KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 09, 2010

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, 2010

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 ¨ No

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

Large accelerated filer £ Accelerated filer ¨

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

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 58,921,322 shares of the registrant's common stock, $0.001 par value, outstanding as of August 3, 2010.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2010

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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 clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of KRX-0401 (perifosine), ZerenexTM (ferric citrate), and our additional product candidates 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 business strategy, 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, 2010 and December 31, 2009

(in thousands, except share and per share amounts)

	June 30, 2010 (Unaudited)	December 31, 2009
Assets		
Current assets:		
Cash and cash equivalents	$ 21,638	$ 16,386
Short-term investment securities	10,064	17,548
Interest receivable	1	66
Other current assets	1,224	1,521
Total current assets	32,927	35,521
Long-term investment securities	—	1,914
Property, plant and equipment, net	67	94
Goodwill	3,208	3,208
Other assets, net	79	81
Total assets	$ 36,281	$ 40,818
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 5,834	$ 5,001
Accrued compensation and related liabilities	263	755
Deferred revenue	156	156
Liabilities of discontinued operations	120	120
Total current liabilities	6,373	6,032
Contingent equity rights	2,639	2,639
Other liabilities	16	50
Total liabilities	9,028	8,721
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, 58,996,270 and 56,560,478 shares issued, 58,916,322 and 56,480,530 shares outstanding at June 30, 2010 and December 31, 2009, respectively)	59	57
Additional paid-in capital	358,153	353,650
Treasury stock, at cost, 79,948 shares at June 30, 2010 and December 31, 2009, respectively	(357)	(357)
Accumulated other comprehensive income	—	180
Accumulated deficit	(330,602)	(321,433)
Total stockholders' equity	27,253	32,097
Total liabilities and stockholders' equity	$ 36,281	$ 40,818

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, 2010 and 2009 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Revenue:				
License revenue	$ —	$ 18,289	$ —	$ 21,616
Service revenue	—	—	—	3
Other revenue	—	75	—	75
Total revenue	—	18,364	—	21,694
Operating expenses:				
Research and development:				
Non-cash compensation	434	361	676	562
Other research and development	3,129	1,456	5,683	2,830
Total research and development	3,563	1,817	6,359	3,392
General and administrative:				
Non-cash compensation	261	1,028	668	1,398
Other general and administrative	1,356	1,528	2,254	2,569
Total general and administrative	1,617	2,556	2,922	3,967
Total operating expenses	5,180	4,373	9,281	7,359
Operating (loss) income	(5,180)	13,991	(9,281)	14,335
Interest and other income, net	26	141	112	248
(Loss) income before income taxes	(5,154)	14,132	(9,169)	14,583
Income taxes	—	—	—	—
Net (loss) income	$ (5,154)	$ 14,132	$ (9,169)	$ 14,583
Basic net (loss) income per common share	$ (0.09)	$ 0.30	$ (0.16)	$ 0.30
Diluted net (loss) income per common share	$ (0.09)	$ 0.29	$ (0.16)	$ 0.30
Weighted average shares used in computing basic net (loss) income per common share	58,426,995	47,855,425	57,658,247	47,854,664
Weighted average shares used in computing diluted net (loss) income per common share	58,426,995	48,189,552	57,658,247	48,149,600

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity
for the six months ended June 30, 2010 (Unaudited)

(in thousands, except share amounts)

	Common stock Shares	Amount	Additional paid-in Capital	Treasury stock Shares	Amount	Accumulated other comprehensive income	Accumulated deficit	Total
Balance at December 31, 2009	56,560,478	$ 57	$ 353,650	79,948	$ (357)	$ 180	$ (321,433)	$ 32,097
Changes during the period:								
Issuance of restricted stock	690,500	1	—	—	—	—	—	1
Forfeiture of restricted stock	(7,635)	(—)*	—	—	—	—	—	(—)*
Issuance of common stock in connection with the exercise of warrants from public offering (net of offering costs of $105)	650,000	—*	1,617	—	—	—	—	1,617
Issuance of common stock in connection with the exercise of options	1,102,927	1	1,542	—	—	—	—	1,543
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	1,344	—	—	—	—	1,344
Reduction of unrealized gain on long-term investment securities						(180)		(180)
Net loss	—	—	—	—	—	—	(9,169)	(9,169)
Balance at June 30, 2010	58,996,270	$ 59	$ 358,153	79,948	$ (357)	$ —	$ (330,602)	$ 27,253

* Amount less than one thousand dollars.

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

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Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows
for the six months ended June 30, 2010 and 2009 (Unaudited)

(in thousands)

	Six months ended June 30,	
	2010	2009
CASH FLOWS FROM OPERATING ACTIVITIES		
Net (loss) income	$ (9,169)	$ 14,583
Adjustments to reconcile net (loss) income to cash flows used in operating activities:		
Stock compensation expense	1,344	1,960
Depreciation and amortization	33	49
Loss on sale of available-for-sale securities	82	—
Impairment of investment securities	32	68
Changes in assets and liabilities:		
Decrease in other current assets	297	286
Decrease in accrued interest receivable	65	21
Decrease in other assets	2	22
Increase (decrease) in accounts payable and accrued expenses	833	(581)
(Decrease) increase in accrued compensation and related liabilities	(492)	218
Decrease in other liabilities	(34)	(34)
Decrease in deferred revenue	—	(18,616)
Net cash used in operating activities	(7,007)	(2,024)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(6)	(4)
Investment in held-to-maturity short-term securities	(14,246)	(1)
Proceeds from maturity of held-to-maturity short-term securities	21,730	2,300
Proceeds from sale of available-for-sale long-term securities	1,620	—
Net cash provided by investing activities	9,098	2,295
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of warrants from public offering, net	1,618	—
Proceeds from exercise of options	1,543	—
Net cash provided by financing activities	3,161	—
NET INCREASE IN CASH AND CASH EQUIVALENTS	5,252	271
Cash and cash equivalents at beginning of period	16,386	13,143
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 21,638	$ 13,414

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)

NOTE 1 - GENERAL

Basis of Presentation

Keryx Biopharmaceuticals, Inc. and subsidiaries ("Keryx" or the "Company") is a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. Most of the Company's biopharmaceutical development and substantially all of its administrative operations during the three and six months ended June 30, 2010 and 2009 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 Company's audited consolidated financial statements contained in its Annual Report on Form 10-K for the year ended December 31, 2009. The results of operations for the three and six months ended June 30, 2010, are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

The Company has incurred substantial operating losses since its inception, except for 2009, and expects to continue to incur operating losses for the foreseeable future and may never become profitable. As of June 30, 2010, the Company has an accumulated deficit of $330.6 million. The Company is dependent upon significant financing to provide the working capital necessary to execute its business plan. The Company currently anticipates that its cash, cash equivalents and investment securities as of June 30, 2010, exclusive of anticipated milestones to be received and expected exercises of expiring options and warrants, are sufficient to meet the Company's anticipated working capital needs and fund its business plan for approximately 16 to 18 months from June 30, 2010. The actual amount of funds that the Company will need to operate is subject to many factors, including, but not limited to, the timing, design and conduct of clinical trials for the Company's drug candidates. The Company has not yet commercialized any of its drug candidates and cannot be sure if it will ever be able to do so. Even if the Company commercializes one or more of its drug candidates, the Company may not become profitable. The Company's ability to achieve profitability depends on a number of factors, including its ability to obtain regulatory approval for its drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its drug candidates alone or in partnership. The Company may continue to incur substantial operating losses even if it begins to generate revenues from its drug candidates, if approved.

