KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 12, 2009

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, 2009

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).
x 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 47,838,960 shares of the registrant's common stock, $0.001 par value, outstanding as of August 7, 2009.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2009

TABLE OF CONTENTS

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this report, including matters discussed under the caption “Management’s Discussion and Analysis of Financial Condition and Results of Operations,” may constitute forward-looking statements for purposes of the Securities Act of 1933, as amended, or the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from the future results, performance or achievements expressed or implied by such forward-looking statements. The words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. Our actual results may differ materially from the results anticipated in these forward-looking statements due to a variety of factors, including, without limitation, those discussed under the captions “Risk Factors,” “Management’s Discussion and Analysis of Financial Condition and Results of Operations” and elsewhere in this report, as well as other factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the 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, including auction rate securities;
- ability to continue as a going concern;
- expected losses; and
- expectations for future capital requirements.

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

We qualify all of our forward-looking statements by these cautionary statements. In addition, with respect to all of our forward-looking statements, we claim the protection of the safe harbor for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995.

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc.
Consolidated Balance Sheets as of June 30, 2009 and December 31, 2008

(in thousands, except share and per share amounts)

	June 30, 2009 (Unaudited)	December 31, 2008
Assets		
Current assets:		
Cash and cash equivalents	$ 13,414	$ 13,143
Short-term investment securities	—	2,299
Interest receivable	4	25
Other current assets	222	508
Total current assets	13,640	15,975
Long-term investment securities	7,117	7,185
Property, plant and equipment, net	137	182
Goodwill	3,208	3,208
Other assets, net	62	84
Total assets	$ 24,164	$ 26,634
Liabilities and stockholders' equity (deficiency)		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,152	$ 4,613
Accrued compensation and related liabilities	714	496
Current portion of deferred revenue	156	1,464
Liabilities of discontinued operations	—	120
Total current liabilities	5,022	6,693
Deferred revenue, net of current portion	—	17,308
Contingent equity rights	4,004	4,004
Other liabilities	84	118
Total liabilities	9,110	28,123
Commitments and contingencies		
Stockholders' equity (deficiency):		
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, 47,908,908 and 47,729,507 shares issued, 47,828,960 and 47,649,559 shares outstanding at June 30, 2009 and December 31, 2008, respectively)	48	48
Additional paid-in capital	332,698	330,738
Treasury stock, at cost, 79,948 shares at June 30, 2009 and December 31, 2008, respectively	(357)	(357)
Accumulated deficit	(317,335)	(331,918)
Total stockholders' equity (deficiency)	15,054	(1,489)
Total liabilities and stockholders' equity (deficiency)	$ 24,164	$ 26,634

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Operations
for the three and six months ended June 30, 2009 and 2008 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Revenue:				
License revenue	$ 18,289	$ 327	$ 21,616	$ 526
Service revenue	—	62	3	62
Other revenue	75	—	75	—
Total revenue	18,364	389	21,694	588
Operating expenses:				
Cost of services	—	14	—	14
Research and development:				
Non-cash compensation	361	251	562	(729)
Other research and development	1,456	4,242	2,830	35,069
Total research and development	1,817	4,493	3,392	34,340
Selling, general and administrative:				
Non-cash compensation	1,028	1,767	1,398	3,484
Other selling, general and administrative	1,528	2,078	2,569	3,965
Total selling, general and administrative	2,556	3,845	3,967	7,449
Total operating expenses	4,373	8,352	7,359	41,803
Operating income (loss)	13,991	(7,963)	14,335	(41,215)
Interest and other income (expense), net	141	274	248	(929)
Income (loss) from continuing operations before income taxes	14,132	(7,689)	14,583	(42,144)
Income taxes	—	—	—	—
Income (loss) from continuing operations	14,132	(7,689)	14,583	(42,144)
Loss from discontinued operations	—	(8)	—	(89)
Net income (loss)	$ 14,132	$ (7,697)	$ 14,583	$ (42,233)
Basic net income (loss) per common share:				
Continuing operations	$ 0.30	$ (0.17)	$ 0.30	$ (0.96)
Discontinued operations	—	(—)*	—	(—)*
Basic net income (loss) per common share	$ 0.30	$ (0.17)	$ 0.30	$ (0.96)
Diluted net income (loss) per common share:				

Continuing operations	$ 0.29	$ (0.17)	$ 0.30	$ (0.96)
Discontinued operations	—	(—)*	—	(—)*
Diluted net income (loss) per common share	$ 0.29	$ (0.17)	$ 0.30	$ (0.96)
Weighted average shares used in computing basic net income (loss) per common share	47,855,425	44,095,873	47,854,664	43,906,974
Weighted average shares used in computing diluted net income (loss) per common share	48,189,552	44,095,873	48,149,600	43,906,974

* Amount less than one cent.

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statement of Changes in Stockholders' Equity (Deficiency)
for the six months ended June 30, 2009 (Unaudited)

(in thousands, except share amounts)

	Common stock Shares	Amount	Additional paid-in capital
Balance at December 31, 2008	47,729,507	$ 48	$ 330,738
Changes during the period:			
Issuance of restricted stock	478,539	—*	—
Forfeiture of restricted stock	(299,138)	(—)*	—
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	1,960
Net income	—	—	—
Balance at June 30, 2009	47,908,908	$ 48	$ 332,698

	Treasury stock Shares	Amount	Accumulated Deficit	Total
Balance at December 31, 2008	79,948	$ (357)	$ (331,918)	$ (1,489)
Changes during the period:				
Issuance of restricted stock	—	—	—	—*
Forfeiture of restricted stock	—	—	—	(—)*
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	—	1,960
Net income	—	—	14,583	14,583
Balance at June 30, 2009	79,948	$ (357)	$ (317,335)	$ 15,054

* Amount less than one thousand dollars.

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows
for the six months ended June 30, 2009 and 2008 (Unaudited)

(in thousands)

	Six months ended June 30,	
	2009	2008
CASH FLOWS FROM OPERATING ACTIVITIES		
Net income (loss)	$ 14,583	$ (42,233)
Loss from discontinued operations	—	(89)
Net income (loss) from continuing operations	14,583	(42,144)
Adjustments to reconcile income (loss) from continuing operations to cash flows used in operating activities in continuing operations:		
Stock compensation expense	1,960	2,755
Depreciation and amortization	49	66
Impairment of investment securities	68	1,875
Other impairment charges	—	11,037
Changes in assets and liabilities, net of effects of acquisitions:		
Decrease in other current assets	286	129
Decrease in accrued interest receivable	21	184
Decrease in security deposits	—	242
Decrease in other assets	22	—
Decrease in accounts payable and accrued expenses	(581)	(9,109)
Increase (decrease) increase in accrued compensation and related liabilities	218	(390)
Decrease in other liabilities	(34)	(46)
(Decrease) increase in deferred revenue	(18,616)	7,412
Net cash used in operating activities in continuing operations	(2,024)	(27,989)
Net cash used in operating activities in discontinued operations	—	(107)
Net cash used in operating activities	(2,024)	(28,096)
CASH FLOWS FROM INVESTING ACTIVITIES		
Purchases of property, plant and equipment	(4)	(163)
Investment in held-to-maturity short-term securities	(1)	(32)
Proceeds from maturity of held-to-maturity short-term securities	2,300	12,842
Investment in available-for-sale short-term securities	—	(12,000)
Proceeds from sale of available-for-sale short-term securities	—	22,200
Investment in held-to-maturity long-term securities	—	(1)
Net cash provided by investing activities	2,295	22,846
CASH FLOWS FROM FINANCING ACTIVITIES		
Proceeds from exercise of options and warrants	$ —	$ 222
Net cash provided by financing activities	—	222
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	271	(5,028)

Cash and cash equivalents at beginning of period		13,143		19,065
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$	13,414	$	14,037

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

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 renal disease and cancer. Most of the Company's biopharmaceutical development and substantially all of its administrative operations during the three and six months ending June 30, 2009 and 2008 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 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, 2008. The results of operations for the three and six months ended June 30, 2009 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 and, except for the three and six months ended June 30, 2009, expects to continue to incur operating losses for the foreseeable future and may never become profitable. As of June 30, 2009, the Company has an accumulated deficit of $317.3 million. The Company is dependent upon significant financing to provide the working capital necessary to execute its business plan. 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 currently anticipates that its cash, cash equivalents and investment securities as of June 30, 2009, with the additional $3.5 million of settlement proceeds from Alfa Wassermann S.p.A (see Note 8), but exclusive of its holdings in auction rate securities, are sufficient to meet the Company's anticipated working capital needs and fund its business plan through the end of the second quarter of 2010. However, if the Company is not able to receive proceeds from some portion of its auction rate securities by the third quarter of 2010, the Company may not have the ability to continue as a going concern for any significant period beyond that point. The actual amount of funds that the Company will need to operate is subject to many factors, including the timing, design and conduct of clinical trials for the Company's drug candidates. The Company is evaluating market conditions to determine the appropriate timing and extent to which it will seek to obtain additional debt, equity or other type of financing. If the Company determines that it is necessary to seek additional funding, there can be no assurance that it will be able to obtain any such funding on terms that are acceptable to the Company, if at all.

