KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 11, 2008

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, 2008

OR

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

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

Indicate by checkmark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes £ No x

There were 45,075,559 shares of the registrant's common stock, $0.001 par value, outstanding as of August 4, 2008.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2008

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations for increases or decreases in expenses;
- expectations for the development, manufacturing, regulatory approval, and commercialization of Zerenex™ (ferric citrate), KRX-0401 (perifosine), 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;
- expected losses;
- ability to continue to satisfy the listing requirements of the NASDAQ Stock Market; and
- expectations for future capital requirements.

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

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

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PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Balance Sheets as of June 30, 2008 and December 31, 2007

(in thousands, except share and per share amounts)

	June 30, 2008 (Unaudited)	December 31, 2007
Assets		
Current assets		
Cash and cash equivalents	$ 14,037	$ 19,065
Short-term investment securities	10,325	43,038
Interest receivable	99	283
Other current assets	1,201	1,330
Total current assets	25,662	63,716
Long-term investment securities	10,125	2,296
Property, plant and equipment, net	254	11,497
Goodwill	3,208	3,208
Other assets, net	102	344
Total assets	$ 39,351	$ 81,061
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 9,704	$ 19,134
Accrued compensation and related liabilities	864	1,254
Current portion of deferred revenue	1,495	1,023
Total current liabilities	12,063	21,411
Deferred revenue, net of current portion	17,962	11,022
Contingent equity rights	4,004	4,004
Other liabilities	156	202
Total liabilities	34,185	36,639
Commitments and contingencies (Note 6)		
Stockholders' equity		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)	—	—
Common stock, $0.001 par value per share (95,000,000 shares authorized, 45,163,007 and 43,751,101 shares issued, 45,083,059 and 43,671,153 shares outstanding at June 30, 2008 and December 31, 2007, respectively)	45	44
Additional paid-in capital	325,985	323,009
Treasury stock, at cost, 79,948 shares at June 30, 2008 and December 31, 2007, respectively	(357)	(357)
Deficit accumulated during the development stage	(320,507)	(278,274)
Total stockholders' equity	5,166	44,422
Total liabilities and stockholders' equity	$ 39,351	$ 81,061

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

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Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statements of Operations
for the Three and Six Months Ended June 30, 2008 and 2007 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,		Amounts accumulated during the development stage
	2008	2007	2008	2007	
Revenue:					
License revenue	$ 327	$ —	$ 526	$ —	$ 730
Diagnostic revenue	—	36	—	66	169
Service revenue	62	14	62	26	1,928
Other revenue	—	—	—	—	1,027
Total revenue	389	50	588	92	3,854
Operating expenses:					
Cost of diagnostics sold	—	16	—	38	178
Cost of services	14	30	14	62	2,182
Research and development:					
Non-cash compensation	251	1,178	(729)	2,173	17,083
Non-cash acquired in-process research and development	—	—	—	—	18,800
Other research and development	4,243	15,685	35,071	33,131	229,993
Total research and development	4,494	16,863	34,342	35,304	265,876
Selling, general and administrative:					
Non-cash compensation	1,767	1,407	3,484	3,413	24,419
Other selling, general and administrative	2,085	2,394	4,052	5,189	48,167
Total selling, general and administrative	3,852	3,801	7,536	8,602	72,586
Total operating expenses	8,360	20,710	41,892	44,006	340,822
Operating loss	(7,971)	(20,660)	(41,304)	(43,914)	(336,968)
Interest and other income (expense), net	274	1,200	(929)	2,641	16,988
Net loss before income taxes	(7,697)	(19,460)	(42,233)	(41,273)	(319,980)
Income taxes	—	—	—	—	527
Net loss	$ (7,697)	$ (19,460)	$ (42,233)	$ (41,273)	$ (320,507)

Basic and diluted loss per common share	$ (0.17)	$ (0.45)	$ (0.96)	$ (0.95)	$ (13.66)
Weighted average shares used in computing basic and diluted net loss per common share	44,095,873	43,556,475	43,906,974	43,531,495	23,469,443

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statement of Changes in Stockholders' Equity
for the Six Months Ended June 30, 2008 (Unaudited)

(in thousands, except share amounts)

	Common stock		Additional paid-in capital
	Shares	Amount	
Balance at December 31, 2007	43,751,101	$ 44	$ 323,009
Changes during the period:			
Issuance of restricted stock	1,401,906	1	—
Forfeiture of restricted stock	(65,000)	(—)*	—
Exercise of options	75,000	—*	222
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	2,754
Net loss	—	—	—
Balance at June 30, 2008	45,163,007	$ 45	$ 325,985

	Treasury stock		Deficit accumulated during the development Stage	Total
	Shares	Amount		
Balance at December 31, 2007	79,948	$ (357)	$ (278,274)	$ 44,422
Changes during the period:				
Issuance of restricted stock	—	—	—	1
Forfeiture of restricted stock	—	—	—	(—)*
Exercise of options	—	—	—	222
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	—	2,754
Net loss	—	—	(42,233)	(42,233)
Balance at June 30, 2008	79,948	$ (357)	$ (320,507)	$ 5,166

* Amount less than one thousand dollars.