The Company's common stock is listed on the NASDAQ Capital Market and trades under the symbol "KERX."

Recently Issued Accounting Standards

In October 2009, the Financial Accounting Standards Board (the "FASB") issued Accounting Standards Update ("ASU") No. 2009-13, Multiple-Deliverable Revenue Arrangements. This ASU eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The ASU also eliminates the use of the residual method and instead requires an entity to allocate revenue using the relative selling price method. Additionally, the guidance expands disclosure

requirements with respect to multiple-deliverable revenue arrangements. This ASU is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the potential impact of this standard on its consolidated financial statements.

Effective during the quarter ended March 31, 2010, the FASB issued ASU No. 2010-09, Subsequent Events, amending Accounting Standards Codification 855, Subsequent Events, to state that an entity that is a SEC filer is required to evaluate subsequent events through the date that the financial statements are issued, but is not required to disclose the date. The amendment was effective commencing with the quarter ended March 31, 2010. The adoption of this standard did not have a significant impact on the Company’s financial statements.

Cash and Cash Equivalents

The Company treats liquid investments with original maturities of less than three months when purchased as cash and cash equivalents.

Investment Securities

The Company records its investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investment securities (which are comprised of auction rate 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, if determined to be temporary, are included in accumulated other comprehensive income in stockholders' equity.

The following table summarizes the Company's investment securities at June 30 2010, and December 31, 2009:

(in thousands)	June 30, 2010	December 31, 2009
Short-term investment securities:		
Obligations of domestic governmental agencies (mature December 2010) (held-to-maturity)	$ 5,016	$ 12,532
Bank deposits (mature July 2010) (held-to-maturity)	5,048	5,016
Total short-term investment securities	10,064	17,548
Long-term investment securities:		
Auction rate security	$ —	$ 1,914

Revenue Recognition

The Company recognizes license revenue in accordance with the revenue recognition guidance of the FASB Accounting Standards Codification, or Codification. The Company analyzes each element of its licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to the Company of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes 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. The Company recognizes 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, the Company defers the milestone payment and recognizes it as revenue over the estimated period of performance under the contract (see Note 4).

Service revenue consists of clinical trial management and site recruitment services. Revenues generated from providing clinical trial management and site recruitment services are recognized at the time such services are provided. Deferred revenue is incurred when the Company receives a deposit or prepayment for services to be performed at a later date.

Stock-Based Compensation

The Company recognizes all share-based payments to employees and to non-employee directors as compensation for service on the 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. The Company records 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, 2010, the Company has U.S. net operating loss carryforwards of approximately $282.7 million which expire from 2019 through 2030. The Company has established a 100% valuation allowance against its net deferred tax assets due to the Company's history of pre-tax losses and the resulting likelihood that the deferred tax assets will not be realizable. Due to the Company's 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.

The Company has not recorded any income tax provision for the three and six months ended June 30, 2009, since the Company has estimated that its estimated annual effective income tax rate will be zero.

The Company is not aware of any unrecorded tax liabilities which would impact the Company's financial position or its results of operations.

Basic and Diluted Net (Loss) Income per Common Share

Basic net loss or income per share is based upon the weighted average number of common shares outstanding during the period. Diluted net loss or income per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options and warrants. Common equivalent shares have not been included in the net loss per share calculations for three and six months ended June 30, 2010, because the effect of including them would have been anti-dilutive.

Basic and diluted net (loss) income per share were determined as follows:

	Three months ended June 30,		Six months ended June 30,	
(in thousands, except share and per share amounts)	2010	2009	2010	2009
Basic:				
Net (loss) income	$ (5,154)	$ 14,132	$ (9,169)	$ 14,583
Weighted average shares outstanding	58,426,995	47,855,425	57,658,247	47.854.664
Basic net (loss) income per common share	$ (0.09)	$ 0.30	$ (0.16)	$ 0.30
Diluted:				
Net (loss) income	$ (5,154)	$ 14,132	$ (9,169)	$ 14,583
Weighted average shares outstanding	58,426,995	47,855,425	57,658,247	47,854,664
Effect of dilutive options and warrants	—	334,127	—	294,936
Weighted average shares outstanding assuming dilution	58,426,995	48,189,552	57,658,247	48,149,600

Diluted net (loss) income per common share	$ (0.09)	$ 0.29	$ (0.16)	$ 0.30

The Company did not include the following securities in the table below in the computation of diluted net (loss) income per common share because the securities were anti-dilutive during the periods presented:

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Stock options	7,768,616	9,259,472	7,768,616	9,319,472
Warrants	2,258,000	—	2,258,000	—
Total	10,026,616	9,259,472	10,026,616	9,319,472

Comprehensive (Loss) Income

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

(in thousands)	Three months ended June 30, 2010	Three months ended June 30, 2009	Six months ended June 30, 2010	Six months ended June 30, 2009
Net (loss) income – as reported	$ (5,154)	$ 14,132	$ (9,169)	$ 14,583
Other comprehensive (loss) income:				
Reduction of unrealized gain on available-for-sale long-term investment securities	—	—	(180)	—
Comprehensive (loss) income	$ (5,154)	$ 14,132	$ (9,349)	$ 14,583

Impairment of Goodwill

Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. The Company tests 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.

Discontinued Operations

In September 2008, the Company terminated its license agreement related to its Accumin product and ceased all operations related to its Diagnostic segment.

The liabilities of discontinued operations are stated separately as of June 30, 2010, and December 31, 2009, on the accompanying consolidated balance sheets. The major liabilities are as follows:

(in thousands)	June 30, 2010	December 31, 2009
Liabilities		
Accounts payable and accrued expenses	$ 120	$ 120
Liabilities of discontinued operations	$ 120	$ 120

NOTE 2 – FAIR VALUE MEASUREMENTS

The Company measures 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, the Company sold its 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. Quarterly, the Company had assessed the fair value of its auction rate securities portfolio. As a result of this valuation process, as described below, the Company reported an other comprehensive loss of $0 and $180,000 in the three months and six months ended June 30, 2010, respectively, for a reduction of a temporary unrealized gain related to the estimated fair value of its auction rate security, and reported other-than-temporary impairment charges and realized losses in interest and other income, net, as per the following table.

