drawbacks from the use of some of the currently marketed phosphate binders, increase the risk of soft tissue calcification and may contribute to the substantial morbidity and mortality seen in patients with ESRD.

Certain iron parameters, including ferritin and TSAT, were measured in the study. Modest upward trends in ferritin and TSAT levels were observed in the 6 grams/day and 8 grams/day dose groups, which further support our belief that Zerenex may have the potential to reduce the need for intravenous, or IV, iron supplements and/or erythropoiesis-stimulating agents, or ESAs, in dialysis patients. IV iron and ESA use is under evaluation in the ongoing Phase 3 long-term study.

Zerenex appeared to be safe and well-tolerated in the study, with no serious adverse events deemed to be drug-related by the Data Safety Monitoring Committee, which further supports Zerenex’s favorable safety profile seen in prior clinical trials.

On May 2, 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 we will not need to conduct any additional clinical trials with 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.

GENERAL CORPORATE

On May 4, 2011, we announced the pricing of an underwritten registered offering of 7,021,277 shares of our common stock at a price of $4.70 per share for gross proceeds of approximately $33 million. Net proceeds from this offering were approximately $30.8 million, net of underwriting discounts and offering expenses of approximately $2.2 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-171517) that was previously filed and declared effective by the SEC on January 28, 2011.

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 of our drug candidates.

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 will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain diseases or conditions, there is no guarantee that we will be able to record commercial sales of any of our drug candidates 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 candidates following approval, if any, by the FDA or regulatory authorities of other countries, which would result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

RESULTS OF OPERATIONS

Three months ended June 30, 2011 and June 30, 2010

License Revenue. License revenue for the three months ended June 30, 2011 was $5.0 million due to the receipt and recognition of a non-refundable milestone payment in April 2011 from JT and Torii for the achievement of the Phase 3 commencement in Japan milestone. There was no license revenue for the three months ended June 30, 2010. We do not expect our license revenue to have a material impact on our financial results for the remainder of 2011.

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Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants decreased by $229,000 to $205,000 for the three months ended June 30, 2011, as compared to $434,000 for the three months ended June 30, 2010. The decrease in non-cash compensation expense in the three months ended June 30, 2011, as compared to June 30, 2010, was primarily related to recording the fair value of equity awards granted to research and development personnel over the respective vesting periods of the individual awards.

Other Research and Development Expenses. Other research and development expenses increased by $3,166,000 to $6,295,000 for the three months ended June 30, 2011, as compared to $3,129,000 for the three months ended June 30, 2010. The increase in other research and development expenses was due primarily to a $1,528,000 increase in research and development expenses related to the two KRX-0401 Phase 3 clinical trials, as well as to a $1,686,000 increase in research and development expenses related to the Zerenex Phase 3 clinical program. We expect our other research and development costs to increase for the remainder of 2011 due to increased patient recruitment into our ongoing Phase 3 clinical programs for KRX-0401 and Zerenex.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense (general and administrative) related to equity incentive grants increased by $53,000 to $314,000 for the three months ended June 30, 2011, as compared to $261,000 for the three months ended June 30, 2010. The increase in non-cash compensation expense in the three months ended June 30, 2011, as compared to June 30, 2010, was primarily related to grants of equity awards to general and administrative personnel and directors and recording the related fair value of the awards over the respective vesting periods of the individual awards.

Other General and Administrative Expenses. Other general and administrative expenses increased by $48,000 to $1,404,000 for the three months ended June 30, 2011, as compared to $1,356,000 for the three months ended June 30, 2010. The increase was due primarily to miscellaneous general and administrative expenses. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2011.

Interest and Other Income, Net. Interest and other income, net, increased by $96,000 to $122,000 for the three months ended June 30, 2011, as compared to $26,000 for the three months ended June 30, 2010. The increase was due primarily to the realized loss of $82,000 during the three months ended June 30, 2010 related to the sale in May 2010 of our last auction rate security investment.

Six months ended June 30, 2011 and June 30, 2010

License Revenue. License revenue for the six months ended June 30, 2011 was $5.0 million due to the receipt and recognition of a non-refundable milestone payment in April 2011 from JT and Torii for the achievement of the Phase 3 commencement in Japan milestone. There was no license revenue for the six months ended June 30, 2010. We do not expect our license revenue to have a material impact on our financial results for the remainder of 2011.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants decreased by $212,000 to $464,000 for the six months ended June 30, 2011, as compared to $676,000 for the six months ended June 30, 2010. The decrease in non-cash compensation expense in the six months ended June 30, 2011, as compared to June 30, 2010, was primarily related to recording the fair value of equity awards granted to research and development personnel over the respective vesting periods of the individual awards.