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statements of Cash Flows
for the Six Months Ended June 30, 2008 and 2007 (Unaudited)

(in thousands)

	Six months ended June 30,		Amounts accumulated during the development stage
	2008	**2007**	**stage**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (42,233)	$ (41,273)	$ (320,507)
Adjustments to reconcile net loss to cash flows used in operating activities:			
Acquired in-process research and development	—	—	18,800
Stock compensation expense	2,755	5,586	41,502
Issuance of common stock to technology licensor	—	—	359
Interest on convertible notes settled through issuance of preferred shares	—	—	253
Depreciation and amortization	69	84	3,055
(Gain) loss on disposal of property, plant and equipment	—	(1)	171
Impairment of investment securities	1,875	—	1,875
Other impairment charges	11,037	600	14,119
Exchange rate differences	—	—	94
Changes in assets and liabilities, net of effects of acquisitions:			
Decrease (increase) in other current assets	129	1,622	(729)
Decrease (increase) in accrued interest receivable	184	143	(99)
Decrease (increase) in security deposits	242	—	(21)
(Decrease) increase in accounts payable and accrued expenses	(9,130)	(248)	7,959
(Decrease) increase in accrued compensation and related liabilities	(390)	(928)	269
(Decrease) increase in other liabilities	(46)	(46)	1
Increase (decrease) in deferred revenue	7,412	65	19,001
Net cash used in operating activities	(28,096)	(34,396)	(213,898)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(163)	(2,763)	(16,310)
Proceeds from disposals of property, plant and equipment	—	15	740
Increase in note and accrued interest receivable from related party	—	—	(356)
Payments of transaction costs	—	—	(231)
Increase in other assets	—	—	(1,192)
Investment in held-to-maturity short-term securities	(32)	(2,034)	(55,081)

Proceeds from maturity of held-to-maturity short-term securities	12,842	8,504	88,883
Investment in available-for-sale short-term securities	(12,000)	(10,000)	(126,800)
Proceeds from sale of available-for-sale short-term securities	22,200	18,750	114,800
Investment in held-to-maturity long-term securities	(1)	(2,329)	(44,320)
Proceeds from maturity of held-to-maturity long-term securities	—	2	193
Net cash provided by (used in) investing activities	22,846	10,145	(39,674)

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statements of Cash Flows
for the Six Months Ended June 30, 2008 and 2007 (Unaudited)
(continued)

(in thousands)

	Six months ended June 30,		Amounts accumulated during the development stage
	2008	**2007**	**stage**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from short-term loans	$ —	$ —	$ 500
Proceeds from long-term loans	—	—	3,251
Payment of assumed notes payable and accrued interest in connection with the ACCESS Oncology acquisition	—	—	(6,322)
Issuance of convertible note, net	—	—	2,150
Issuance of preferred shares, net	—	—	8,453
Receipts on account of shares previously issued	—	—	7
Proceeds from initial public offering, net	—	—	46,298
Proceeds from subsequent public offerings, net	—	—	158,487
Proceeds from private placements, net	—	—	45,795
Proceeds from exercise of options and warrants	222	203	9,342
Purchase of treasury stock	—	(268)	(357)
Net cash provided by financing activities	222	(65)	267,604
Cash acquired in acquisition	—	—	99
Effect of exchange rate on cash	—	—	(94)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(5,028)	(24,316)	14,037
Cash and cash equivalents at beginning of period	19,065	48,736	—
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 14,037	$ 24,420	$ 14,037
NON - CASH TRANSACTIONS			
Sale of manufacturing facility assets	$ 300	$ —	$ 300
Issuance of common stock in connection with acquisition	—	—	9,635
Contingent equity rights in connection with acquisition	—	—	4,004
Assumption of liabilities in connection with acquisition	—	—	9,068
Conversion of short-term loans into contributed capital	—	—	500
Conversion of long-term loans into contributed capital	—	—	2,681
Conversion of long-term loans into convertible notes of Partec	—	—	570

Conversion of convertible notes of Partec and accrued interest into stock in Keryx		—	—	2,973
Issuance of warrants to related party as finder's fee in private placement		—	—	114
Declaration of stock dividend		—	—	3
SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION				
Cash paid for interest	$	—	$ —$	1,166
Cash paid for income taxes	$	—	$ —$	468

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
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, novel pharmaceutical products for the treatment of life-threatening diseases, including renal disease and cancer. The Company was incorporated in Delaware in October 1998 (under the name Paramount Pharmaceuticals, Inc., which was later changed to Lakaro Biopharmaceuticals, Inc. in November 1999, and finally to Keryx Biopharmaceuticals, Inc. in January 2000). The Company commenced activities in November 1999, focusing on the development and commercialization of clinical compounds and core technologies for the life sciences.

Until November 1999, most of the Company's activities were carried out by Partec Limited, an Israeli corporation formed in December 1996, and its subsidiaries - SignalSite Inc. (85% owned), SignalSite Israel Ltd. (wholly-owned), Vectagen Inc. (87.25% owned) and Vectagen Israel Ltd. (wholly-owned) (hereinafter collectively referred to as "Partec"). In November 1999, the Company acquired substantially all of the assets and liabilities of Partec and, as of that date, the activities formerly carried out by Partec were performed by the Company. On the date of the acquisition, Keryx and Partec were entities under common control (the controlling interest owned approximately 79.7% of Keryx and approximately 76% of Partec) and accordingly, the assets and liabilities were recorded at their historical cost basis by means of "as if" pooling, with Partec being presented as a predecessor company. Consequently, these financial statements include the activities performed in previous periods by Partec by aggregating the relevant historical financial information with the financial statements of the Company as if they had formed a discrete operation under common management for the entire development stage.