	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2010	2009	2010	2009
Impairment of investment securities	$ —	$ —	$ 32	$ 68
Net realized losses	82	—	82	—
	$ 82	$ —	$ 114	$ 68

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 the Company's 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.

The Company reviews investment securities for impairment and to determine the classification of the impairment as temporary or other-than-temporary. Losses are recognized in the Company's consolidated statement of operations when a decline in fair value is determined to be other-than-temporary. The Company reviews its 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 Company believes that the impairment charges related to its auction rate securities investments are other-than-temporary. The primary factors the Company considers in classifying an impairment include the extent and time the fair value of each investment has been below cost and the Company's ability to hold such investment to maturity.

The following table provides the fair value measurements of applicable Company financial assets as of June 30, 2010:

(in thousands)	Financial assets at fair value as of June 30, 2010 Level 1	Level 2	Level 3
Money market funds (1)	$ 16,005	$ —	$ —
Obligations of domestic governmental agencies (held-to-maturity) (2)	5,016	—	—
Bank deposits (held-to-maturity)	5,048	—	—
Total	$ 26,069	$ —	$ —

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

(2) Amortized cost approximates fair value.

The following table summarizes the change in carrying value associated with Level 3 financial assets for the six months ended June 30, 2010:

(in thousands)		Available-for-sale long-term investments
Balance at January 1, 2010	$	1,914
Total impairment charges included in net (loss) income		(32)
Other comprehensive loss (reduction of temporary unrealized gain)		(180)
Sale of security		(1,620)
Realized loss on sale of security		(82)
Balance at June 30, 2010	$	—

NOTE 3 – STOCKHOLDERS' EQUITY

Common Stock

On September 30, 2009, the Company completed a registered direct offering to certain investors of 8,000,000 shares of its common stock and warrants to purchase up to a total of 2,800,000 shares of its common stock for gross proceeds of approximately $20 million. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.35 of a share of common stock. The purchase price per unit was $2.50. Subject to certain ownership limitations, the warrants are exercisable at any time on or prior to October 1, 2010, at an exercise price of $2.65 per warrant share. In addition, the placement agent received a warrant to purchase up to 108,000 shares of common stock at an exercise price of $3.125 per warrant share, exercisable at any time on or prior to October 1, 2010. Total proceeds to the Company from this public offering were approximately $18.4 million, net of offering costs of approximately $1.6 million. The shares and warrants were sold under a shelf registration statement on Form S-3 (File No. 333-161607) filed with the SEC on August 28, 2009, and declared effective by the SEC on September 23, 2009. The registration statement provides for the offering of up to $40 million of the Company's common stock and warrants.

Subsequent to this registered direct offering, there remains approximately $12.2 million of the Company's common stock and warrants available for sale under the shelf registration statement. The Company may offer the remaining securities under its shelf registration from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interest of the Company and its stockholders. The Company believes that the shelf registration provides it with the flexibility to raise additional capital to finance its operations as needed.

Equity Incentive Plans

Shares available for the issuance of stock options or other stock-based awards under the Company’s stock option and incentive plans were 1,927,181 shares at June 30, 2010.

Stock Options

The following table summarizes stock option activity for the six months ended June 30, 2010:

	Number	Weighted-average	Weighted-average	Aggregate intrinsic

	of shares	exercise price	contractual term (in years)	value
Outstanding at December 31, 2009	9,353,572	$ 6.63	3.3	$ 6,513,185
Granted	285,840	3.38	4.0	
Exercised	(1,102,927)	1.40		$ 3,908,505
Forfeited	(2,120)	9.80		
Expired	(765,749)	10.20		
Outstanding at June 30, 2010	7,768,616	$ 6.90	3.5	$ 9,697,122
Vested and expected to vest at June 30, 2010	7,734,984	$ 6.91	3.5	$ 9,638,857
Exercisable at June 30, 2010	6,699,235	$ 7.28	2.7	$ 7,957,868

Upon the exercise of stock options, the Company issues new shares of its common stock. As of June 30, 2010, 3,328,833 options issued to employees, and 93,000 options issued to consultants, are milestone-based, of which 3,203,833 options issued to employees, and 43,000 options issued to consultants, are vested and exercisable.

Restricted Stock

Certain employees, directors and consultants have been awarded restricted stock under the 2004 Long-Term Incentive Plan and 2007 Incentive Plan. Generally, the restricted stock vests over a period of two to four years. The following table summarizes restricted share activity for the six months ended June 30, 2010:

	Number of shares	Weighted average grant date fair value	Aggregate intrinsic value
Outstanding at December 31, 2009	1,492,136	$ 0.59	$ 3,730,340
Granted	690,500	2.77	
Vested	(749,684)	0.69	$ 3,252,031
Forfeited	(7,634)	1.41	
Outstanding at June 30, 2010	1,425,318	$ 1.59	$ 5,216,664

On September 14, 2009, the Company entered in an employment agreement with Ron Bentsur, its 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, 2010, 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, 2010, 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) the Company's filing of an accepted new drug application, or NDA, with the U.S. Food and Drug Administration for Zerenex or Perifosine, or (b) the Company's 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 of the Company 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) the Company's first commercial sale of Zerenex or Perifosine in the U.S. off an approved NDA, (b) the Company's receipt of the first royalty upon the commercial sale of Zerenex or Perifosine in the U.S. by a partner to whom the Company has sold exclusive or non-exclusive commercial rights, or (c) the Company's 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 of the Company during such vesting period.

(3) 100,000 shares of restricted stock will be granted to Mr. Bentsur upon each event of the Company's outlicensing Zerenex in a foreign market, other than Japan, resulting in a greater than $10 million non-refundable cash payment to the Company with a gross deal value to the Company 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 of the Company during such vesting period.

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Warrants

	Warrants	Weighted-average exercise price	Aggregate intrinsic value
Outstanding at December 31, 2009	2,908,000	$ 2.67	$ —
Issued	—	—	
Exercised	(650,000)	2.65	
Canceled	—	—	
Outstanding at June 30, 2010	2,258,000	$ 2.67	$ 2,229,280

As discussed above, as part of the registered direct offering completed on September 30, 2009, the Company issued warrants to purchase up to 2,800,000 shares of the Company's common stock, of which 650,000 have been exercised as of June 30, 2010. The warrants have an exercise price of $2.65 per warrant share and, subject to certain ownership limitations, are exercisable at any time on or after the initial issue date and on or prior to October 1, 2010. The grant date fair value was $1.03 per warrant, for a total fair value of $2,877,000, which is included in additional paid-in capital on the consolidated balance sheet. In addition, the Company issued to the placement agent in the transaction warrants to purchase up to 108,000 shares of its common stock at an exercise price of $3.125 per warrant share, exercisable at any time on or prior to October 1, 2010, with a grant date fair value of $0.93 per warrant. The fair value of the warrants described above is estimated at the date of grant using the Black-Scholes pricing model. For as long as the warrants issued in the registered direct offering are outstanding, if there is no effective registration statement covering the resale of the warrant shares by the holders, such warrants may be exercisable, in whole or in part, at such time by means of a “cashless exercise.”