The accompanying financial statements have been prepared assuming that the Company continues as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The factors discussed above, taken together with the Company's limited cash, cash equivalents, and illiquid investments in auction rate securities raise substantial doubt about the Company's ability to continue as a going concern. The financial

statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

In addition to the Company's restructuring efforts in March 2008 (see Note 4 - Restructuring), in an ongoing effort to further reduce costs, there have been additional staff reductions through June 30, 2009. As of June 30, 2009, the Company had 15 full and part-time employees.

The Company's common stock is listed on the NASDAQ Capital Market and trades under the symbol "KERX." On June 17, 2009, the Company issued a press release announcing that the Company received a letter from The NASDAQ Stock Market confirming that it had regained compliance with the minimum bid price requirement for continued listing on The NASDAQ Capital Market under Listing Rule 5550(a)(2). The Company also received a letter from the NASDAQ Listing Qualifications Hearings Panel (the "Panel") confirming that it had demonstrated a market value of listed securities over the required minimum of $35 million for 10 consecutive trading days, for continued listing on The NASDAQ Capital Market under Listing Rule 5550(b)(2), and that the Panel had determined to continue the listing of the Company's securities on The NASDAQ Stock Market.

Changes in Company Management

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 with the Company dated December 23, 2002, as amended on December 26, 2008 (the "Employment Agreement"), he remained an employee of the Company for a period of 90 days; however, during such notice period, he did not serve as the Company's Chairman and Chief Executive Officer.

The Employment Agreement provided that Mr. Weiss was entitled to receive as severance (i) a lump-sum payment equal to one year's base salary, payable after a six-month delay, as required under Section 409A of the tax code, (ii) payment of his salary during the 90 days following formal notice of termination of employment, and (iii) a pro rata bonus for the year of termination, determined with respect to the amount to which Mr. Weiss would have been entitled for the year of termination (based upon the achievement of corporate goals and objectives) if he had remained employed throughout the calendar year, payable at the time bonuses are paid to other executives. In addition, under the terms of the Employment Agreement, all of Mr. Weiss' outstanding stock options and shares of restricted stock vested, and all stock options will remain exercisable for two years following termination. In the second quarter of 2009, the Company recorded approximately $551,000 of expense, in other selling, general and administrative expenses, associated with the cash severance and salary during the notice period (excluding a pro rata bonus, if any, which is not determinable at this time), and approximately $660,000 in non-cash compensation expense (selling, general and administrative) associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.

On April 23, 2009, Michael P. Tarnok, who has served on the Company's Board of Directors since September 2007, was appointed Interim Chairman and Chief Executive Officer of the Company.

On May 20, 2009, the Company announced that it appointed Ron Bentsur as Chief Executive Officer of the Company. The terms of Mr. Bentsur's employment are being finalized and will be set forth in an employment agreement with the Company. As an inducement to his employment, on May 20, 2009, the Company granted Mr. Bentsur options to purchase 600,000 shares of Company common stock, at an exercise price equal to the fair market value of the stock as of the date of grant. The options will vest in equal annual installments over a four-year period or upon an earlier change in control of the Company. The options were granted as an inducement award and were not issued under the Company's 2007 Incentive Plan. As of June 30, 2009, there are no unrecorded obligations that would have been recorded in the three or six months ended June 30, 2009, related to the employment agreement.

On June 16, 2009, Ron Bentsur was appointed to the Board of Directors of the Company by unanimous vote of the Board of Directors, and Michael P. Tarnok was appointed Chairman of the Board by unanimous vote of the Board of Directors.

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 (expense), net.

The following table summarizes the Company's investment securities at June 30, 2009 and December 31, 2008:

(in thousands)	June 30, 2009	December 31, 2008
Short-term investment securities:		
Obligations of domestic governmental agencies (matured May 2009) (held-to-maturity)	$ —	$ 2,299
Long-term investment securities:		
Auction rate securities (mature between 2037 and 2047) (available-for-sale) ($10.0 million par value)	$ 7,117	$ 7,185

Revenue Recognition

The Company recognizes license revenue consistent with the provisions of Staff Accounting Bulletin ("SAB") No. 104 and Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." 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 5).

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.

Other revenue consists of fees and payments arising from technology transfer, termination and settlement agreements related to the Company's prior license agreements. Other revenues are recognized at the time such fees and payments are earned.

Stock-Based Compensation

The Company adopted SFAS No. 123R, "Share-Based Payment" ("SFAS No. 123R") on January 1, 2006 using the modified prospective transition method. SFAS No. 123R requires all share-based payments to employees, and to non-employee directors as compensation for service on the Board of Directors, to be recognized 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. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value method prescribed by the provisions of EITF Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services” (“EITF 96-18”).

Income Taxes

As of June 30, 2009, the Company has U.S. net operating loss carryforwards of approximately $276 million which expire from 2019 through 2028. The Company has established a 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 are not realizable. Due to the Company's various equity transactions, the utilization of certain tax loss carryforwards could be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision.

The Company has not recorded any income tax provision for the three and six months ended June 30, 2009, since pursuant to the provisions of SFAS 109, "Accounting for Income Taxes," the Company has estimated that its estimated annual effective income tax rate will be zero.

The Company is not aware of any FIN 48 tax liabilities which would impact the financial statements.

Basic and Diluted Net Income (Loss) per Common Share

The Company follows the provisions of SFAS 128, "Earnings per Share." Basic net income or loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income or loss 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, under SFAS No. 123R, 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 the three and six months ended June 30, 2008 because the effect of including them would have been anti-dilutive. Total potential gross common equivalent shares consisted of the following:

	June 30, 2009	March 31, 2009
Stock options	365,652	305,652
Warrants	72,564	72,564
Total	438,216	378,216

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

	Three months ended June 30,		Six months ended June 30,	
(in thousands, except share and per share amounts)	2009	2008	2009	2008
Basic:				
Income (loss) from continuing operations	$ 14,132	$ (7,689)	$ 14,583	$ (42,144)
Loss from discontinued operations	—	(8)	—	(89)
Net income (loss)	$ 14,132	$ (7,697)	$ 14,583	$ (42,233)
Weighted average shares outstanding	47,855,425	44,095,873	47.854.664	43,906,974
Basic net income (loss) per common share:				
Continuing operations	$ 0.30	$ (0.17)	$ 0.30	$ (0.96)
Discontinued operations	—	(—)*	—	(—)*

Basic net income (loss) per common share	$ 0.30	$ (0.17)	$ 0.30	$ (0.96)
Diluted:				
Income (loss) from continuing operations	$ 14,132	$ (7,689)	$ 14,583	$ (42,144)
Loss from discontinued operations	—	(8)	—	(89)
Net income (loss)	$ 14,132	$ (7,697)	$ 14,583	$ (42,233)
Weighted average shares outstanding	47,855,425	44,095,873	47,854,664	43,906,974
Effect of dilutive options and warrants	334,127	—	294,936	—
Weighted average shares outstanding assuming dilution	48,189,552	44,095,873	48,149,600	43,906,974
Diluted net income (loss) per common share:				
Continuing operations	$ 0.29	$ (0.17)	$ 0.30	$ (0.96)
Discontinued operations	—	(—)*	—	(—)*
Diluted net income (loss) per common share	$ 0.29	$ (0.17)	$ 0.30	$ (0.96)

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

	Three months ended June 30,		Six months ended June 30,	
	2009	2008	2009	2008
Stock options	9,259,472	9,524,640	9,319,472	9,524,640
Warrants	—	321,976	—	321,976
Total	9,259,472	9,846,616	9,319,472	9,846,616

Comprehensive Loss

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

Accounting for Manufacturing Suite

The Company spent approximately $11.3 million in capital expenditures building a manufacturing suite for Sulonex. With the cessation of the Company's development of Sulonex in March 2008, the Company took an impairment charge of $11.0 million, which is included in other research and development expenses in the six months ended June 30, 2008, to write the assets down to their fair value of $300,000, the amount for which the assets were subsequently sold during 2008. The sale of the assets offset a related payable and, therefore, cash was not received by the Company. In addition, the Company recognized a $2.1 million expense, which is included in other research and development expenses in the six months ended June 30, 2008, for costs related to the required restoration of the leased facility to its original condition. See Note 4 – Restructuring.