The Company owns a 100% interest in each of ACCESS Oncology, Inc., Neryx Biopharmaceuticals, Inc., and Accumin Diagnostics, Inc., all U.S. corporations incorporated in the State of Delaware, and Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd., each organized in Israel. In 2003, the Company's subsidiaries in Israel ceased operations and are currently in the process of being closed down. Most of the Company's biopharmaceutical development and substantially all of its administrative operations during the three and six months ended June 30, 2008 and 2007, were conducted in the United States of America.

On February 5, 2004, the Company completed the acquisition of ACCESS Oncology, Inc. and its subsidiaries ("ACCESS Oncology"). The transaction was structured as a merger of AXO Acquisition Corp., a Delaware corporation and the Company's wholly-owned subsidiary, with and into ACCESS Oncology, with ACCESS Oncology remaining as the surviving corporation and a wholly-owned subsidiary of the Company. The transaction was accounted for under the purchase method of accounting. The assets and liabilities of ACCESS Oncology that the Company acquired and assumed pursuant to the acquisition have been included in the Company's consolidated financial statements as of February 5, 2004.

On April 6, 2006, Accumin Diagnostics, Inc., a wholly-owned subsidiary of the Company, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. The transaction was accounted for under the purchase method of accounting. The assets and liabilities of Accumin that the Company acquired and assumed pursuant to the acquisition have been included in the Company's consolidated financial statements as of April 6, 2006.

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 do 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, 2007. The results of operations for the three and six months ended June 30, 2008 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 operating losses since its inception and expects to continue to incur operating losses for the foreseeable future and may never become profitable. The Company has not generated any revenues from its planned principal operations and 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 complete its development efforts, obtain regulatory approval for its drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its drug candidates. The Company may continue to incur substantial operating losses even if it begins to generate revenues from its drug candidates, if approved. If the Company determines that it is necessary to seek additional funding, there can be no assurance that the Company will be able to obtain any such funding on terms that are acceptable to it, if at all.

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 investments securities (which are comprised of the auction rate securities we own) 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, 2008 and December 31, 2007:

(in thousands)	**June 30, 2008**	**December 31, 2007**
Short-term investment securities:		
Obligations of domestic governmental agencies (mature between October 2008 and May 2009) (held-to-maturity)	$ 10,325	$ 20,838
Auction rate securities (mature between 2031 and 2047) (available-for-sale)	—	22,200
Total short-term investment securities	$ 10,325	$ 43,038
Long-term investment securities:		
Obligations of domestic governmental agencies (held-to-maturity)	$ —	$ 2,296
Auction rate securities (mature between 2031 and 2047) (available-for-sale)	10,125	—
Total long-term investment securities	$ 10,125	$ 2,296

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 Company recognizes revenue on upfront payments and milestone 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 may recognize milestone payments in revenue upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones and royalties that are deferred will be recognized when earned under the agreements.

The Company recognizes diagnostic revenue when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured.

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

Stock-Based Compensation

The Company adopted Statement of Financial Accounting Standards ("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").

Net Loss per Share

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options and warrants outstanding as of June 30, 2008 and 2007, which are not included in the computation of net loss per share amounts, were 9,846,616 and 10,894,094, respectively.

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 sold during the three months ended June 30, 2008. The sale of the assets offset a 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.

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. The Company will continue to perform impairment tests under SFAS No. 142 annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

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, 2008, $10.1 million of the Company's long-term investment securities were auction rate securities, which represent interests in student loan-backed securities. 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 these investments are currently rated AA or higher, the Company is uncertain as to when, or if, the liquidity issues relating to these investments will improve. Given the complexity of auction rate securities and the lack of readily observable market quotes related to these investments, the Company obtained the assistance of an independent valuation firm, Pluris Valuation Advisors LLC, to assist management in assessing the fair value of its auction rate securities portfolio. As a result of this valuation process, the Company recorded impairment charges of $1.8 million and $0.1 million, in the three months ended March 31, 2008, and June 30, 2008, respectively, for other-than-temporary declines in the value of its auction rate securities to an estimated fair value of $10.1 million at June 30, 2008. These other-than-temporary impairment charges were included in interest and other income (expense), net. In addition, in the first quarter of 2008, the Company reclassified the entire auction rate securities portfolio from short-term to long-term investments due to the uncertainty of when the Company will be able to sell these securities.

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 included numerous assumptions such as 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.

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 will continue 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 impairments 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 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, 2008:

(in thousands)	Financial assets at fair value as of June 30, 2008 Level 1	Level 2	Level 3
Money market funds (1)	$ 11,014	$ —	$ —
Short-term investment securities (held-to-maturity) (2)	10,325	—	—
Auction rate securities (3)	—	—	10,125
Total	$ 21,339	$ —	$ 10,125

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

(2) Amortized cost approximates fair value.

(3) 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, 2008:

(in thousands)	Available-for-sale long-term investments
Balance at January 1, 2008	$ —
Transfer into Level 3 (1)	12,000
Total unrealized losses included in net loss	(1,811)
Balance at March 31, 2008	$ 10,189
Total unrealized losses included in net loss	(64)
Balance at June 30, 2008	$ 10,125

(1) Based on deteriorated market conditions experienced in the first quarter of 2008, the Company changed the fair value measurement methodology of its auction rate securities portfolio that the Company classifies as available-for-sale from quoted prices in active markets to a discounted cash flow model. Accordingly, these securities were re-classified from Level 1 to Level 3.