Stock-Based Compensation

The Company incurred $695,000 and $1,389,000 of non-cash compensation expense related to equity incentive grants during the three months ended June 30, 2010 and 2009, respectively, and $1,344,000 and $1,960,000 during the six months ended June 30, 2010 and 2009, 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 the Company’s 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. The Company has 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,	
	2010	2009	2010	2009
Risk-free interest rates	1.8%	2.0%	1.9%	2.0%
Dividend yield	—	—	—	—
Volatility	126.5%	123.3%	127.9%	123.3%
Weighted-average expected term	4.0 years	4.8 years	4.0 years	4.8 years

The weighted average grant date fair value of options granted for the three months ended June 30, 2010 and 2009 was $3.39 and $0.32 per option, respectively, and for the six months ended June 30, 2010 and 2009 was $2.72 and $0.32 per option. The Company used historical information to estimate forfeitures within the valuation model. As of June 30, 2010, there was $1.4 million and $2.1 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 2.3 years and 2.4 years, respectively. These amounts do not include, as of June 30, 2010, 175,000 options outstanding which are milestone-based and vest upon certain corporate milestones, such as FDA approval of the Company’s drug

candidates, market capitalization targets, and change in control. Stock-based compensation will be measured and recorded if and when a milestone occurs.

On April 23, 2009, the Company's Board of Directors voted to terminate the employment of Michael S. Weiss as the Company's Chairman and Chief Executive Officer. Under the terms of Mr. Weiss' employment agreement, 1,800,000 shares of restricted stock vested and all of Mr. Weiss' outstanding stock options vested and will remain exercisable for two years following termination. In the second quarter of 2009, the Company recorded approximately $660,000 in non-cash compensation expense (general and administrative) associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.

NOTE 4 - LICENSE AGREEMENTS

In September 2007, the Company entered into a Sublicense Agreement with Japan Tobacco Inc. (“JT”) and Torii Pharmaceutical Co., Ltd. (“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 United States 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, the Company 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. Accordingly, in accordance with the Company’s revenue recognition policies, all remaining deferred revenue pertaining to this sublicense has been recognized in the second quarter of 2009.

Prior to the Revised Agreement, an upfront payment of $12.0 million, which was received in October 2007, was being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last-to-expire patent covered by the agreement in 2023, and represented the estimated period over which the Company had certain significant ongoing responsibilities under the original sublicense agreement. An additional milestone payment of $8.0 million, for the achievement of certain milestones reached in March 2008, was received in April 2008, and was being recognized as license revenue on a straight-line basis over the life of the original agreement (as discussed above). As a result of the signing of the Revised Agreement, the unamortized portion of the upfront payment of $12.0 million and the additional milestone payment of $8.0 million were recognized in the three months ended June 30, 2009.

In March 2009, JT and Torii informed the Company that they had initiated a Phase 2 clinical study of Zerenex in Japan, which triggered a $3.0 million non-refundable milestone payment, which was received by the Company in March 2009. As a result, the Company recorded license revenue of $3.0 million in accordance with its revenue recognition policy, which is included in the six months ended June 30, 2009.

The Company may receive up to an additional $77.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, JT and Torii will make royalty payments to the Company on net sales of ferric citrate in Japan.

In July 2009, the Company settled a dispute with Alfa Wassermann S.p.A. over issues arising from the terminated license agreement for Sulonex (sulodexide). Under the terms of the settlement agreement, Alfa Wassermann paid the Company $3,500,000 (of which $2,750,000 was received in July 2009, and $750,000 was received in July 2010), and the Company was required to deliver to Alfa Wassermann all of its data, information and other intellectual property related to Sulonex.

NOTE 5 – SEGMENT INFORMATION

The Company has 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 life-threatening diseases, including 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)	2010	2009	2010	2009

Services	$ —	$ —	$ —	$ 3
Products	—	18,364	—	21,691
Total	$ —	$ 18,364	$ —	$ 21,694

(in thousands)	Operating (loss) income			
	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Services	$ —	$ —	$ —	$ 3
Products	(5,180)	13,991	(9,281)	14,332
Total	$ (5,180)	$ 13,991	$ (9,281)	$ 14,335

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

(in thousands)	Net (loss) income			
	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Operating (loss) income of reportable segments	$ (5,180)	$ 13,991	$ (9,281)	$ 14,335
Interest and other income, net	26	141	112	248
Income taxes	—	—	—	—
Consolidated (loss) income	$ (5,154)	$ 14,132	$ (9,169)	$ 14,583

(in thousands)	Assets (1)	
	June 30, 2010	December 31, 2009
Services	$ —	$ —
Products	4,578	4,904
Total assets of reportable segments	4,578	4,904
Cash, cash equivalents, interest receivable and investment securities	31,703	35,914
Consolidated total assets	$ 36,281	$ 40,818

(1) Assets for the Company's reportable segments include fixed assets, goodwill, accounts receivable and prepaid expenses.

The carrying amount of goodwill by reportable segment as of June 30, 2010 and December 31, 2009 was as follows:

(in thousands)	Goodwill	
	June 30, 2010	December 31, 2009
Services	$ —	$ —
Products	3,208	3,208
Total	$ 3,208	$ 3,208

NOTE 6 – SUBSEQUENT EVENT

Subsequent to June 30, 2010, the Company received $750,000 of cash proceeds from its July 2009 settlement with Alfa Wassermann S.p.A. (see Note 4).

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, 2009.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of life-threatening diseases, including 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 (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 has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. KRX-0401 is currently in Phase 3 clinical development for both refractory advanced colorectal cancer and multiple myeloma, and in Phase 1 and 2 clinical development for several other tumor types. Each of the KRX-0401 Phase 3 programs are being conducted under Special Protocol Assessment (SPA) agreements with the FDA.

We are also developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 3 clinical development, under an SPA, as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. Zerenex has also completed Phase 2 development in Japan by our Japanese partner, Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii"). The Phase 3 program in Japan is pending commencement.

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 our Japanese partner, 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
	Multiple 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 2 completed by sublicensee (JT and Torii), Japan Phase 3 is pending commencement

KRX-0401 (perifosine)

Refractory Advanced Colorectal Cancer

In June 2010, we announced final results from a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda(R)) versus capecitabine plus placebo in patients with second- or third-line metastatic colorectal cancer. The data was presented at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago in a poster entitled, "Final results of a randomized

phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colorectal cancer (mCRC).”