Impairment of Goodwill

The Company accounts for impairment of goodwill using the provisions of SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). This statement addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. SFAS No. 142 also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. SFAS No. 142 requires goodwill be tested using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. The negative outcome of the Company's pivotal SUN-MICRO Phase 3 clinical trial of Sulonex™ (sulodexide) for the treatment of diabetic nephropathy, announced on March 7, 2008, and the Company's subsequent decision to terminate the ongoing SUN-MACRO Phase 4 clinical trial triggered an impairment test. As of March 31, 2008, management concluded that there was no impairment of the Company's goodwill. Additionally, as of December 31, 2008, management conducted its annual assessment of goodwill and concluded that there was no impairment to its goodwill. The Company will continue to perform impairment tests under SFAS No. 142 annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

Subsequent Events

The Company has performed a review of events subsequent to the balance sheet date through August 11, 2009, the date the financial statements were available for issuance.

NOTE 2 – FAIR VALUE MEASUREMENTS

As of January 1, 2008, the Company adopted SFAS No. 157, “Fair Value Measurements” (“SFAS No. 157”) for its financial assets and liabilities carried at fair value on a recurring basis in the financial statements only. SFAS No. 157 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. The SFAS No. 157 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.

As of June 30, 2009, $7.1 million of the Company’s investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. Auction rate securities are structured to provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally every 28 days. This mechanism has historically allowed existing investors either to rollover their holdings, whereby they would continue to own their respective securities, or liquidate their holdings by selling such securities at par. This auction process has historically provided a liquid market for these securities; however, the uncertainties in the credit markets have affected all of the Company’s holdings in auction rate securities. Since February 2008, the auctions for the auction rate securities held by the Company have not had sufficient buyers to cover investors’ sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at June 30, 2009, the Company is uncertain as to when, or if, the liquidity issues relating to these investments will improve. The Company assessed the fair value of its auction rate securities portfolio. As a result of this valuation process, as described below, the Company recorded impairment charges totaling $0 and $0.1 million during the three months ended June 30, 2009 and 2008, respectively, and $0.1 and $1.9 million during the six months ended June 30, 2009 and 2008, respectively, for other-than-temporary declines in the value of its auction rate securities. These other-than-temporary impairment charges were included in interest and other income (expense), net. The estimated fair value of the Company’s remaining auction rate securities is $7.1 million at June 30, 2009.

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 fair value of the Company’s auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue or if these securities experience credit

rating downgrades, the Company may incur additional impairment charges with respect to its auction rate securities portfolio. The Company continues to monitor the fair value of its auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges.

The Company reviews investment securities for impairment in accordance with the guidance in FSP SFAS 115-1 and 124-1, “The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments,” 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 according to the fair value levels defined by SFAS No. 157 as of June 30, 2009:

(in thousands)	Financial assets at fair value as of June 30, 2009 Level 1	Level 2	Level 3
Money market funds (1)	$ 13,414	$ —	$ —
Auction rate securities (2)	—	—	7,117
Total	$ 13,414	$ —	$ 7,117

(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) Included in long-term investment securities on the Company's consolidated balance sheet.

The following table summarizes the change in carrying value associated with Level 3 financial assets for the six months ended June 30, 2009:

(in thousands)	Available-for-sale long-term investments
Balance at January 1, 2009	$ 7,185
Total impairment charges included in net loss	(68)
Balance at June 30, 2009	$ 7,117

NOTE 3 – STOCKHOLDERS' EQUITY

Equity Incentive Plans

The following table summarizes stock option activity for the six months ended June 30, 2009:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2008	9,114,459	$ 7.19		
Granted	640,000	0.39	4.8	
Exercised	—	—		$ —
Forfeited	(112,597)	7.26		
Expired	(16,738)	12.55		
Outstanding at June 30, 2009	9,625,124	$ 6.72	3.7	$ 599,722
Vested and expected to vest at June 30, 2009	9,589,409	$ 6.73	3.6	$ 588,667
Exercisable at June 30, 2009	8,467,809	$ 6.86	3.0	$ 269,722

Upon the exercise of stock options, the Company issues new shares. As of June 30, 2009, 3,328,833 options issued to employees and directors, and 93,000 options issued to consultants, are milestone-based, of which 3,203,833 options

issued to employees and directors, and 43,000 options issued to consultants, are vested and exercisable.

On May 20, 2009, the Company granted Ron Bentsur options to purchase 600,000 shares of Company common stock at an exercise price of $0.35, the fair market value of the stock on the date of grant. The options will vest in equal annual installments over a four-year period or upon an earlier change in control of the Company. The options were granted as an inducement award and were not issued under the Company's 2007 Incentive Plan.

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, 2009:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2008	3,982,572	$ 0.36	
Granted	478,539	0.43	
Vested	(2,700,567)	0.30	$ 1,307,712
Forfeited	(299,138)	0.32	
Outstanding at June 30, 2009	1,461,406	$ 0.50	$ 1,315,265

Shares available for the issuance of stock options or other stock-based awards under the Company's stock option and incentive plans were 2,443,862 shares at June 30, 2009.

Warrants

	Warrants	Weighted-average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2008	72,564	$ 0.01	
Issued	—	—	
Exercised	—	—	
Canceled	—	—	
Outstanding at June 30, 2009	72,564	$ 0.01	$ 64,821

Stock-Based Compensation

The Company incurred $1,389,000 and $2,018,000 of non-cash compensation expense related to equity incentive grants during the three months ended June 30, 2009 and 2008, respectively, and $1,960,000 and $2,755,000 during the six months ended June 30, 2009 and 2008, 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,	
	2009	2008	2009	2008
Risk-free interest rates	2.0%	2.9%	2.0%	2.6%
Dividend yield	—	—	—	—
Volatility	123.3%	111.0%	123.3%	76.3%
Weighted-average expected term	4.8 years	2.0 years	4.8 years	4.3 years

The weighted average grant date fair value of options granted for the three months ended June 30, 2009 and 2008 was $0.32 and $0.28 per option, respectively, and for the six months ended June 30, 2009 and 2008 was $0.32 and $2.40 per option. The Company used historical information to estimate forfeitures within the valuation model. As of June 30, 2009, there was $1.8 million and $0.6 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over weighted-average periods of 1.8 years and 2.1 years, respectively. These amounts do not include, as of June 30, 2009, 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 (see Note 1). Under the terms of Mr. Weiss' employment agreement, 1,800,000 shares of restricted stock vested, which is included in the restricted share activity table above. In addition, 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 (selling, general and administrative) associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.

NOTE 4 – RESTRUCTURING

On March 26, 2008, the Company implemented a strategic restructuring plan to reduce its cash burn rate and re-focus its development efforts (the "2008 Restructuring"). The 2008 Restructuring, which was prompted by the negative outcome of the Company's pivotal SUN-MICRO Phase 3 clinical trial of Sulonex™ (sulodexide) for the treatment of diabetic nephropathy, announced on March 7, 2008, and subsequent decision by the Company to terminate the ongoing SUN-MACRO Phase 4 clinical trial, was intended to conserve the financial resources of the Company and enable it to focus its efforts on programs and opportunities that management believed were most likely to provide long-term shareholder value. The 2008 Restructuring included a workforce reduction of approximately 50% as compared to the Company's workforce at December 31, 2007. Following the workforce reduction, the Company had approximately 25 full and part-time employees.