NOTE 3 – STOCKHOLDERS' EQUITY

Common Stock

The Company filed a shelf registration statement on Form S-3 (File No. 333-130809) with the Securities and Exchange Commission, or SEC, on December 30, 2005, that was declared effective by the SEC on January 13, 2006, covering shares of the Company's Common Stock having a value not to exceed $150 million. At June 30, 2008, $67 million remain available for future sale under this shelf registration statement. The Company may offer the remaining securities under its shelf registration from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interest of the Company and its stockholders. The Company believes that the shelf registration provides it with the flexibility to raise additional capital to finance its operations as needed. However, there are no assurances that the Company will be able to sell securities on acceptable terms, or at all, even though an effective shelf registration statement remains available. Securities sold via the shelf registration statement may dilute existing stockholders' interests in the Company.

Equity Incentive Plans

The following table summarizes stock option activity for the six months ended June 30, 2008:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2007	10,869,173	$ 7.69		
Granted	243,800	4.28		
Exercised	(75,000)	2.96		$ 259,900
Forfeited	(1,205,214)	10.35		
Expired	(308,119)	8.54		
Outstanding at June 30, 2008	9,524,640	$ 7.27	6.0	$ 119,804
Vested and expected to vest at June 30, 2008	9,466,026	$ 7.25	6.0	$ 119,794
Exercisable at June 30, 2008	7,644,167	$ 6.24	5.4	$ 119,504

Upon the exercise of stock options, the Company issues new shares. As of June 30, 2008, 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.

Certain employees and consultants have been awarded restricted stock under the 2004 Long-Term Incentive Plan and 2007 Incentive Plan. The restricted stock vests primarily over a period of two to four years. The following table summarizes restricted share activity for the six months ended June 30, 2008:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2007	138,334	$ 10.09	
Granted	1,401,906	0.52	
Vested	(50,000)	10.17	$ 24,500
Forfeited	(65,000)	10.37	
Outstanding at June 30, 2008	1,425,240	$ 0.66	$ 698,368

Shares available for the issuance of stock options or other stock-based awards under our stock option and incentive plans were 4,758,997 at June 30, 2008.

Warrants

	Warrants	Weighted-average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2007	321,976	$ 4.65	
Issued	—	—	
Exercised	—	—	

Canceled	—	—	
Outstanding at June 30, 2008	321,976	$ 4.65	$ 35,070

Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes 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 and the Company's assessment of its future volatility. 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,	
	2008	2007	2008	2007
Risk-free interest rates	2.9%	4.7%	2.6%	4.7%
Dividend yield	—	—	—	—
Volatility	111.0%	71.4%	76.3%	71.6%
Weighted-average expected term	2.0 years	4.4 years	4.3 years	4.5 years

The weighted average grant date fair value of options granted for the three months ended June 30, 2008 and 2007, was $0.28 and $6.25 per option, respectively, and for the six months ended June 30, 2008 and 2007, was $2.40 and $6.42 per option, respectively. The Company used historical information, industry data and the Company's assessment of future forfeitures to estimate forfeitures within the valuation model. As of June 30, 2008, there was $8.3 million and $0.9 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over a weighted-average period of 2.0 years and 2.9 years, respectively. The amounts do not include, as of June 30, 2008, 175,000 options outstanding, which are milestone-based and vest upon certain corporate milestones, such as FDA approval of our drug candidates and market capitalization targets. Stock-based compensation will be measured and recorded if and when a milestone occurs.

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%. 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, Vice President, Finance, 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 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	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

(in thousands)

Restructuring liabilities at December 31, 2007	$	—
Manufacturing facility restoration		2,063
Accrued severance		723
Restructuring liabilities at March 31, 2008	$	2,786
Payment of manufacturing facility restoration		(2,063)
Payment of severance		(395)
Restructuring liabilities at June 30, 2008	$	328

The Company expects to pay out the remaining $328,000 of restructuring liabilities accrued for at June 30, 2008 over the next six months.

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.

An upfront payment of $12.0 million, which was received in October 2007, is 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 represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement. The Company recorded license revenue of approximately $194,000 and $387,000 in the three and six months ended June 30, 2008, respectively, and, at June 30, 2008, has deferred revenue of approximately $11.4 million (approximately $774,000 of which has been classified as a current liability), associated with this $12.0 million payment.

An additional milestone payment of $8.0 million, for the achievement of certain milestones reached in March 2008, was received in April 2008, and is being recognized as license revenue on a straight-line basis over the life of the agreement (as discussed above). The Company recorded license revenue of approximately $133,000 and $139,000 for the three and six months ended June 30, 2008, and, at June 30, 2008, has deferred revenue of approximately $7.9 million (approximately $533,000 of which has been classified as a current liability) associated with this $8.0 million payment. The Company may receive up to an additional $80.0 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 – COMMITMENTS ANDCONTINGENCIES

Obligations and Commitments

As of June 30, 2008, the Company has known contractual obligations, commitments and contingencies of $2,676,000. Of this amount, $1,290,000 relates to research and development agreements (relating to the Company’s KRX-0401 and Zerenex clinical programs), all of which is due within the next year. Certain of these commitments are contingent upon the Company’s continuing development of its drug candidates. The additional $1,386,000 relates to the Company’s operating lease obligations, of which $629,000 is due within the next year, with the remaining balance due as per the schedule below.