In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colorectal cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colorectal cancer which is marketed by Roche as Xeloda®) at 825 mg/m2 BID (total daily dose of 1650 mg/m2) on days 1 – 14 every 21 days plus either perifosine or placebo at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater. Median age of patients was 65 (32-83); 61% of the patients were male. Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm). Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were inevaluable due to toxicity (days 14, 46) and 1 was inevaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response.

The patients in the study were heavily pre-treated, with the arms well-balanced in terms of prior treatment regimens. The prior treatment regimens for all 38 patients are shown in the table below. Notably, all of the patients (with the exception of one CAP arm patient) had been treated with FOLFIRI and/or FOLFOX, almost 80% treated with Avastin®, and half treated with an EGFR antibody:

Prior RX	P-CAP (n=20)	CAP (n=18)	All Patients (n=38)
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Response (CR) + Partial Response (PR) by RECIST, and Overall Survival (OS) were measured as secondary endpoints.

The P-CAP arm demonstrated a statistically significant advantage for TTP and OS, as well as for the percentage of patients achieving Stable Disease (SD) or better lasting 12 or more weeks, as compared to the CAP arm. The P-CAP arm demonstrated a greater than 60% improvement in OS, a more than doubling of median TTP, and almost a doubling of the percentage of patients achieving SD or better. In addition, the ORR was 20% (including one CR, and durable responses) in the P-CAP arm versus 7% in the CAP arm. The final efficacy results are as follows:

ALL EVALUABLE PATIENTS (n=35):

Group	n	CR n (%)	PR n (%)	Duration of Response	> SD (min 12 wks) n (%) p=0.036	PD< 12 wks n (%)	Median TTP Wks p=0.0012	Median OS* Months p=0.0161
P-CAP	20	1 (5%)	3 (15%)	CR: 36 m PR: 21, 19, 11 m	11 (55%)	5 (25%)	28 [95% CI (12-48)]	17.7 [95% CI (8.5-24.6)]
CAP	15	0	1 (7%)	PR: 7 m	5 (33%)	9 (60%)	11 [95% CI (9-15.9)]	10.9 [95% CI (5-16.9)]

*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

Of notable interest were the patients who were previously refractory to a 5-FU based regimen. The P-CAP arm again demonstrated a statistically significant increase in both TTP and OS compared to the CAP arm. The final data is illustrated below:

5-FU REFRACTORY PATIENTS (n=25):

Group	n (%)	PR n (%)	Duration of Response	> SD (min 12 wks) n (%) p=0.066	PD <12 wks n (%)	Median TTP Weeks p=0.0004	Median OS Months P=0.0112
P-CAP	14 (70%)	1 (7%)	19 m	8 (57%)	5 (36%)	18 [95% CI (12-36)]	15.1 [95% CI (7.3-22.3)]
CAP	11 (73%)	0	-	3 (27%)	8 (73%)	10 [95% CI (6.6-11)]	6.6 [95% CI (4.7-11.7)]

All 38 patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP arm as follows: hand-foot syndrome (30% vs. 0%), anemia (15% vs. 0%), fatigue (0% vs. 11%) and abdominal pain (5% vs. 11%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

Perifosine is currently in Phase 3 clinical development for refractory advanced colorectal cancer and multiple myeloma, both of these Phase 3 programs being conducted under Special Protocol Assessment (SPA) agreements with the FDA with Fast Track designations obtained for both indications.

Recurrent Pediatric Solid Tumors, Including Neuroblastoma

In June 2010, we announced Phase 1 data of perifosine in recurrent pediatric solid tumors. The data was presented in the pediatric solid tumor poster discussion session held at the 46th Annual Meeting of the American Society of Clinical Oncology (ASCO) in Chicago. The study was conducted by the Memorial Sloan-Kettering Cancer Center pediatric group and marked the first time that perifosine had been administered in a pediatric patient setting.

This Phase 1 study is a single center, open-label, dose-escalating study to assess safety, tolerability, pharmacokinetics (PK), and to identify any dose limiting toxicity (DLT) of single agent perifosine in pediatric patients with any solid tumor that has failed standard therapy. Eleven patients (4 males, 7 females), at a median age of 13 years (5-18) were treated in this study to date. The following tumor types were treated thus far: high-grade glioma (5), medulloblastoma (2), neuroblastoma (3), and ependymoma (1). Most patients were heavily pretreated, with a median of three prior lines of therapy. Cohorts of three patients were treated at three dose levels: 25mg/m2/day, 50mg/m2/day and 75mg/m2/day using 50mg tablets of perifosine after a loading dose on day 1, and taking into account the drug's long half-life (>100hrs). No DLTs were observed at any of the three dose levels; dose level 4 is currently open for accrual. PK data thus far suggests similar drug absorption by pediatric patients relative to adult patients treated with single agent perifosine.

Of particular interest were the early signs of clinical activity observed in two of the three patients with Stage 4 refractory neuroblastoma. Both patients were refractory to prior treatments upon entering the study and achieved stable disease for 48 weeks and 55+ weeks (ongoing). The investigators concluded that perifosine is well-tolerated in children with recurrent solid tumors and that these early signals of activity warrant further investigation in patients with advanced neuroblastoma and select brain tumors. Recently, National Cancer Institute investigators published in

vitro and in vivo data demonstrating that perifosine targets the activation of Akt in neuroblastoma cells and xenografts, significantly inhibits tumor growth in vivo and improves the survival of mice bearing neuroblastoma tumors.

In July 2010, we announced that perifosine received Orphan-Drug designation from the FDA for the treatment of neuroblastoma.

Zerenex (ferric citrate)

In April 2010, we reported updated long-term efficacy and safety data on Zerenex™ (ferric citrate), our iron-based phosphate binder for the treatment of hyperphosphatemia (elevated phosphate levels) from an open-label extension study in patients with end-stage renal disease (ESRD) who are on dialysis. This data was presented at the National Kidney Foundation (NKF) 2010 Spring Clinical Meeting in a poster entitled “Long-Term Use of Ferric Citrate in End-Stage Renal Disease Patients.”

After the completion of a 28-day fixed dose Phase 2 clinical trial of ferric citrate in ESRD patients, 29 patients who had participated in this trial at the site in Taiwan were offered to continue onto an Open-Label Extension (OLE) trial for up to one year. There was approximately a two month period between the completion of the Phase 2 dose-ranging trial and enrollment into the OLE trial. During this time interval, no patient was exposed to ferric citrate as a phosphate binder. Patients were immediately switched back to ferric citrate from other phosphate binders and there was no washout period prior to starting ferric citrate treatment in the OLE trial. Of the 29 patients enrolled, 28 were exposed to ferric citrate. The patients were started on doses of ferric citrate of 2 to 6 g/day. The maximum allowed dose was 6 g/day. The average dose per patient throughout the study was approximately 4.5 g/day. The average duration of the patient's participation in the trial was 306 +/- 85 days. The primary objective of this OLE trial of ferric citrate was to assess the long-term efficacy and safety of ferric citrate as a phosphate binder in ESRD patients for up to one year. The secondary objective of this OLE trial was to assess for the potential for iron absorption.