Other Research and Development Expenses. Other research and development expenses increased by $5,230,000 to $10,913,000 for the six months ended June 30, 2011, as compared to $5,683,000 for the six months ended June 30, 2010. The increase in other research and development expenses was due primarily to a $2,652,000 increase in research

and development expenses related to the two KRX-0401 Phase 3 clinical trials, as well as to a $2,601,000 increase in research and development expenses related to the Zerenex Phase 3 clinical program. We expect our other research and development costs to increase for the remainder of 2011 due to increased patient recruitment into our ongoing Phase 3 clinical programs for KRX-0401 and Zerenex.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense (general and administrative) related to equity incentive grants decreased by $40,000 to $628,000 for the six months ended June 30, 2011, as compared to $668,000 for the six months ended June 30, 2010. The decrease in non-cash compensation expense in the six months ended June 30, 2011, as compared to June 30, 2010, was primarily related to grants of equity awards to general and administrative personnel and directors and recording the related fair value of the awards over the respective vesting periods of the individual awards.

Other General and Administrative Expenses. Other general and administrative expenses increased by $434,000 to $2,688,000 for the six months ended June 30, 2011, as compared to $2,254,000 for the six months ended June 30, 2010. The increase was due primarily to miscellaneous general and administrative expenses, including patent filing and maintenance costs. We expect our other general and administrative expenses to remain at a comparable level for the remainder of 2011.

Interest and Other Income, Net. Interest and other income, net, increased by $80,000 to $192,000 for the six months ended June 30, 2011, as compared to $112,000 for the six months ended June 30, 2010. The increase was due primarily to the realized loss of $82,000 during the six months ended June 30, 2010 related to the sale in May 2010 of our last auction rate security investment.

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 any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, 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 candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

In April 2011, we received a non-refundable milestone payment of $5.0 million from JT and Torii.

On May 4, 2011, we announced the pricing of an underwritten registered offering of 7,021,277 shares of our common stock at a price of $4.70 per share for gross proceeds of approximately $33 million. Net proceeds from this offering were approximately $30.8 million, net of underwriting discounts and offering expenses of approximately $2.2 million.

As of June 30, 2011, we had $52.5 million in cash, cash equivalents, interest receivable, and investment securities, an increase of $24.0 million from December 31, 2010. We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2011 are sufficient to fund our anticipated operating cash requirements for approximately 24 months from June 30, 2011. 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 candidates. We are dependent upon significant financing to provide the cash necessary to execute our current operations, including the commercialization of any of our drug candidates.

Subsequent to the May 2011 offering, 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.

- On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607) and declared effective by the SEC on September 23, 2009. The registration statement provided for the offering of up to $40 million of our common stock and warrants. Subsequent to the registered direct offering completed on September 30, 2009, there remains approximately $12 million of our common stock and warrants available for sale under the shelf registration statement.

- On January 3, 2011, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-171517) that was declared effective by the SEC on January 28, 2011, providing for the offering of up to $100 million of our

common stock and warrants to purchase our common stock. Subsequent to the registered offering in May 2011, there remains approximately $67 million of our common stock and warrants available for sale under the 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 raise additional capital to finance our operations as needed.

Cash used in operating activities for the six months ended June 30, 2011 was $8.1 million, as compared to $7.0 million for the six months ended June 30, 2010. This increase in cash used in operating activities was due primarily to increased expenditures associated with our Phase 3 clinical programs for KRX-0401 and Zerenex, offset by the $5.0 million non-refundable milestone payment received from JT and Torii in April 2011.

For the six months ended June 30, 2011, net cash used in investing activities of $9.3 million was primarily the result of the investments in held-to-maturity short-term securities, partially offset by maturities of held-to-maturity short-term securities. For the six months ended June 30, 2011, net cash provided by financing activities of $32.1 million was related to net proceeds of $30.8 million received from the underwritten registered offering in May 2011 and $1.3 million in net proceeds from the exercise of stock options.

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.

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 service revenues as the services are provided. Deferred revenue is recorded when we receive a deposit or prepayment for services to be performed at a later date.

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

Accounting Related to Goodwill. As of June 30, 2011, 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.