		Payment due by period			
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Research and development agreements	$ 1,290,000	$ 1,290,000	$ —	$ —	$ —
Operating leases	1,386,000	629,000	757,000	—	—
Total	$ 2,676,000	$ 1,919,000	$ 757,000	$ —	$ —

The Company has undertaken to make contingent milestone payments to certain of its licensors of up to approximately $73.0 million over the life of the licenses, of which approximately $60.5 million will be due upon or following regulatory approval of the licensed drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, the Company remains obligated to pay one licensor $75,000 annually until the license expires. The Company has also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights (up to 3,372,422 shares of the Company's common stock) if its drug candidates meet certain development milestones. A substantial portion of the contingent shares would be payable to related parties of the Company. The contingent equity rights have been recognized as a non-current liability on the consolidated balance sheet. The Company has also entered into a royalty arrangement under which its wholly-owned subsidiary may be required to pay up to a maximum of $16.1 million to AusAm on revenue from a next generation product following FDA marketing approval, as part of the Company's acquisition of Accumin. The uncertainty relating to the timing of the commitments described in this paragraph prevents the Company from including them in the table above.

Litigation

In July 2003, Keryx (Israel) Ltd., one of the Company's Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of the Company's Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, the Company's Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,316,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. The Company intends to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. and Michael S. Weiss to vacate service of process outside of Israel was held in June 2006. On October 15, 2006, the Court held that the service of the claim against Mr. Weiss is vacated. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. However, the service against the Company was sustained. The Company appealed this holding. The appeal was denied on June 18, 2007, and the Company filed a petition for certiorari to the Supreme Court of Israel. The Company's motion for certiorari was denied as well. The Company filed its testimonial affidavit along with an expert opinion contesting the interest and the accumulated debt claimed by plaintiff. The trial is scheduled for November 2008. The Court will hear the motion to dismiss parallel to the trial. The Company has not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

The Company prevailed in an arbitration proceeding with Alfa Wasserman concerning certain terms of the 1998 License Agreement between Alfa Wasserman and the Company related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. An arbitration hearing was held in October 2007 and the arbitrator issued his decision on March 25, 2008, rejecting Alfa Wasserman's claims that the Company was in material breach of the License Agreement. Under the terms of the License Agreement, the Company may be entitled to recoup a portion of its legal fees and expenses associated with the arbitration from Alfa Wasserman. The Company's claim for legal fees is presently before the arbitrator for determination.

In April 2008, the Company notified Alfa Wasserman of its intention to terminate the License Agreement. The Company offered to transfer to Alfa Wasserman all regulatory applications as provided in the License Agreement and demanded payment by Alfa Wasserman of 25% of the Company's 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 the Company is in material breach of the agreement for failing to diligently develop sulodexide by terminating the Phase 4 clinical trial. By seeking to terminate the License Agreement, Alfa Wasserman is thereby seeking to avoid reimbursement to Keryx of development costs. The Company intends to submit its claim for development costs and Alfa Wasserman's claim of material breach to arbitration for resolution.

In November 2007, the Company initiated an action in the US District Court for the Southern District of New York against Panion to enjoin Panion from improperly terminating the November 2005 License Agreement between Panion and the Company for an alleged breach of contract by Keryx related to certain manufacturing provisions of the agreement, to enjoin Panion from interfering with the Company's contractual relationships with certain third-parties, as well as to enforce the Company's right with respect to the prosecution of certain patents. On November 27, 2007, the Court granted the Company a motion for a preliminary injunction. Panion asserted counterclaims for breach of contract relating to certain manufacturing provisions of the license agreement. On March 17, 2008, the parties agreed to settle their dispute and as a result have entered into an Amended and Restated License Agreement, which resulted in an expansion of the scope of the original license grant and granted to the Company greater control over patent prosecution and maintenance. In consideration of these amendments and the settlement of the litigation, the Company paid Panion $2.5 million in March 2008, which had been accrued for in 2007. Following execution of the Amended and Restated License Agreement, the parties entered a voluntary dismissal of the action, including Panion's asserted counterclaims.

NOTE 7 – SEGMENT INFORMATION

The Company has three reportable segments: Diagnostics, Services and Products. The Diagnostics business sells diagnostic products for the direct measurement of total, intact urinary albumin. 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, novel 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 and six month periods were as follows:

	Revenue				
(in thousands)	Three months ended June 30, 2008	2007	Six months ended June 30, 2008	2007	Amounts accumulated during the development Stage
Diagnostics	$ —	$ 36	$ —	$ 66	$ 169
Services	62	14	62	26	1,928
Products	327	—	526	—	1,757
Total	$ 389	$ 50	$ 588	$ 92	$ 3,854

	Operating loss				
	Three months ended June 30,		Six months ended June 30,		Amounts accumulated during the

(in thousands)	2008	2007	2008	2007	development Stage
Diagnostics	$ (8)	$ (21)	$ (89)	$ (695)	$ (1,861)
Services	48	(16)	48	(36)	(254)
Products	(8,011)	(20,623)	(41,263)	(43,183)	(334,852)
Total	$ (7,971)	$ (20,660)	$ (41,304)	$ (43,914)	$ (336,967)

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

	Net loss				
(in thousands)	Three months ended June 30, 2008	2007	Six months ended June 30, 2008	2007	Amounts accumulated during the development Stage
Operating losses of reportable segments	$ (7,971)	$ (20,660)	$ (41,304)	$ (43,914)	$ (336,968)
Interest and other income (expense), net	274	1,200	(929)	2,641	16,988
Income taxes	—	—	—	—	(527)
Consolidated net loss	$ (7,697)	$ (19,460)	$ (42,233)	$ (41,273)	$ (320,507)

	Assets (1)	
(in thousands)	As of June 30, 2008	As of December 31, 2007
Diagnostics	$ 84	$ 87
Services	—	—
Products	4,681	16,293
Total assets of reportable segments	4,765	16,380
Cash, cash equivalents, interest receivable and investment securities	34,586	64,681
Consolidated total assets	$ 39,351	$ 81,061

(1) Assets for our reportable segments include fixed assets, goodwill, as well as accounts receivable and inventory.