As part of the 2008 Restructuring, on March 26, 2008, the Company notified its President, I. Craig Henderson, M.D., that the Company was terminating his employment, effective April 15, 2008. Dr. Henderson remained in his position as a member of the Company's Board of Directors until the annual meeting in June 2008. The Company recognized a $1,569,000 credit to expense, in the six months ended June 30, 2008, related to the forfeiture of stock options and restricted stock issued to Dr. Henderson. In addition, the Company reached a mutual agreement with its Chief Accounting Officer, Mark Stier, that Mr. Stier resigned effective June 30, 2008. His responsibilities were assumed by James F. Oliviero, the Company's current Chief Financial Officer, who was appointed Principal Financial and Accounting Officer on May 6, 2008.

The following table summarizes restructuring costs that were provided for and/or incurred by the Company during the comparable six months ended June 30, 2008:

(in thousands)	Six months ended June 30, 2008
Research and development	
Impairment of manufacturing facility	$ 11,037
Manufacturing facility restoration provision	2,063
Severance	624
Non-cash compensation	(1,569)
Total research and development	12,155
Selling, general and administrative	
Severance	99
Total selling, general and administrative	99
Total restructuring costs	$ 12,254

At December 31, 2008 and June 30, 2009, there were no remaining restructuring liabilities.

16

NOTE 5 - LICENSE AGREEMENT

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 three months ended June 30, 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, as discussed above, the unamortized portion of the upfront payment of $12.0 million and the additional milestone payment of $8.0 million, approximately $18.0 million, was recognized in the three months ended June 30, 2009.

In March 2009, the Company's Japanese partner, 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.

NOTE 6 – DISCONTINUED OPERATIONS

In September 2008, the Company terminated its license agreement related to the Accumin product and ceased all operations related to the Diagnostic segment. The results of the Company's Diagnostic segment and the related financial position have been reflected as discontinued operations in the consolidated financial statements in accordance with SFAS No. 144 and EITF Issue No. 03-13, "Applying the Conditions in Paragraph 42 of FASB Statement No. 144 in Determining Whether to Report Discontinued Operations" ("EITF Issue No. 03-13"). The consolidated financial statements have been reclassified to conform to discontinued operations presentation for all historical periods presented.

Summarized selected financial information for discontinued operations are as follows:

(in thousands)	Six months ended June 30, 2008
Diagnostic revenue	$ —
Operating expenses:	
Cost of diagnostics sold	—

Research and development		2
Selling, general and administrative		87
Total operating expenses		89
Loss from discontinued operations	$	(89)

The assets and liabilities of discontinued operations are stated separately as of June 30, 2009 and December 31, 2008 on the accompanying consolidated balance sheets. The major assets and liabilities categories are as follows:

(in thousands)	June 30, 2009	December 31, 2008
Assets		
Assets of discontinued operations	$ —	$ —
Liabilities		
Accounts payable and accrued expenses	$ 120	$ 120
Liabilities of discontinued operations	$ 120	$ 120

NOTE 7 – 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 renal disease and cancer, and also includes license revenue, other revenue and associated costs.

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

	Revenue			
	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2009	2008	2009	2008
Services	$ —	$ 62	$ 3	$ 62
Products	18,364	327	21,691	526
Total	$ 18,364	$ 389	$ 21,694	$ 588

	Operating income (loss)			
	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2009	2008	2009	2008
Services	$ —	48	$ 3	48
Products	13,991	(8,011)	14,332	(41,263)
Total	$ 13,991	$ (7,963)	$ 14,335	$ (41,215)

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

	Income (loss) from continuing operations			
	Three months ended June 30,		Six months ended June 30,	
(in thousands)	2009	2008	2009	2008

Operating income (loss) of reportable segments	$ 13,991	$ (7,963)	$ 14,335	$ (41,215)
Interest and other income (expense), net	141	274	248	(929)
Income taxes	—	—	—	—
Consolidated income (loss) from continuing operations	$ 14,132	$ (7,689)	$ 14,583	$ (42,144)

(in thousands)	Assets (1) June 30, 2009	December 31, 2008
Services	$ —	$ —
Products	3,629	3,982
Total assets of reportable segments	3,629	3,982
Cash, cash equivalents, interest receivable and investment securities	20,535	22,652
Consolidated total assets	$ 24,164	$ 26,634

(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, 2009 and December 31, 2008 was as follows:

(in thousands)	Goodwill	
	June 30, 2009	December 31, 2008
Services	—	—
Products	$ 3,208	$ 3,208
Total	$ 3,208	$ 3,208

NOTE 8 – SUBSEQUENT EVENT

On August 4, 2009, the Company announced that it 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 will pay the Company US$3,500,000 (of which US$2,750,000 was received on July 31, 2009, and US$750,000 will be paid on or before July 30, 2010), and the Company is required to deliver to Alfa Wassermann all of its data, information and other intellectual property related to Sulonex.

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, 2008.

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 renal disease and cancer. We are developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that inhibits the phosphoinositide 3-kinase (PI3K)/Akt pathway, a key signaling cascade that has been shown to induce cell growth and cell transformation. KRX-0401 has demonstrated both safety and clinical efficacy in several adult and pediatric tumor types, both as a single agent and in combination with novel therapies. KRX-0401 also modulates a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase 2 clinical development for multiple tumor types, with a Phase 3 in multiple myeloma, under Special Protocol Assessment, or SPA, pending commencement.

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 has recently completed a U.S. Phase 2 clinical program as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, and we are in the process of finalizing the U.S. Phase 3 program for Zerenex in consultation with the FDA. Zerenex is also in Phase 2 development in Japan by our Japanese partner, Japan Tobacco Inc. (“JT”) and Torii Pharmaceutical Co., Ltd. (“Torii”).

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)	Multiple myeloma	Phase 3 pending, under SPA.
	Multiple other forms of cancer	Phase 2 trials ongoing.
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	U.S. Phase 2 complete; U.S. Phase 3 program pending; Japan Phase 2 ongoing by sublicensee (JT and Torii).

KRX-0401 (perifosine)

Multiple Myeloma

On August 3, 2009, we announced that we had reached agreement with the FDA regarding a Special Protocol Assessment (SPA) on the design of a Phase 3 trial for KRX-0401 (perifosine) in relapsed or relapsed / refractory multiple myeloma patients previously treated with bortezomib (VELCADE®). The SPA provides agreement that the Phase 3 study design adequately addresses objectives in support of a regulatory submission. The trial, entitled, “A Phase 3 Randomized Study to Assess the Efficacy and Safety of Perifosine Added to the Combination of Bortezomib and Dexamethasone in Multiple Myeloma Patients Previously Treated with Bortezomib” will be a double-blind, placebo-controlled trial comparing the efficacy and safety of KRX-0401 versus placebo when combined with bortezomib and dexamethasone. The trial, powered at 90%, will enroll approximately 400 patients with relapsed or relapsed / refractory multiple myeloma. The primary endpoint is progression-free survival and secondary endpoints include overall response rate, overall survival and safety. Drs. Paul Richardson and Kenneth Anderson, from the Jerome Lipper Multiple Myeloma Center, Dana-Farber Cancer Institute, have agreed to lead the Phase 3 trial.

Metastatic Colon Cancer

In June 2009, we announced positive data from a randomized, multi-center, 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 colon cancer. The data was presented in a poster during the Gastrointestinal Cancer — Colorectal session at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Orlando, Florida. In this randomized, double-blind, placebo-controlled study conducted at 11 centers across the United States, patients with 2nd or 3rd line metastatic colon cancer were randomized to receive capecitabine (Xeloda(R)), an approved drug for metastatic colon cancer, at a dose of 825 mg/m2 BID (total daily dose of 1650 mg/m2) on days 1 to 14 every 21 days, plus either KRX-0401 (perifosine) or placebo at 50 mg daily. Treatment was continued until progression. The study enrolled a total of 38 patients, of which 35 patients were evaluable for response (20 patients on the capecitabine plus perifosine arm and 15 patients on the capecitabine plus placebo arm). The three patients not evaluable for response were all in the capecitabine plus placebo arm; 2 patients were inevaluable due to toxicity (days 14, 46) and 1 patient was inevaluable due to a new malignancy on day 6.

The median prior treatment regimens was two, with prior treatment regimens as follows: 91% of the patients received prior FOLFIRI (Irinotecan + 5FU + Leucovorin); 74% prior FOLFOX (Oxaliplatin + 5FU + Leucovorin); 63% were previously treated with both FOLFIRI and FOLFOX; 77% received prior Avastin(R); and 43% prior Erbitux(R). Prior treatment with single agent capecitabine was excluded.