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Impairment of Investment Securities. In May 2010, we sold our one remaining auction rate security investment for $1.6 million, representing a loss of $82,000. Auction rate securities were recorded at their fair value and were classified as long-term investments. In prior quarters, we assessed the fair value of our auction rate securities portfolio. As a result of this valuation process, as described below, we reported an other comprehensive loss of $180,000 in the six months ended June 30, 2010, for a reduction of a temporary unrealized gain related to the estimated fair value of our last auction rate security, and recorded an impairment charge of $32,000 in the six months ended June 30, 2010, for an other-than-temporary decline in the value of our last auction rate security, which was included in interest and other income, net.

The valuation methods used to estimate the auction rate securities' fair value were (1) a discounted cash flow model, where the expected cash flows of the auction rate securities are discounted to the present using a yield that incorporates compensation for illiquidity, and (2) a market comparables method, where the auction rate securities are valued based on indications, from the secondary market, of what discounts buyers demand when purchasing similar auction rate securities. The valuation also included assessments of the underlying structure of each security, expected cash flows, discount rates, credit ratings, workout periods, and overall capital market liquidity. These assumptions, assessments and the interpretations of relevant market data are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value of our prior investments in auction rate securities. In addition, the estimated fair value of the auction rates securities may differ from the values that would have been used had a ready market existed, and the differences could be material to the consolidated financial statements.

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 primary factors we consider in classifying an impairment include the extent and time the fair value of each investment has been below cost and our ability to hold such investment to maturity.

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.

RECENTLY ISSUED ACCOUNTING STANDARDS

In June 2011, the FASB issued ASU No. 2011-05, “Comprehensive Income (Topic 220).” This newly issued accounting standard (1) eliminates the option to present the components of other comprehensive income as part of the statement of changes in stockholders’ equity; (2) requires the consecutive presentation of the statement of net income and other comprehensive income; and (3) requires an entity to present reclassification adjustments on the face of the financial statements from other comprehensive income to net income. The amendments in this ASU do not change the items that must be reported in other comprehensive income or when an item of other comprehensive income must be reclassified to net income nor do the amendments affect how earnings per share is calculated or presented. This ASU is required to be applied retrospectively and is effective for fiscal years and interim periods within those years beginning after December 15, 2011, which for us means January 1, 2012. As this accounting standard only requires enhanced disclosure, the adoption of this standard will not impact our financial position or results of operations.

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 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, 2011, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including money market funds and bank deposits. 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, 2011, 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, 2011, 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, 2011, 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, other than as noted below.

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. In this arbitration proceeding, we seek damages arising from that broker-dealer’s recommendations and purchases of auction rate securities for our cash management account. The claim will be determined by a panel of three FINRA arbitrators. In January 2010, the broker-dealer filed an answer to the statement of claim and denied liability. The arbitration panel has been selected and the parties are in the process of exchanging documents relevant to the claims. A hearing has been scheduled for October 2011 concerning our claims against the broker-dealer.

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.

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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, 2011, we had an accumulated deficit of $351.3 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 candidates.

We have not yet commercialized any of our drug candidates and cannot be sure that we will ever be able to do so. Even if we commercialize one or more of our drug candidates, 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 candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates.

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 diseases that we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates. They may also incur additional costs if enrollment is increased in order to achieve the desired number of events. 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. We are 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. For example, we have limited clinical experience with our new one gram caplet formulation for Zerenex, and therefore, there is no assurance that this new formulation will be safe and efficacious when assessed in a large and/or long-term clinical trial setting. We used this one gram caplet formulation in our completed Phase 3 short-term study for Zerenex and are currently using it in our ongoing Phase 3 long-term study for Zerenex. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

In December 2009, we initiated a Phase 3 clinical trial for KRX-0401 (perifosine) in relapsed / refractory multiple myeloma patients pursuant to a SPA with the FDA. In April 2010, we initiated a Phase 3 clinical trial for KRX-0401 (perifosine) in patients with refractory advanced colorectal cancer also pursuant to a SPA with the FDA. 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 approvals under SPAs, 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. Even though our product candidate, KRX-0401, is designated for “fast track” in the indications of metastatic colorectal cancer and relapsed/refractory multiple myeloma, we cannot assure you that we will receive “priority review” status. Even with “fast track” or “priority review” status, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures.

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 we will not need to conduct any additional clinical trials with 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 candidates do not receive the necessary regulatory approvals, we will be unable to commercialize our drug candidates.