The carrying amount of goodwill by reportable segment as of June 30, 2008 and December 31, 2007, was as follows:

	Goodwill	
(in thousands)	June 30, 2008	December 31, 2007
Diagnostics	$ —	$ —
Services	—	—
Products	3,208	3,208
Total	$ 3,208	$ 3,208

ITEM 2. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

Unless the context requires otherwise, references in this report to "Keryx," the "Company," "we," "us" and "our" refer to Keryx Biopharmaceuticals, Inc., its predecessor company and our subsidiaries.

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results

anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in “Risk Factors.” See also the “Special Cautionary Notice Regarding Forward-Looking Statements” set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management’s discussion and analysis and the audited consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2007.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including renal disease and cancer. We are developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 2 clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. We are also developing clinical-stage oncology compounds, including KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth. 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. We also have an in-licensing and acquisition program designed to identify and acquire additional drug candidates. 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.

The table below summarizes the status of our product pipeline.

Product candidate	**Target indication**	**Development status**
Endocrine/Renal		
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	Phase 2
Oncology		
KRX-0401 (perifosine)	Multiple forms of cancer	Phase 2
KRX-0404 (ErPC)	Multiple forms of cancer	Pre-clinical
Neurology		
KRX-0701 (dexlipotam)	Diabetic neuropathy	Phase 2
KRX-0501	Neurological disorders	Phase 1

Recent Developments

KRX-0401 (perifosine)

In June 2008, Phase 2 results of KRX-0401 (perifosine) in patients with relapsed/refractory Waldenstroms macroglobulinemia was presented at the 44th Annual Meeting of the American Society of Clinical Oncology. A poster presentation by Dr. Irene Ghobrial, Instructor of Medicine at the Dana-Farber Cancer Institute, discussed the Phase 2 results on the single agent clinical activity of perifosine in patients with both relapsed and/or refractory Waldenstroms macroglobulinemia.

Thirty-seven patients (median age 65 years) with advanced Waldenstroms macroglobulinemia (76% had at least two prior treatments) were enrolled, with most patients (>75%) previously treated with at least one course of therapy on rituximab. All patients were scheduled to receive 150 mg of perifosine daily in a 28 day cycle for at least 6 cycles. Toxicities were generally well managed and tolerated with Grade 1 & 2 gastrointestinal-related toxicities occurring in 30% of the patients. Thirty-six patients were evaluable for response, assessed by criteria established at the second consensus panel for Waldenstroms macroglobulinemia, with results as follows:

Response	N	Median Duration of Therapy (wks)
Partial Response	2 (5%)	60+, 24+
Minimal Response	10 (28%)	)

	36 (range 9 - 68+
ORR (PR + MR)	12 (33%)
Stable Disease	22 (61%)
Progression	2 (5%)

PR: > 50% reduction in IgM / MR: > 25% reduction in IgM / ORR: > Overall Response Rate

At the time of presentation, 11 of 36 patients remained on treatment and the median Time to Progression (TTP) had not been reached (8 cycles with a range of 2 - 17+).

General Corporate

We are a development stage company and have no drug product sales to date. 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, and, beginning in 2007, from the upfront and milestone payments from our Sublicense Agreement with Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii") and miscellaneous payments from our other prior licensing activities. We have devoted substantially all of our efforts to the identification, in-licensing and development 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 and in-licensing and acquisition activities.

Our license revenues currently consist of license fees arising from our agreement with JT and Torii. We recognize these revenues ratably over the estimated period which we will have certain ongoing responsibilities under the sublicense agreement, with un-amortized amounts recorded as deferred revenue.

Our diagnostic revenue is based on the sale of a diagnostic product for the direct measurement of total, intact urinary albumin. Diagnostic revenue is recognized when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured.

Our service revenues consist entirely of clinical trial management and site recruitment services. Revenues from providing these services are recognized as the services are provided. Deferred revenue is recorded when we receive a deposit or prepayment for services to be performed at a later date.

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

Our cost of diagnostics sold consists specifically of costs associated with the manufacture of the diagnostic products such as payments to third-party vendors, material costs and other support facilities associated with delivering of the diagnostics to our customers. Cost of diagnostics sold are recognized as diagnostic revenue is recognized.

Our cost of services consists of all costs specifically associated with our clinical trial management and site recruitment client programs such as salaries, benefits paid to personnel, payments to third-party vendors and other support facilities associated with delivering services to our clients. Costs of services are recognized as services are performed.

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, 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, general 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 stock options. The expense is included in the respective categories of expense in the 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, because some of the options, restricted stock and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

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, 2008 and June 30, 2007

License Revenue. License revenue was $327,000 for the three months ended June 30, 2008 as compared to no revenue for the three months ended June 30, 2007. License revenue for the three months ended June 30, 2008 was related to the amortization of a portion of the license fees of $12.0 million and milestone payment of $8.0 million associated with our sublicense agreement with JT and Torii. Such amounts were 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 represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement.