The primary endpoints of this study were to measure 1) Time to Progression (TTP); 2) Overall Response Rate (ORR), defined as the percentage of patients achieving a Complete Response (CR) or Partial Response (PR) by RECIST, and 3) Clinical Benefit Rate (CBR) defined as the percentage of patients on treatment for greater than three months with at least Stable Disease. Safety of perifosine plus capecitabine vs. capecitabine + placebo in this patient population was evaluated as a secondary endpoint. Perifosine in combination with capecitabine was well tolerated with hand/foot syndrome (14%) and anemia (11%) as the highest reported grade 3/4 adverse events.

Best response and median time to progression of capecitabine plus perifosine vs. capecitabine plus placebo were as follows:

Group	n	CR n (%)	PR n (%)	ORR n (%)	Stable Disease > 12 wks n (%)	CBR* n (%)	Median TTP
Xeloda + Perifosine	20	1 (5%)	3 (15%)	4 (20%)	11 (55%)	15 (75%)	28.9 weeks {95% CI (13, 48.1)}
Xeloda + Placebo	15	0	1 (7%)	1 (7%)	5 (33%)	6 (40%)	11 weeks {95% CI (9, 15.9)}

* CBR: Clinical Benefit Rate as defined by ORR + Stable Disease

Perifosine plus capecitabine more than doubled time to progression vs. capecitabine + placebo with a statistically significant p-value = 0.0006. In addition, perifosine plus capecitabine more than doubled the ORR and almost doubled the Clinical Benefit Rate vs. capecitabine plus placebo.

Although not a primary endpoint in the study, overall survival was analyzed with results as follows:

Group	Median Overall Survival*	% Change
Xeloda + Perifosine	22 months [95% CI (12.1, NR)]	35% increase**
Xeloda + Placebo	16.3 months [95% CI (5.3, 17.1)]	

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

** As of May 2009, median overall survival in the perifosine plus capecitabine patient group is ongoing with 10 of the 20 patients in this arm still alive.

Renal Cell Carcinoma

In May 2009, we announced data on the clinical activity of KRX-0401 (perifosine) as a treatment for advanced renal cell carcinoma (RCC). The data was presented in a poster session at the 45th Annual Meeting of the American Society of Clinical Oncology (ASCO), held in Orlando, Florida. The study enrolled a total of 50 patients, of which 46 patients were evaluable for response. Evaluable patients were defined as those who had greater than seven days of treatment. The primary endpoint of this study was clinical benefit, defined as response rate (RECIST), and progression-free survival (PFS) in RCC patients who failed a prior VEGF receptor inhibitor (sunitinib or sorafenib). Safety of perifosine in this patient population was evaluated as a secondary endpoint. Best response to single agent perifosine was as follows:

Group	n	PR n (%)	Stable Disease > 12 wks n (%)	CBR* n (%)	Median PFS (SD or greater)
All patients	46	5 (11%)	16 (35%)	21 (46%)	33 weeks [95% CI (24, 60)]

* CBR: Clinical Benefit Rate defined as patients with Stable Disease or Partial Response.

The median PFS for all 46 patients was 12.5 weeks [95% CI (11.9, 19)]. The median overall survival has not been reached with 33 of 46 patients (72%) still alive as of May 2009.

Also reported was the patient subgroup who had failed both a VEGF receptor inhibitor (sunitinib or sorafenib) and an mTOR inhibitor (either everolimus or temsirolimus). For this group, best response and median PFS to single agent perifosine was as follows:

Group	n	PR n (%)	Stable Disease > 12 wks n (%)	CBR* n (%)	Median PFS (SD or greater)
VEGF + mTOR	16	1 (6%)	7 (44%)	8 (50%)	16 weeks [95% CI (11.7, 33.6)]

Three patients out of the group of patients previously treated with and failed both a VEGF and an mTOR inhibitor remain on active treatment, out 5, 9 and 17 months as of May 2009.

Pediatric Solid Tumors

In July 2009, we announced the initiation of a Phase 1 clinical study to evaluate KRX-0401 (perifosine) as a single agent treatment for recurrent solid tumors in pediatric patients. This Phase 1 study is now open for enrollment at Memorial Sloan-Kettering Cancer Center in New York City. The study is being fully funded by an external grant provided by a private organization.

Zerenex (ferric citrate)

Effective on June 8, 2009, we entered into an Amended and Restated Sublicense Agreement (the “Revised Agreement”) with JT and Torii. The parties had originally entered into a sublicense agreement on September 26, 2007. As a result of the Revised Agreement, we no longer have significant on-going involvement or obligations under the sublicense agreement. As such, in accordance with our revenue recognition policies, all deferred revenue balances pertaining to this sublicense agreement have been recognized as revenue in the three months ended June 30, 2009.

In June 2009, we announced results of the U.S. Phase 2 study of Zerenex for the treatment of elevated serum phosphorous levels, or hyperphosphatemia, in patients with end-stage renal disease (ESRD) on thrice weekly hemodialysis. The study was a multicenter, open-label clinical trial, which enrolled 55 patients. The primary objective of this study was to assess the tolerability and safety of Zerenex with doses ranging from approximately 1 gram per day to 12 grams per day.

The top line efficacy and safety results from this Phase 2 study were submitted to the FDA, and discussed at a recent face to face meeting with the Division of Cardiovascular and Renal Drug Products. The FDA also reviewed the final reports for the 90-day rat and 16-week canine toxicology studies. The FDA indicated that the results of the Phase 2 study and the toxicology studies were adequate to support entry into a Phase 3 program. Keryx is in the process of finalizing the Phase 3 program in consultation with the FDA.

The FDA also reviewed the protocols for the ongoing chronic toxicology studies (6-month rat and 42-week canine), which can be completed after the U.S. Phase 3 program has begun.

In the first part of the Phase 2 study, 34 ESRD patients who were taking approximately 6 to 15 tablets/capsules per day of calcium acetate, calcium carbonate, lanthanum carbonate or sevelamer hydrochloride or any combination of these agents were eligible for enrollment and immediately switched to a starting dose of 4.5 grams per day of Zerenex. In the second part of the study, 21 ESRD patients who were taking greater than 12 tablets/capsules per day of calcium acetate, calcium carbonate, lanthanum carbonate or sevelamer hydrochloride or any combination of these agents were eligible for enrollment and immediately switched to a starting dose of 6.0 grams per day of Zerenex. Patients were treated with Zerenex for four weeks and were titrated weekly to achieve and maintain normal serum phosphorus levels, between 3.5 to 5.5 mg/dL, the therapeutic goal.

Although designed primarily as a safety study, key efficacy parameters were evaluated, with results as follows:

At baseline:

- Baseline mean +/- standard deviation (SD) serum phosphorus was approximately 5.9 +/- 1.5 mg/dL immediately prior to the switch to Zerenex;

- The average daily dose of PhosLo(R) (calcium acetate) was 6.9 grams per day and for Renagel(R) (sevelamer hydrochloride) was 9.9 grams per day, for patients not on combination therapy prior to the switch to Zerenex.

Following the treatment period (four weeks on Zerenex):

- At the end of the treatment period (after four weeks on Zerenex) the mean +/- SD serum phosphorus was approximately 5.4 +/- 1.3 mg/dL;

    - The average daily dose of Zerenex at the end of four weeks of treatment was 6.8 grams per day;

In the subset of 29 patients who had a serum phosphorus above the normal range (> 5.5 mg/dL) at baseline, immediately prior to the switch to Zerenex, the mean (SD) baseline serum phosphorus was 7.0 (1.1) mg/dL, and at the end of treatment with Zerenex the mean (SD) serum phosphorus was 5.6 (1.6) mg/dL;

In the Phase 2 study, there were four serious adverse events which were deemed unrelated to Zerenex. Darkened stool was reported in the study and was associated with the presence of iron in the gastrointestinal tract. With the exception of the reporting of darkened stool as an (asymptomatic) adverse event, the gastrointestinal adverse event profile was similar in incidence to that reported for other currently marketed phosphate binders. There was no increase in serum calcium noted in the study.