The therapeutic goal of the study was to achieve and maintain a serum phosphorus level below 5.5 mg/dL. The mean levels of serum phosphorus (SP) and phosphorus x calcium product (PxC) for the evaluable patients at each time point over the treatment period were as follows:

	SP (mg/dL)	PxC (mg/dL)2
Baseline (sd)	5.63 (1.22)	50.79 (12.74)
3 months (sd)	5.48 (1.33)	51.84 (12.67)
6 months (sd)	5.16 (1.20)	48.40 (9.60)
9 months (sd)	5.24 (1.20)	48.72 (12.04)
12 months (sd)	5.21 (1.09)	50.05 (11.82)

Iron parameters were measured at baseline and then quarterly through month 9. On average, slight increases were observed over time, across all key parameters, as follows:

	Baseline (sd)	9 Months (sd)
Ferritin (ng/mL)	520 (328)	781 (364)
TSAT (%)	39.2 (19.7)	45.5 (21.1)
Iron (mcg/dL)	87.8 (37.9)	88.3 (37.2)
HCT (%)	30.8 (6.9)	32.9 (9.7)

If a patient had a ferritin greater than 600 ng/mL and a TSAT greater than 50%, the use of IV iron was withheld until the patient's ferritin and TSAT were below the above levels during the treatment period. If a patient had a hematocrit (HCT) greater than 36%, the use of EPO was withheld until the HCT was greater than 36% during the treatment period.

There were 8 patients that had IV iron supplements withheld for approximately 3 to 6 months and there were 8 patients that had EPO withheld for approximately 1 to 10 months during the OLE trial. Out of the 16 patients in the two groups, three patients had both IV iron and EPO withheld.

Ferric citrate was well-tolerated throughout the OLE study. There were no patient deaths during the OLE and no serious adverse events reported related to ferric citrate.

The investigators concluded that in this OLE trial of ferric citrate with doses as high as 6 g/day, ferric citrate demonstrated the potential to be used long-term as a phosphate binder in ESRD patients. Ferric citrate appeared to be efficacious in controlling serum phosphorus and well-tolerated and safe for up to one year. Additionally, it is the investigators' opinion that this OLE trial, along with data from both animal studies and the Phase 2 high dose trial supports the notion that some iron absorption may be occurring with the use of ferric citrate as a phosphate binder in ESRD patients and that if a reduction in the use of IV-iron supplements and/or EPO are documented in future

long-term clinical trials, the cost-benefit and cost-effectiveness of ferric citrate as a phosphate binder, as compared to currently marketed phosphate binders, would be significant.

In May 2010, we announced the initiation of our short-term Phase 3 study of Zerenex as a treatment of elevated serum phosphorous levels, or hyperphosphatemia, in patients with end-stage renal disease on dialysis. The initiation of this study marked the commencement of our Phase 3 registration program for Zerenex, which is being conducted in accordance with a SPA agreement with the FDA. Pursuant to our SPA agreement, the Zerenex Phase 3 registration program will consist of a short-term efficacy study and 58-week long-term safety and efficacy study.

The short-term efficacy study recently initiated is a multicenter, randomized, open-label clinical trial with a planned enrollment of approximately 150 patients on hemodialysis. All patients will undergo a 2-week washout period, following which the patients will be randomized 1:1:1 to receive a fixed dose of Zerenex (1 gram, 6 grams or 8 grams per day) for a treatment period of 28 days. The primary endpoint of the study is to demonstrate a dose response in the change of serum phosphorous from baseline (end of washout period) to end of the treatment period (day 28). Approximately 15 sites in the U.S. will participate in the study.

Corporate

On July 21, 2010, we appointed Joseph Feczko, M.D. to our Board of Directors. Dr. Feczko is a seasoned pharmaceutical executive, with broad industry experience across the spectrum of medical, regulatory and operational affairs. Dr. Feczko was, until his retirement in May 2009, Senior Vice President and Chief Medical Officer (CMO) of Pfizer Inc and member of the Executive Leadership Team with global responsibilities for all aspects of the company's medical, regulatory and safety activities. Following a time in private practice, Dr. Feczko joined Pfizer in 1982 in New York, and then worked for ten years in the United Kingdom for both Pfizer and Glaxo where his responsibilities included supervising clinical research, regulatory affairs, data management and safety reporting. Dr. Feczko returned to Pfizer in New York in 1996, where he held positions of increasing responsibility in clinical research and regulatory affairs and safety, culminating in the role of CMO. Dr. Feczko is board-certified in Internal Medicine and a specialist in Infectious Diseases. He has a B.Sc. degree from Loyola University Chicago, and an M.D. from the University of Illinois College of Medicine.

General Corporate

Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, public offerings of our common stock, interest income, and, beginning in 2007, 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 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 upfront license fee revenues ratably over the estimated period in which we will have certain significant ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue. 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 as we complete our performance obligations.

Our service revenues consist entirely of clinical trial management and site recruitment services. Revenues from providing these services are recognized 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 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 indications, 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, 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, 2010 and June 30, 2009

License Revenue. License revenue decreased by $18,289,000 to $0 for the three months ended June 30, 2010, as compared to $18,289,000 for the three months ended June 30, 2009. The decrease in license revenue was due primarily to the recognition of all remaining deferred revenue related to the JT and Torii sublicense agreement originally signed in September 2007, and amended and restated in June 2009. The Amended and Restated Sublicense Agreement, among other things, provided for the elimination of all significant on-going obligations under the sublicense agreement. Accordingly, all remaining deferred revenue pertaining to this sublicense has been recognized in the three months ended June 30, 2009. We expect to recognize additional license revenue from our sublicense agreement in the second half of 2010 upon JT’s initiation of a Phase 3 clinical trial for Zerenex in Japan.

Service Revenue. There was no service revenue in the three months ended June 30, 2010 and 2009, respectively. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2010.

Other Revenue. There was no other revenue for the three months ended June 30, 2010. Other revenue for the three months ended June 30, 2009 was $75,000, and was related to a payment earned in June 2009 from a December 2008 license termination agreement for KRX-0501. Payments associated with this license termination agreement are recognized as earned since we have no on-going responsibilities under the terminated license agreement or the termination agreement. We do not expect our other revenue to have a material impact on our financial results during the remainder of 2010.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants increased by $73,000 to $434,000 for the three months ended June 30, 2010, as compared to $361,000 for the three months ended June 30, 2009. The increase in non-cash compensation expense in the three months ended June 30, 2010, as compared to June 30, 2009, was primarily related to grants of equity awards to research and development personnel and the recording of the related fair value of the awards over the respective vesting periods of the individual awards.