Diagnostic Revenue. We recognized no diagnostic revenue for the three months ended June 30, 2008, as compared to diagnostic revenue of $36,000 for the three months ended June 30, 2007. We do not expect our diagnostic revenue to have a material impact on our financial results during 2008.

Service Revenue. Service revenue increased by $48,000 to $62,000 for the three months ended June 30, 2008, as compared to service revenue of $14,000 for the three months ended June 30, 2007. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2008.

Cost of Diagnostics Sold. We recognized no cost of diagnostics sold for the three months ended June 30, 2008, as compared to an expense of $16,000 for the three months ended June 30, 2007. We do not expect our cost of diagnostics sold to have a material impact on our financial results during the remainder of 2008.

Cost of Services. Cost of services decreased by $16,000 to $14,000 for the three months ended June 30, 2008, as compared to an expense of $30,000 for the three months ended June 30, 2007. We do not expect our cost of services to have a material impact on our financial results during the remainder of 2008.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to equity incentive grants decreased by $927,000 to $251,000 for the three months ended June 30, 2008, as compared to an expense of $1,178,000 for the three months ended June 30, 2007. The decrease was primarily attributable to $674,000 of expense in the three months ended June 30, 2007 related to restricted stock granted to our former President, as well as due to a reduction in research and development personnel following our March 2008 restructuring.

Other Research and Development Expenses. Other research and development expenses decreased by $11,442,000 to $4,243,000 for the three months ended June 30, 2008, as compared to $15,685,000 for the three months ended June 30, 2007. The decrease in other research and development expenses was due primarily to a $10,390,000 million reduction in expenses related to the cessation of the development of Sulonex in March 2008, and an $852,000 decrease in expenses related to our other clinical compounds.

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We expect our other research and development costs to decrease during the remainder of 2008 as a result of the 2008 Restructuring, which was intended to reduce our cash burn rate and re-focus our development efforts.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to equity incentive grants increased by $360,000 to $1,767,000 for the three months ended June 30, 2008, as compared to an expense of $1,407,000 for the three months ended June 30, 2007. The increase was primarily related to a reduction of expense, in the three months ended June 30, 2007, of $479,000 associated with stock option forfeitures following the resignation of our chief financial officer in June 2007.

Other Selling General and Administrative Expenses. Other selling, general and administrative expenses decreased by $309,000 to $2,085,000 for the three months ended June 30, 2008, as compared to an expense of $2,394,000 for the three months ended June 30, 2007. The decrease was primarily related to a reduction of expenses as a result of the 2008 Restructuring.

We expect our other selling, general and administrative costs to decrease over the remainder of 2008 as a result of the 2008 Restructuring, which was intended to reduce our cash burn rate and re-focus our development efforts.

Interest and Other Income (Expense), Net. Interest and other income (expense), net, decreased by $926,000 to $274,000 for the three months ended June 30, 2008, as compared to $1,200,000 for the three months ended June 30, 2007. The decrease resulted from a lower level of invested funds and market interest rates as compared to the comparable period last year. The decrease was also due to a $64,000 impairment charge recorded in the three months ended June 30, 2008, related to our investments in auction rate securities.

Six months ended June 30, 2008 and June 30, 2007

License Revenue. License revenue was $526,000 for the six months ended June 30, 2008 as compared to no revenue for the six months ended June 30, 2007. License revenue for the six months ended June 30, 2008 was related to the amortization of a portion of the license fees of $12.0 million and milestone payment of $8.0 million associated with our sublicense agreement with JT and Torii. Such amounts were 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 represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement.

Diagnostic Revenue. We recognized no diagnostic revenue for the six months ended June 30, 2008, as compared to diagnostic revenue of $66,000 for the six months ended June 30, 2007. We do not expect our diagnostic revenue to have a material impact on our financial results during 2008.

Service Revenue. Service revenue increased by $36,000 to $62,000 for the six months ended June 30, 2008, as compared to service revenue of $26,000 for the six months ended June 30, 2007. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2008.

Cost of Diagnostics Sold. We recognized no cost of diagnostics sold for the six months ended June 30, 2008, as compared to an expense of $38,000 for the six months ended June 30, 2007. We do not expect our cost of diagnostics sold to have a material impact on our financial results during the remainder of 2008.

Cost of Services. Cost of services decreased by $48,000 to $14,000 for the six months ended June 30, 2008, as compared to an expense of $62,000 for the six months ended June 30, 2007. We do not expect our cost of services to have a material impact on our financial results during the remainder of 2008.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to equity incentive grants decreased by $2,902,000 to a credit of $729,000 for the six months ended June 30, 2008, as compared to an expense of $2,173,000 for the six months ended June 30, 2007. The decrease was primarily attributable to a $2,840,000 decrease in expense related to stock options and restricted stock issued to our President, who was terminated as part of the 2008 Restructuring, as well as due to a reduction in research and development personnel following our 2008 Restructuring.

Other Research and Development Expenses. Other research and development expenses increased by $1,940,000 to $35,071,000 for the six months ended June 30, 2008, as compared to $33,131,000 for the six months ended June 30, 2007. The increase in other research and development expenses was due primarily to a $2,904,000 increase in research and development expenses related the Sulonex program which was terminated 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. Including the impairment charge and restoration expense discussed above, other research and development expenses related to Sulonex were $26,726,000 and $23,822,000 during the six months ended June 30, 2008 and 2007, respectively. Offsetting the $2,904,000 increase in other research and development expenses related to Sulonex discussed above, was a decrease of $772,000 in expenses related to our other clinical compounds.