General Corporate

On May 20, 2009, we announced the appointment of Ron Bentsur as our Chief Executive Officer. The terms of Mr. Bentsur's employment are being finalized and will be set forth in an employment agreement with us. As an inducement to his employment, on May 20, 2009, we granted Mr. Bentsur options to purchase 600,000 shares of our common stock, at an exercise price equal to the fair market value of the stock on the date of grant. The options will vest in equal annual installments over a four-year period or upon an earlier change in control of Keryx. The options were granted as an inducement award and were not issued under our 2007 Incentive Plan.

On June 16, 2009, Ron Bentsur was appointed to our Board of Directors by a unanimous vote of our directors, and Michael P. Tarnok was appointed Chairman of the Board by unanimous vote of our directors. Mr. Tarnok has served on our Board of Directors since September 2007.

On June 17, 2009, we issued a press release announcing that we had received a letter from The NASDAQ Stock Market confirming that we had regained compliance with the minimum bid price requirement for continued listing on The NASDAQ Capital Market under Listing Rule 5550(a)(2). We also received a letter from the NASDAQ Listing Qualifications Hearings Panel (the "Panel") confirming that we had demonstrated a market value of listed securities over the required minimum of $35 million for 10 consecutive trading days, for continued listing on The NASDAQ Capital Market under Listing Rule 5550(b)(2), and that the Panel has determined to continue the listing of our securities on The NASDAQ Stock Market.

On August 4, 2009, we announced that we and Alfa Wassermann S.p.A. settled a dispute over issues arising from the terminated license agreement for Sulonex (sulodexide). Under the terms of the settlement agreement, Alfa Wassermann will pay Keryx US$3,500,000 (of which US$2,750,000 was received on July 31, 2009, and US$750,000 will be paid to Keryx on or before July 30, 2010), and we are required to deliver to Alfa Wassermann all of our data, information and other intellectual property related to Sulonex.

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 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.

Our other revenues consist of fees and payments arising from technology transfer, termination and settlement agreements related to our prior license agreements.

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, restricted stock and warrants. 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 as a result of Statement of Financial Accounting

Standards (“SFAS”) No. 123R, “Share-Based Payment” (“SFAS No. 123R”), which we adopted on January 1, 2006.

For awards of options and warrants to consultants and other third-parties, compensation expense is determined at the “measurement date,” in accordance with the fair value method prescribed by the provisions of Emerging Issues Task Force (“EITF”) Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services” (“EITF 96-18”). 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.

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, 2009 and June 30, 2008

License Revenue. License revenue increased by $17,962,000 to $18,289,000 for the three months ended June 30, 2009, as compared to $327,000 for the three months ended June 30, 2008. The increase in license revenue during the three months ended June 30, 2009, was due to the recognition of deferred revenue related to the JT and Torii sublicense agreement originally signed in September 2007, and amended and restated on June 8, 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.

Service Revenue. There was no service revenue in the three months ended June 30, 2009, as compared to service revenue of $62,000 for the three months ended June 30, 2008. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2009.

Other Revenue. 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. There was no other revenue for the three months ended June 30, 2008. We do not expect our other revenue to have a material impact on our financial results during the remainder of 2009.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants increased by $110,000 to $361,000 for the three months ended June 30, 2009, as compared to $251,000 for the three months ended June 30, 2008. The increase in non-cash compensation expense in the three months ended June 30, 2009, as compared to June 30, 2008, was primarily related to reduced expense in the three months ended June 30, 2008 due to forfeitures of equity awards by terminated research and development personnel associated with the 2008 restructuring.

Other Research and Development Expenses. Other research and development expenses decreased by $2,786,000 to $1,456,000 for the three months ended June 30, 2009, as compared to $4,242,000 for the three months ended June 30, 2008. The decrease in other research and development expenses was due primarily to a $1,756,000 reduction in research and development expenses related to KRX-0401, primarily due to reductions in headcount and other expenses related to this development program, and a $996,000 reduction in research and development expenses related to the cessation of the development of Sulonex in March 2008. We expect our other research and development

costs to increase for the remainder of 2009 due to the preparation for, and initiation of, our expected Phase 3 clinical programs for our drug candidates.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense (selling, general and administrative) related to equity incentive grants decreased by $739,000 to $1,028,000 for the three months ended June 30, 2009, as compared to an expense of $1,767,000 for the three months ended June 30, 2008. The decrease was primarily due to a $1,368,000 decrease in non-cash compensation related to equity incentive grants previously issued to Mr. Weiss, our former chief executive officer, who was terminated on April 23, 2009, partially offset by $660,000 in non-cash compensation associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.

Other Selling General and Administrative Expenses. Other selling, general and administrative expenses decreased by $550,000 to $1,528,000 for the three months ended June 30, 2009, as compared to an expense of $2,078,000 for the three months ended June 30, 2008. The decrease was primarily related to a reduction of expenses as a result of the 2008 Restructuring, offset by approximately $551,000 of expense for severance and notice pay related to the termination of our former chief executive officer on April 23, 2009. We expect our other selling, general and administrative expenses to decrease for the remainder of 2009.

Interest and Other Income (Expense), Net. Interest and other income (expense), net, decreased by $133,000 to $141,000 for the three months ended June 30, 2009, as compared to $274,000 for the three months ended June 30, 2008. The decrease in interest and other income (expense) was primarily due a lower level of invested funds and lower interest rates as compared to the comparable period last year.

Six months ended June 30, 2009 and June 30, 2008

License Revenue. License revenue increased by $21,090,000 to $21,616,000 for the six months ended June 30, 2009, as compared to $526,000 for the six months ended June 30, 2008. The increase in license revenue during the six months ended June 30, 2009, was primarily due 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 on June 8, 2009, as discussed above. In addition, during the six months ended June 30, 2009, we recognized $3.0 million in license revenue from a milestone received from JT and Torii due to their initiation of a Phase 2 clinical study of Zerenex in Japan.

Service Revenue. Service revenue decreased by $59,000 to $3,000 for the six months ended June 30, 2009, as compared to service revenue of $62,000 for the six months ended June 30, 2008. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2009.

Other Revenue. 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. There was no other revenue for the six months ended June 30, 2008. We do not expect our other revenue to have a material impact on our financial results during the remainder of 2009.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense (research and development) related to equity incentive grants increased by $1,291,000 to $562,000 for the six months ended June 30, 2009, as compared to a credit of $729,000 for the six months ended June 30, 2008. Non-cash compensation expense in the six months ended June 30, 2008 included a $1,233,000 credit to expense related to stock options and restricted stock issued to our former President, who was terminated as part of the 2008 Restructuring.

Other Research and Development Expenses. Other research and development expenses decreased by $32,239,000 to $2,830,000 for the six months ended June 30, 2009, as compared to $35,069,000 for the six months ended June 30,

2008. The decrease in other research and development expenses was due primarily to a $26,890,000 reduction in research and development expenses related to the cessation of the development of Sulonex in March 2008. Included in the research and development expenses related to Sulonex for the six months ended June 30, 2008 are an $11,037,000 impairment charge related to the write-down of the assets of the Sulonex manufacturing suite to their fair value following the cessation of our development of Sulonex, and a $2,063,000 expense for costs relating to the required restoration of the leased manufacturing facility to its original condition. For more information regarding these expenses please see “Note 4 - Restructuring” above. In addition to the $26,890,000 decrease in other research and development expenses related to Sulonex discussed above, there were decreases of $4,426,000, and $242,000 in research and development expenses related to KRX-0401 and Zerenex, respectively, primarily due to reductions in headcount and other expenses related to these development programs. We expect our other research and development costs to increase for the remainder of 2009 due to the preparation for, and initiation of, our expected Phase 3 clinical programs for our drug candidates.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense (selling, general and administrative) related to equity incentive grants decreased by $2,086,000 to $1,398,000 for the six months ended June 30, 2009, as compared to an expense of $3,484,000 for the six months ended June 30, 2008. The decrease was primarily due to a $2,525,000 decrease in non-cash compensation related to equity incentive grants previously issued to Mr. Weiss, our former chief executive officer, who was terminated on April 23, 2009, partially offset by $660,000 in non-cash compensation associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.

Other Selling General and Administrative Expenses. Other selling, general and administrative expenses decreased by $1,396,000 to $2,569,000 for the six months ended June 30, 2009, as compared to an expense of $3,965,000 for the six months ended June 30, 2008. The decrease was primarily related to a reduction of expenses as a result of the 2008 Restructuring, offset by approximately $551,000 of expense for severance and notice pay related to the termination of our chief executive officer on April 23, 2009. We expect our other selling, general and administrative expenses to decrease for the remainder of 2009.