Other Research and Development Expenses. Other research and development expenses increased by $1,673,000 to $3,129,000 for the three months ended June 30, 2010, as compared to $1,456,000 for the three months ended June 30, 2009. The increase in other research and development expenses was due primarily to a $1,025,000 increase in research and development expenses related to KRX-0401, primarily due to the two ongoing Phase 3 clinical trials, as well to a $352,000 increase in research and development expenses related to the ongoing Phase 3 clinical trial for Zerenex. We expect our other research and development costs to increase over the remainder of 2010, due to increased patient recruitment into our 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 $767,000 to $261,000 for the three months ended June 30, 2010, as compared to an expense of $1,028,000 for the three months ended June 30, 2009. The decrease in non-cash compensation expense in the three months ended June 30, 2010, as compared to June 30, 2009, was primarily related to an expense in the second quarter of 2009 of approximately $660,000 associated with the equity modifications of outstanding stock options and shares of restricted stock of our former chief executive officer, whose employment was terminated in April 2009.

Other General and Administrative Expenses. Other general and administrative expenses decreased by $172,000 to $1,356,000 for the three months ended June 30, 2010, as compared to an expense of $1,528,000 for the three months ended June 30, 2009. The decrease was due primarily to an expense in the second quarter of 2009 of approximately $551,000 for severance and notice pay related to the termination of our former chief executive officer in April 2009, partially offset by increased expenses in the three months ended June 30, 2010 of $316,000 related to general and administrative personnel and investor outreach initiatives. We expect our other general and administrative expenses to remain at a comparable level over the reminder of 2010.

Interest and Other Income, Net. Interest and other income, net, decreased by $115,000 to $26,000 for the three months ended June 30, 2010, as compared to $141,000 for the three months ended June 30, 2009. The decrease was due primarily to a lower effective interest earned on our investment portfolio as well as a realized loss of $82,000 related to the sale in May 2010 of our last auction rate security investment.

Six months ended June 30, 2010 and June 30, 2009

License Revenue. License revenue decreased by $21,616,000 to $0 for the six months ended June 30, 2010, as compared to $21,616,000 for the six months ended June 30, 2009. The decrease in license revenue was due primarily to the recognition of all remaining deferred revenue related to the JT and Torii sublicense agreement originally signed in September 2007, and amended and restated in June 2009, and due to the recognition in the six months ended June 30, 2009, of a $3.0 million milestone payment received from JT and Torii due to their initiation of a Phase 2 clinical study of Zerenex in Japan. We expect to recognize additional license revenue from our sublicense agreement in the second half of 2010 upon JT’s initiation of a Phase 3 clinical trial for Zerenex in Japan.

Service Revenue. There was no service revenue in the six months ended June 30, 2010, as compared to service revenue of $3,000 for the six months ended June 30, 2009. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2010.

Other Revenue. There was no other revenue for the six months ended June 30, 2010. Other revenue for the six months ended June 30, 2009 was $75,000, and was related to a payment earned in June 2009 from a December 2008 license termination agreement for KRX-0501. Payments associated with this license termination agreement are recognized as earned since we have no on-going responsibilities under the terminated license agreement or the termination agreement. We do not expect our other revenue to have a material impact on our financial results during the remainder of 2010.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants increased by $114,000 to $676,000 for the six months ended June 30, 2010, as compared to $562,000 for the six months ended June 30, 2009. The increase in non-cash compensation expense in the six months ended June 30, 2010, as compared to June 30, 2009, was primarily related to grants of equity awards to research and development personnel and the recording of the related fair value of the awards over the respective vesting periods of the individual awards.

Other Research and Development Expenses. Other research and development expenses increased by $2,853,000 to $5,683,000 for the six months ended June 30, 2010, as compared to $2,830,000 for the six months ended June 30, 2009. The increase in other research and development expenses was due primarily to a $1,600,000 increase in research and development expenses related to KRX-0401, primarily due to the two ongoing Phase 3 clinical trials, as well to a $854,000 increase in research and development expenses related to the Zerenex program. We expect our other research and development costs to increase over the remainder of 2010, due to increased patient recruitment into our 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 $730,000 to $668,000 for the six months ended June 30, 2010, as compared to an expense of $1,398,000 for the six months ended June 30, 2009. The decrease in non-cash compensation expense in the six months ended June 30, 2010, as compared to June 30, 2009, was primarily related to an expense in the second quarter of 2009 of approximately $660,000 associated with the equity modifications of outstanding stock options and shares of restricted stock of our former chief executive officer, whose employment was terminated in April 2009, and due to lower expenses related to grants of equity awards to general and administrative personnel and the recording of 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 decreased by $315,000 to $2,254,000 for the six months ended June 30, 2010, as compared to an expense of $2,569,000 for the six months ended June 30, 2009. The decrease was due primarily to an expense in the second quarter of 2009 of approximately $551,000 for severance and notice pay related to the termination of our former chief executive officer in April 2009. We expect our other general and administrative expenses to remain at a comparable level over the reminder of 2010.

Interest and Other Income, Net. Interest and other income, net, decreased by $136,000 to $112,000 for the six months ended June 30, 2010, as compared to $248,000 for the six months ended June 30, 2009. The decrease was due primarily to a lower effective interest earned on our investment portfolio as well as a realized loss of $82,000 related to the sale in May 2010 of our last auction rate security investment.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations from inception primarily through public offerings of our common stock, various private placement transactions, option and warrant exercises, interest income, and, beginning in 2007, from the upfront and milestone payments from our sublicense agreement with JT and Torii and miscellaneous payments from our other prior licensing activities.

On September 30, 2009, we completed a registered direct offering to certain investors of 8,000,000 shares of our common stock and warrants to purchase up to a total of 2,800,000 shares of our common stock for gross proceeds of approximately $20 million. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.35 of a share of common stock. The purchase price per unit was $2.50. Subject to certain ownership limitations, the warrants are exercisable at any time on or prior to October 1, 2010, at an exercise price of $2.65 per warrant share. In addition, the placement agent received a warrant to purchase up to 108,000 shares of our common stock at an exercise price of $3.125 per warrant share, exercisable at any time on or

prior to October 1, 2010. Total proceeds to us from this public offering were approximately $18.4 million, net of offering costs of approximately $1.6 million. The shares and warrants were sold under a shelf registration statement on Form S-3 (File No. 333-161607) filed with the SEC on August 28, 2009, and declared effective by the SEC on September 23, 2009. The registration statement provides for the offering of up to $40 million of our common stock and warrants. Subsequent to this registered direct offering, there remains approximately $12.2 million of our common stock and warrants available for sale under the shelf registration statement. We may offer the remaining securities under our shelf registration 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 the shelf registration provides us with the flexibility to raise additional capital to finance our operations as needed.

As of June 30, 2010, we had $31.7 million in cash, cash equivalents, interest receivable, and investment securities, a decrease of $4.2 million from December 31, 2009. We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2010, exclusive of our anticipated milestones to be received and expected exercises of expiring options and warrants, are sufficient to meet our anticipated working capital needs and fund our business plan for approximately 16 to 18 months from June 30, 2010.