We have not received, and may never receive, regulatory approval for the commercial sale of any of our drug candidates. 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 clinical substantiation. It may take us many years to complete the testing of our drug candidates 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 initial 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 candidates 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 candidates. Top-line results are based on a preliminary analysis of then available data (both safety and efficacy) and there is the risk that 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 would significantly limit the likelihood of obtaining regulatory approval for Zerenex. In addition, we may not be able to replicate in the Phase 3 trials for KRX-0401, the efficacy and safety results for KRX-0401 observed in previous clinical trials. In addition, we will need to re-input our safety information on KRX-0401 into a database compliant with Good Clinical Practice. We can provide no assurance that safety concerns will not subsequently arise.

Independent Data Safety Monitoring Committees, or DSMCs, are monitoring the safety of our Phase 3 clinical trials for KRX-0401 (perifosine) and Zerenex (ferric citrate) and, in accordance with the protocols for the clinical trials, will periodically assess whether the Phase 3 trials should continue as planned. The DSMCs 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 DSMCs are independent from us and we have no control or influence on their decisions. In accordance with the protocol, we expect the independent DSMC overseeing our Phase 3 trial in refractory advanced colorectal cancer to meet in the third quarter of 2011 to conduct an interim analysis of the clinical trial. We can provide no assurance that the DSMC will recommend that the clinical trial continue to completion.

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 candidates 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 candidates.

We do not own any of our drug candidates. We have licensed the rights, patent or otherwise, to our drugs candidates from third parties. These license agreements require us to meet development milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates. 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 drug candidates, 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 products. If these third parties do not successfully manufacture and test our products, 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 products 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 product candidates will depend on the ability of such third parties to manufacture our products 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. Prior to approval, we will need to conduct 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 any of our drug candidates. 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 a commercial batch manufacturer for 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 candidates. 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 may occur that change their regulatory standing. The same issues apply to contract analytical services which we use for testing of our products. 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 Phase 3 clinical trials and/or obtain FDA approval. Switching or engaging multiple third-party contractors to produce our products may be difficult because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance must be identical 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 change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve these 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 products on our own. From time to time, we may need to contract with third parties to:

- manufacture our product candidates;

assist us in developing, testing and obtaining regulatory approval for and commercializing some of our compounds and technologies; and

market and distribute our drug products.

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 products independently, which could result in delays. Furthermore, such failure could result in the termination of license rights to one or more of our products. 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 products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we are unable to control whether such products 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 one or more drug candidates.

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 some or all of our product candidates.

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 candidates.

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 products effectively.

In the event that one or more of our drug candidates are approved by the FDA, we currently plan to conduct our own sales and marketing effort to support the drugs. We currently have limited experience in sales, marketing or distribution. To directly market and distribute any products, we must build a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build 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 products. 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 products, 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.

Notwithstanding our current plans to commercialize our drug candidates, 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 products. Any accepted offer may preclude us from commercializing our products effectively.

Even if we obtain FDA approval to market our drug products, if they fail to achieve market acceptance, we may never record meaningful revenues.

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our drug products 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 candidates, 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 products by medical practitioners and the target populations for our products;

the potential advantages that our products offer over existing treatment methods;

the cost-effectiveness of our products relative to competing products;

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

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

the effectiveness of our sales, marketing and distribution efforts.

Because we expect sales of our products, if approved, to generate substantially all of our revenues in the long-term, the failure of our drugs 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 products, 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 products 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.

The drugs that we are attempting to develop will have to compete with existing therapies. For example, KRX-0401 (perifosine), if approved in the U.S. would compete with other anti-cancer agents, such as mTOR inhibitors. Pfizer Inc., Novartis AG and Ariad Pharmaceuticals are developing mTOR inhibitors for use in cancer and Pfizer's mTOR inhibitor, temsirolimus, and Novartis' mTOR inhibitor, everolimus, have been approved to treat patients with advanced kidney disease. Biotechnology companies such as Amgen Inc., Biogen-Idec, Inc., ImClone Systems, Inc. (a wholly-owned subsidiary of Eli Lilly and Company), Merck & Co., Inc., Millennium Pharmaceuticals, Inc. (a wholly-owned subsidiary of Takeda Pharmaceutical Company), Novartis AG, Onyx Pharmaceuticals, Inc. and OSI Pharmaceuticals, Inc. are developing and, in some cases, marketing drugs to treat various diseases, including cancer, by inhibiting cell-signaling pathways. In addition, we are aware of a number of small and large companies developing

competitive products that target Akt and the PI3K pathway. Zerenex, if approved in the U.S., would 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 (expected in the U.S. in 2014), generic formulations of Renagel® and Renvela® 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 products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