Interest and Other Income (Expense), Net. Interest and other income (expense), net, increased by $1,177,000 to income of $248,000 for the six months ended June 30, 2009, as compared to an expense of $929,000 for the six months ended June 30, 2008. The six months ended June 30, 2008, includes $1,875,000 of impairment charges related to our investments in auction rate securities. In addition, interest income related to our investments decreased in the six months ended June 30, 2009, as compared to the six months ended June 30, 2008, due a lower level of invested funds and lower interest rates as compared to the comparable period last year.

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.

As of June 30, 2009, we had $13.4 million in cash, cash equivalents, interest receivable, and short-term investment securities, a decrease of $2.0 million from December 31, 2008. In addition, at June 30, 2009, we had $7.1 million in non-current auction rate securities, as discussed below. Cash used in operating activities in continuing operations for the six months ended June 30, 2009 was $2.0 million, as compared to $28.0 million for the six months ended June 30, 2008. This decrease in cash used in operating activities was due primarily to the cessation of the Sulonex program in March 2008, the 2008 Restructuring, and a $3.0 million non-refundable milestone payment received from JT and Torii associated with their initiation of a Phase 2 trial for Zerenex in Japan.

For the six months ended June 30, 2009, net cash provided by investing activities of $2.3 million was primarily the result of proceeds from the maturity of our investments in short-term securities. For the six months ended June 30, 2009, there was no net cash provided by financing activities.

As of June 30, 2009, $7.1 million of our investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. Auction rate securities are structured to provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally every 28 days. This mechanism has historically allowed existing investors either to rollover their holdings, whereby they would continue to own their respective securities, or liquidate their holdings by selling such securities at par. This auction process has historically provided a liquid market for these securities; however, the uncertainties in the credit markets have affected all of our holdings in auction rate securities. Since February 2008, the auctions for our auction rate securities have not had sufficient buyers

to cover investors' sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at June 30, 2009, we are uncertain as to when, or if, the liquidity issues relating to these investments will improve. We assessed the fair value of our auction rate securities portfolio. As a result of this valuation process, we recorded impairment charges totaling $0.1 and $1.9 million during the six months ended June 30, 2009 and 2008, respectively, for other-than-temporary declines in the value of our auction rate securities. These other-than-temporary impairment charges were included in interest and other income (expense), net. The estimated fair value of our remaining auction rate securities is $7.1 million at June 30, 2009.

We will continue to attempt to sell our auction rate securities until the auctions are successful; however, there is no assurance as to when, or if, the market for auction rate securities will stabilize. The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue or if these securities experience credit rating downgrades, we may incur additional impairment charges with respect to our auction rate securities portfolio, which could negatively affect our financial condition, cash flow and reported earnings, and the lack of liquidity of our auction rate securities could have a material impact on our ability to fund our operations.

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, 2009, we have an accumulated deficit of $317.3 million. We are dependent upon significant financing to provide the working capital necessary to execute our business plan. We have not yet commercialized any of our drug candidates and cannot be sure if we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates, if approved. We currently anticipate that our cash, cash equivalents and investment securities as of June 30, 2009, with the additional $3.5 million of settlement proceeds from Alfa Wassermann, but exclusive of our holdings in auction rate securities, are sufficient to meet our anticipated working capital needs and fund our business plan through the end of the second quarter of 2010. However, if we are not able to receive proceeds from some portion of our auction rate securities by the third quarter of 2010, we may not have the ability to continue as a going concern for any significant period beyond that point. The actual amount of funds that we will need to operate is subject to many factors, including the timing, design and conduct of clinical trials for our drug candidates. We are evaluating market conditions to determine the appropriate timing and extent to which we will seek to obtain additional debt, equity or other type of financing. If we determine that it is necessary to seek additional funding, there can be no assurance that we will be able to obtain any such funding on terms that are acceptable to us, if at all.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The factors discussed above, taken together with our limited cash, cash equivalents, and illiquid investments in auction rate securities raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

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. In applying SFAS No. 123R to 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.

In accordance with EITF 96-18, “Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,” 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 consistent with the provisions of Staff Accounting Bulletin (“SAB”) No. 104 and Emerging Issues Task Force (“EITF”) Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables.” 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.

Prior to discontinuing the sale of our diagnostic product, we had recognized diagnostic revenue when persuasive evidence of an arrangement existed, the product had been shipped, title and risk of loss had passed to the customer and collection from the customer was reasonably assured. Diagnostic revenue is included in discontinued operations.

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, 2009, there was approximately $3.2 million of goodwill on our consolidated balance sheet. SFAS No. 142, “Goodwill and Other Intangible Assets,” or SFAS No. 142, addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. This statement also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. SFAS No. 142 requires goodwill be tested 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 under SFAS No. 142 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 specifically regarding cash flows 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. In accordance with the guidance in SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets,” or SFAS No. 144, 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.

We had entered into a relationship with SPL, a U.S.-based contract manufacturer, for Sulonex to build a larger scale manufacturing suite within their current facility, which they would operate on our behalf. We spent approximately $11.3 million in capital expenditures building the suite. In accordance with the guidance in SFAS No. 144, with the cessation of our development of Sulonex in March 2008, we recognized an impairment charge of $11.0 million, which is included in other research and development expenses in the six months ended June 30, 2008, to write the assets down to their fair value of $300,000, the amount for which the assets were sold during the three months ended June 30, 2008.

Impairment of Investment Securities. As of June 30, 2009, $7.1 million of our investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. The uncertainties in the credit markets have affected all of our holdings in auction rate securities. Since February 2008, the auctions for our auction rate securities have not had sufficient buyers to cover investors’ sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at June 30, 2009, we are

uncertain as to when, or if, the liquidity issues relating to these investments will improve. We assessed the fair value of our auction rate securities portfolio. As a result of this valuation process, as described below, we recorded impairment charges totaling $0.1 and $1.9 million during the six months ended June 30, 2009 and 2008, respectively, for other-than-temporary declines in the value of our auction rate securities. These other-than-temporary impairment charges were included in interest and other income (expense), 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.

The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue or if these securities experience credit rating downgrades, we may incur additional impairment charges with respect to our auction rate securities portfolio. We continue to monitor the fair value of our auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges.

We review investment securities for impairment in accordance with the guidance in FSP SFAS 115-1 and 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," 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.

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 and auction rate securities 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, 2009, our portfolio of financial instruments consists of cash equivalents and long-term auction rate securities. Due to the short-term nature of our money market funds, we believe we have no material exposure to interest rate risk, and/or credit risk, arising from our money market funds.

As of June 30, 2009, $7.1 million of our investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. The uncertainties in the credit markets have affected all of our holdings in auction rate securities. Since February 2008, the auctions for our auction rate securities have not had sufficient buyers to cover investors' sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at June 30, 2009, we are uncertain as to when, or if, the liquidity issues relating to these investments will improve. We will continue to attempt to sell our auction rate securities until the auctions are successful. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any credit rating downgrades on the auction rate securities in our portfolio, we may incur additional impairment charges with respect to our auction rate securities portfolio, which could negatively affect our financial condition, cash flow and reported earnings. We continue to monitor the fair value of our auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges.

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. Assuming a 10% adverse change in the fair value of these securities overall, the fair value of our auction rate securities would decline approximately $700,000. However, each of our auction rate security investments have different features and are subject to different risks and therefore, any market decline would impact these securities to a different degree. 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.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2009, 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, 2009, 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, 2009, 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 April 2008, we notified Alfa Wasserman S.p.A. of our intention to terminate the License Agreement for sulodexide. We offered to transfer to Alfa Wasserman all regulatory applications as provided in the License Agreement and demanded payment by Alfa Wasserman of 25% of our development costs associated with sulodexide, as provided in the License Agreement. Alfa Wasserman itself served a notice of termination of the License Agreement on the alleged grounds that we were in material breach of the agreement for failing to diligently develop sulodexide by terminating the Phase 4 clinical trial. On August 4, 2009, we announced that we and Alfa Wassermann settled the dispute described above. Under the terms of the settlement agreement, Alfa Wassermann will pay Keryx US$3,500,000 (of which US$2,750,000 million was received on July 31, 2009, and US$750,000 will be paid to Keryx on or before July 30, 2010), and Keryx is required to deliver to Alfa Wassermann all of its data, information and other intellectual property related to sulodexide.