Cash used in operating activities for the six months ended June 30, 2010 was $7.0 million, as compared to $2.0 million for the six months ended June 30, 2009. This increase in cash used in operating activities was due primarily to a $3.0 million non-refundable milestone payment received from JT and Torii in the six months ended June 30, 2009, associated with their initiation of a Phase 2 trial for Zerenex in Japan, as well as increased expenditures in the three months ended June 30, 2010, associated with our Phase 3 clinical programs for KRX-0401 and Zerenex.

For the six months ended June 30, 2010, net cash provided by investing activities of $9.1 million was primarily the result of the maturity of held-to-maturity short-term securities, partially offset by investments in held-to-maturity short-term securities. For the six months ended June 30, 2010, net cash provided by financing activities of $3.2 million was related to net proceeds received from the exercise of options and warrants.

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 U.S. generally accepted accounting principles. 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. In addition, administrative costs related to external CROs are recognized on a straight-line basis over the estimated contractual period. 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, 2010, 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.

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.

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, which is included in interest and other income, net, in the three and six months ended June 30, 2010.

Auction rate securities were recorded at their fair value and were classified as long-term investments. Quarterly, we have assessed the fair value of our prior 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 impairment charges of $32,000 and $68,000 in the six months ended June 30, 2010 and 2009, respectively, for other-than-temporary declines in the value of our auction rate securities, all of which were 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 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.

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 October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements. This ASU eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The ASU also eliminates the use of the residual method and instead requires an entity to allocate revenue using the relative selling price method. Additionally, the guidance expands disclosure requirements with respect to multiple-deliverable revenue arrangements. This ASU is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard on our consolidated financial statements.

Effective during the quarter ended March 31, 2010, the FASB issued ASU No. 2010-09, Subsequent Events, amending Accounting Standards Codification 855, Subsequent Events, to state that an entity that is a SEC filer is required to evaluate subsequent events through the date that the financial statements are issued, but is not required to disclose the date. The amendment was effective commencing with the quarter ended March 31, 2010. The adoption of this standard did not have a significant impact on our financial statements.

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, 2010, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including money market funds and government debt. Due to the short-term nature of our investments, we believe we have 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, 2010, 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, 2010, 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, 2010, 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 ("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 is scheduled for February 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.

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, 2010, we had an accumulated deficit of approximately $330.6 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 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 planning clinical trials that will seek to enroll patients with the same diseases 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. In addition, conducting multi-national studies adds another level of complexity and risk. We are subject to events affecting countries outside the United States. 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. 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 pursuant to a SPA with the FDA. In May 2010, we initiated a Phase 3 clinical program 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 agency, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint in a Phase 3 clinical trial is achieved, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

Additionally, we have never filed a NDA, or similar application for approval in the United States, 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. Unless the FDA 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 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 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. The submission of data to the FDA from our long-term rat and canine pre-clinical studies are prerequisites for our initiation of a long-term Phase 3 clinical trial for Zerenex, and any safety signals could potentially delay the start of such clinical trial or lead to a decision to discontinue development of the drug. We recently submitted to the FDA data from these pre-clinical studies and we can provide no assurance that the FDA will not raise any safety concerns. 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. Results from earlier studies may not be indicative of results from future clinical trials. 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. 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 2 clinical trials and the Open Label Extension (OLE) clinical trial. The positive effects of Zerenex on IV iron and EPO use observed in the OLE clinical trial may not be reproducible. 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.

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 United States and abroad. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we may engage a clinical research organization 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, in the ordinary course of business, we may have disagreements with our licensors or collaborators 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 or could require or result in litigation or arbitration, which would be time-consuming and expensive.

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.

Contract manufacturers often encounter difficulties in scaling up production, including problems involving raw material supplies, production yields, 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. 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 current Good Manufacturing Practices, as well as other governmental regulations and corresponding foreign standards. 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 a sole source of ferric citrate active pharmaceutical ingredient. The loss of this sole 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 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 the execution of our current business plan.

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;

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 United States 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 phosphoinositide 3-kinase (PI3K) pathway. Zerenex, if approved in the United States, would compete with other FDA approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Genzyme Corporation, 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 United States in October 2008.

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 3, 2010, we had 17 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 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 United States 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 United States 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 United States, 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. It is too early to project the impact bundling may have on the phosphate binder industry.

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, the future sale of any approved drug candidates and new technologies, and our sale of Accumin prior to its discontinuation, 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 believe that we have obtained sufficient product liability insurance coverage for our clinical trials and the sale of Accumin prior to its discontinuation. 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 providing our clinical trial management and site recruitment services, 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 in 2004, provides 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 contracts 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 perform. 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 United States and numerous entities outside of the United States. We are a relatively small company with 17 full and part-time employees as of August 3, 2010. 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 current cash, cash equivalents and investment securities may not be adequate to support our operations for the length of time that we have estimated.

We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2010, exclusive of our anticipated milestones to be received and expected exercises of expiring options and warrants, are sufficient to meet our anticipated working capital needs and fund our business plan for approximately 16 to 18 months from June 30, 2010. Our forecast of the period of time through which our cash, cash equivalents and investment securities will be adequate to support our 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 capital resources are insufficient to meet future capital 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 are 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 2013 and we cannot assure you that we can obtain an extension to 2018 (the maximum term of extension under the patent term restoration program). Our composition of matter patent covering Zerenex expires in 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 the patented method, or for which there is a substantial use in commerce outside the patented method.

Proof of direct infringement by a competitor for method of use patents can also 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 Food, Drug and Cosmetic Act 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 United States, or, diseases that affect more than 200,000 individuals in the United States 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 that KRX-0401, or any other drug candidates we may acquire or in-license, will obtain such orphan drug designations.

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.

On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607)), that was declared effective by the SEC on September 23, 2009, providing for the offering of up to $40 million of our common stock and warrants to purchase our common stock. Subsequent to the registered direct offering that was completed on September 30, 2009, there remains approximately $12.2 million of our common stock and warrants available for sale on this shelf registration statement. Future sales pursuant to this registration statement 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, we may 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.

In addition, we may be required to issue up to 2,872,422 shares of our common stock to former stockholders of ACCESS Oncology upon the achievement of certain development and sales milestones.

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

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

developments concerning our drug candidates;

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 and liquidity;

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 with 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.
10.1*	Keryx Biopharmaceuticals, Inc. Second Amended and Restated Directors Equity Compensation Plan
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 9, 2010.
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 9, 2010.
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 9, 2010.
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 9, 2010.

* Indicates management contract or compensatory plan or arrangement.

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 9, 2010	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:

10.1*	Keryx Biopharmaceuticals, Inc. Second Amended and Restated Directors Equity Compensation Plan
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 9, 2010.
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