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

As of August 1, 2011, we had 28 full and part-time employees. To successfully develop our drug candidates, 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. Third-party insurance coverage may not be available to patients for our products. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, their 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. In the U.S., health care reform legislation titled the Patient Protection and Affordable Care Act and the Reconciliation Act was signed into law on March 23, 2010. This comprehensive legislation will affect the terms of public and private health insurance and have a substantial impact on the pharmaceutical industry. For example, the new law will impose an annual fee on manufacturers of branded prescription pharmaceuticals that will impact our products. Regulations to implement this and other provisions related to the research, marketing and sale of prescription pharmaceutical products 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 products.

For example, in July 2010, the Centers for Medicare & Medicaid Services, or 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 did not include oral medications without IV equivalents, such as phosphate binders, in the bundle until January 1, 2014. If phosphate binders are bundled into the composite rate beginning in 2014, separate Medicare reimbursement will no longer be available for phosphate binders. While it is too early to project the impact bundling may have on the phosphate binder industry, the impact could potentially cause dramatic price reductions for phosphate binders.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA restrictions on the sale or distribution of approved products.

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

The use of our drug candidates in clinical trials, and the future sale of any approved drug candidates and new technologies, 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 candidates or limit commercialization of any approved products.

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.

The 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 has not entered into a new third-party service contract since 2005 and does not plan to enter into any further service contracts. 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, sales, and reimbursement of our products, 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 28 full and part-time employees as of August 1, 2011. 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, restrictions on our products or manufacturing processes, withdrawal of products 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, 2011 are sufficient to fund our anticipated operating cash requirements for approximately 24 months from June 30, 2011. 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 candidates;
- the timing of expenses associated with manufacturing and product development of the proprietary drug candidates 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 arrangements; 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 products 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 products 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 some of our drug products 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 candidates is limited, which could adversely affect our ability to compete in the market and adversely affect the value of our product candidates.

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market these product candidates. In particular:

Our composition of matter patent covering KRX-0401 (perifosine) expires in the second half of 2013 and we cannot assure you that we can obtain an extension to the second half of 2018 (the maximum term of extension under the patent term restoration program). 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 important. Upon expiration of our composition of matter patents for KRX-0401 and Zerenex, competitors who obtain the requisite regulatory approval can offer products with the same composition as our products 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 products 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 products 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 products.

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 candidates 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 certain of our drug candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the U.S., or, diseases that affect more than 200,000 individuals in the U.S. but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. In September 2009, we announced that KRX-0401 (perifosine) has received Orphan-Drug designation from the FDA for the treatment of multiple myeloma, and in July 2010, we announced that KRX-0401 has received Orphan-Drug designation from the FDA for the treatment of neuroblastoma. We believe that KRX-0401 may be eligible for additional orphan-drug designations; however, we cannot assure you that KRX-0401, or any other drug candidates we may acquire or in-license, will obtain such orphan-drug designations. Additionally, upon FDA approval, we believe that perifosine would qualify as a New Chemical Entity, which provides for five years of exclusivity following approval, however; we cannot assure you that perifosine will qualify and gain the additional exclusivity period.

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 products.

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 products 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 licensors or us that seeks damages or an injunction of our commercial activities relating to our drug products or technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use our drug products or technologies. We cannot predict whether our licensors 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.

- On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607) and declared effective by the SEC on September 23, 2009. The registration statement provided for the offering of up to $40 million of our common stock and warrants. Subsequent to the registered direct offering completed on September 30, 2009, there remains approximately $12 million of our common stock and warrants available for sale under the shelf registration statement.

- On January 3, 2011, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-171517) that was declared effective by the SEC on January 28, 2011, providing for the offering of up to $100 million of our common stock and warrants to purchase our common stock. Subsequent to the registered offering in May 2011, there remains approximately $67 million of our common stock and warrants available for sale under the 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 stockholders would also experience dilution if we are required to issue up to 2,872,422 shares of our common stock to former stockholders of ACCESS Oncology, Inc. upon the achievement of certain development and sales milestones related to KRX-0401.

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 candidates, including safety and efficacy results from clinical trials;

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;

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

changes in the market valuations of similar companies; 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, 2011.
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, 2011.
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, 2011.
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, 2011.

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, 2011	By:	/s/ James F. Oliviero 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, 2011.
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