We are presently engaged in an arbitration proceeding with ICON Central Laboratories (“ICON”), the central laboratory we used for the clinical development of Sulonex (sulodexide), concerning certain fees related mainly to the provision of storage services pursuant to a series of service agreements. In March 2008, we terminated the agreements. ICON is claiming that we owe it $816,647 in unpaid invoices, much of which is made up of charges for annual storage fees. It is our position that we should not have to pay for storage fees incurred after the effective date of the termination of the agreements, and we intend to vigorously defend this proceeding on this basis, and have asserted a counterclaim for a refund of the unused portions of the annual storage fees already paid to ICON.

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, 2009, we had an accumulated deficit of approximately $317.3 million. As we continue our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

We have not yet commercialized any of our drug candidates and cannot be sure 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 as we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred to the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates and may also incur increased 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 on a cost-effective or timely basis. In addition, conducting multi-national studies adds another level of complexity and risk as we are subject to events affecting countries outside the United States. Negative or inconclusive results from the clinical trials we conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. We may change the delivery method or dosage levels which could affect efficacy results for the drug candidate. For example, our new one gram caplet formulation for Zerenex has not been tested in previous clinical trials, and therefore, there is no assurance that this new formulation will be safe and efficacious in a clinical trial setting. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

33

On August 3, 2009, we announced that we had reached agreement with the FDA regarding an Special Protocol Assessment, or SPA, on the design of a Phase 3 trial for KRX-0401 (perifosine) in relapsed or relapsed / refractory multiple myeloma patients previously treated with bortezomib (VELCADE®). Many companies who have been granted an SPA and/or the right to utilize an accelerated approval approach have failed to obtain approval. Since we are seeking accelerated approval under an SPA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint is achieved, an SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, changes in scientific or medical evidence or sentiment or internal inconsistency in the data prior to making their final decision. The FDA may also seek the guidance of an advisory panel prior to making their final decision.

Additionally, we have never filed a new drug application, or 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 not be answered by the time we file our NDA. Unless the FDA waives the requirement to answer any such unanswered questions, submission of an 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 and 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. 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 that has been seen in some high-dose, ferric citrate canine studies, may require us to do additional studies, which could delay the development of the drug or lead to a decision to discontinue development of the drug. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite positive results in initial clinical testing. Results from earlier studies may not be indicative of results from future clinical trials and the risk remains that a pivotal program may generate efficacy data that will be insufficient for the approval of the drug, or may raise 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 and there can be no assurance that safety and/or efficacy concerns from the prior data were overlooked or misinterpreted, which in subsequent, larger studies appear and prevent approval of such drug candidates. We will need to re-input our safety information on KRX-0401 into a Good Clinical Practice-compliant database and 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 and,

accordingly, may encounter unforeseen problems and delays in the approval process. Though we may engage a clinical research organization with experience in conducting regulatory trials, errors in the conduct, monitoring and/or auditing could invalidate the results from a regulatory perspective.

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 begin 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.

Given the current market conditions for raising capital, and given our limited resources, we may be forced to further restructure our workforce, and thus 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, including, without limitation, suspending development of KRX-0401 (perifosine) and/or Zerenex (ferric citrate).

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 will 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, 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. KRX-0401 (perifosine), if approved in the United States would compete with other anti-cancer agents, such as mTOR inhibitors. Wyeth Corp., Novartis AG and Ariad Pharmaceuticals are developing mTOR inhibitors for use in cancer and Wyeth'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), Millennium Pharmaceuticals, Inc. (a wholly-owned subsidiary of Takeda Pharmaceutical Company), Onyx Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc. and Vertex 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 the phosphoinositide 3-kinase (PI3K)/Akt pathway.

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 July 31, 2009, we had 15 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.

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 reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price) and government control of prescription drug pricing. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

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. 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 15 full and part-time employees as of July 31, 2009. 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, 2009, with the additional $3.5 million of settlement proceeds, but exclusive of our holdings in auction rate securities, are sufficient to meet our anticipated working capital needs and fund our business plan through the end of the second quarter of 2010. However, if we are not able to receive proceeds from some portion of our auction rate securities by the third quarter of 2010, we may not have the ability to continue as a going concern for any significant period beyond that point. We are evaluating market conditions to determine the appropriate timing and extent to which we will seek to obtain additional debt, equity or other type of financing. If we determine that it is necessary to seek additional funding, there can be no assurance that we will be able to obtain any such funding on terms that are acceptable to us, if at all.

In addition, the report of our independent registered public accounting firm covering our 2008 Consolidated Financial Statements, included in our Annual Report on Form 10-K for the year ended December 31, 2008, contains an explanatory paragraph that makes reference to uncertainty about our ability to continue as a going concern. Future reports may continue to contain this explanatory paragraph. 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 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;
- the value and liquidity of our investment securities, including our investments in auction rate securities; 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.

With respect to our auction rate securities, we will continue to attempt to sell these securities until the auctions are successful. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any credit rating downgrades on the auction rate securities in our portfolio, we may incur additional impairment charges with respect to our auction rate securities portfolio, which could negatively affect our financial condition, cash flow and reported earnings. We continue to monitor the fair value of our auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges. In addition, the lack of liquidity of our auction rate securities could have a material impact on our ability to fund our operations.

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). We do not hold a composition of matter patent covering Zerenex. 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 patent for KRX-0401, or for Zerenex, where we do not have a composition of matter patent, 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 method of use patents that we may hold.

- For our product candidates, the principal patent protection that covers or those we expect will cover, our product candidate is a method of use patent. This type of patent only protects the product when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical to our product that is labeled for an indication that is outside of the patented method, or for which there is a substantial use in commerce outside the patented method.

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 infringe or induce infringement of method of use patents, the practice is common and 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. We believe that KRX-0401 (perifosine) will be eligible for orphan drug designation; however, we cannot assure that KRX-0401, or any other drug candidates we may acquire or in-license, will obtain such orphan drug designation.

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.

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 3,372,422 shares of our common stock to former stockholders of ACCESS Oncology upon the achievement of certain milestones, of which 500,000 shares may be payable in the next 12 months if we reach the first milestone, which is enrollment of the first patient in a Phase 3 (or other pivotal) clinical trial for KRX-0401 (perifosine). We may also conclude, under certain circumstances, that it is in our best interest to settle this contingent share obligation for all or substantially all of such shares in advance of reaching any 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 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On June 16, 2009, we held our annual meeting of stockholders. The following matters were voted on by the stockholders: the election of directors, and the ratification of the appointment of UHY LLP as our independent registered public accounting firm for the year ending December 31, 2009. At the meeting, Kevin J. Cameron, Wyche Fowler, Jr., Jack Kaye and Michael P. Tarnok were re-elected to the Board.

The vote with respect to each nominee is set forth below:

Nominee	Total Votes For	Total Votes Withheld
Kevin J. Cameron	30,443,243	770,673
Wyche Fowler, Jr.	30,377,353	836,563
Jack Kaye	30,426,485	787,431
Michael P. Tarnok	29,953,435	1,260,481

The vote with respect to the ratification of the appointment of UHY LLP as our independent registered public accounting firm for the year ending December 31, 2009, is set forth below.

Total Votes For	Total Votes Withheld	Abstention and Broker Non-Votes
30,581,212	229,289	403,415

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 June 30, 2007, filed on August 9, 2007 and incorporated herein by reference.
10.1*	Amended and Restated Sublicense Agreement by and among the Company, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd., dated June 8, 2009.
10.2	Settlement Agreement and General Release between the Company and Alfa Wassermann S.p.A. dated July 30, 2009.
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 12, 2009.
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 12, 2009.
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 12, 2009.
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 12, 2009.

* Confidential treatment has been requested with respect to the omitted portions of this exhibit.

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 12, 2009	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*	Amended and Restated Sublicense Agreement by and among the Company, Japan Tobacco, Inc. and Torii Pharmaceutical Co., Ltd., dated June 8, 2009.
10.2	Settlement Agreement and General Release between the Company and Alfa Wassermann S.p.A. dated July 30, 2009.
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 12, 2009.
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 12, 2009.
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 12, 2009.
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 12, 2009.

* Confidential treatment has been requested with respect to the omitted portions of this exhibit.