We expect our other research and development costs to decrease substantially during the remainder of 2008, as compared to the six months ended June 30, 2008 costs, as a result of the cessation of the development of Sulonex in March 2008, as well as the 2008 Restructuring, which was intended to reduce our cash burn rate and re-focus our development efforts.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to equity incentive grants increased by $71,000 to $3,484,000 for the six months ended June 30, 2008, as compared to an expense of $3,413,000 for the six months ended June 30, 2007.

Other Selling General and Administrative Expenses. Other selling, general and administrative expenses decreased by $1,137,000 to $4,052,000 for the six months ended June 30, 2008, as compared to an expense of $5,189,000 for the six months ended June 30, 2007. The decrease was primarily related to an impairment charge, in the six months ended June 30, 2007, of approximately $600,000 related to certain intangibles associated with Accumin’s diagnostic product and due to reduced expenses as a result of the 2008 Restructuring.

We expect our other selling, general and administrative costs to decrease over the remainder of 2008 as a result of the 2008 Restructuring, which was intended to reduce our cash burn rate and re-focus our development efforts.

Interest and Other Income (Expense), Net. Interest and other income (expense), net, decreased by $3,570,000 to an expense of $929,000 for the six months ended June 30, 2008, as compared to income of $2,641,000 for the six months ended June 30, 2007. The decrease was primarily due to $1,875,000 of impairment charges recorded in the six months ended June 30, 2008, related to our investments in auction rate securities. The decrease also resulted from a lower level of invested funds and market 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, 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, 2008, we had $34.6 million in cash, cash equivalents, interest receivable, and short-term and long-term securities (including $10.1 million in non-current auction rate securities as discussed below), a decrease of $30.1 million from December 31, 2007. Cash used in operating activities for the six months ended June 30, 2008 was $28.1 million, as compared to $34.4 million for the six months ended June 30, 2007. This decrease was due primarily to the cessation of the Sulonex program in March 2008. For the six months ended June 30, 2008, net cash provided by

investing activities of $22.8 million was primarily the result of the maturity and sale of short-term securities in our investment portfolio, net of purchases. For the six months ended June 30, 2008, net cash provided by financing activities of $0.2 million was the result of proceeds from the exercise of stock options.

As of June 30, 2008, $10.1 million of our long-term investment securities were auction rate securities, which represent interests in student loan-backed securities. 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 these investments are currently rated AA or higher, we are uncertain as to when, or if, the liquidity issues relating to these investments will improve. Given the complexity of auction rate securities and the lack of readily observable market quotes related to these investments, we obtained the assistance of an independent valuation firm, Pluris Valuation Advisors LLC, to assist us in assessing the fair value of our auction rate securities portfolio. As a result of this valuation process, we recorded impairment charges of $1.8 million and $0.1 million, in the three months ended March 31, 2008, and June 30, 2008, respectively, for other-than-temporary declines in the value of our auction rate securities to an estimated fair value of $10.1 million at June 30, 2008. These other-than-temporary impairment charges were included in interest and other income (expense), net. In addition, in the first quarter of 2008, we reclassified the entire auction rate securities portfolio from short-term to long-term investments due to the uncertainty of when we will be able to sell these securities.

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 included numerous assumptions such as 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 would decline approximately $1.0 million. 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.

We currently anticipate that our cash, cash equivalents, interest receivable and investment securities as of June 30, 2008, exclusive of our holdings in auction rate securities, are sufficient to meet our anticipated working capital needs and fund our business plan for approximately the next 12 months. 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.

On December 30, 2005, we filed a shelf registration statement on Form S-3 with the SEC that was declared effective by the SEC on January 13, 2006. The registration statement provides for the offering of up to $150 million of our common stock. Subsequent to the registered direct offering that was completed in March 2006, there remains approximately $67 million of our common stock available for sale on this shelf registration statement. We may offer these securities from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interest of Keryx and our stockholders. We believe that the availability to conduct such

offerings enhances our ability to raise additional capital to finance our operations. However, there are no assurances that we will be able to sell securities on acceptable terms, or at all, even though an effective shelf registration statement remains available. Securities sold via the shelf registration statement may dilute our existing stockholders' interests.

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.

OBLIGATIONS AND COMMITMENTS

As of June 30, 2008, we have known contractual obligations, commitments and contingencies of $2,676,000. Of this amount, $1,290,000 relates to research and development agreements (relating to our KRX-0401 and Zerenex clinical programs), all of which is due within the next year. Certain of these commitments are contingent upon our continuing development of our drug candidates. The additional $1,386,000 relates to our operating lease obligations, of which $629,000 is due within the next year, with the remaining balance due as per the schedule below.

		Payment due by period			
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Research and development agreements	$ 1,290,000	$ 1,290,000	$ —	$ —	$ —
Operating leases	1,386,000	629,000	757,000	—	—
Total	$ 2,676,000	$ 1,919,000	$ 757,000	$ —	$ —

We have undertaken to make contingent milestone payments to certain of our licensors of up to approximately $73.0 million over the life of the licenses, of which approximately $60.5 million will be due upon or following regulatory approval of the licensed drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, we remain obligated to pay one licensor $75,000 annually until the license expires. We have also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights (up to 3,372,422 shares of our common stock) if its drug candidates meet certain development milestones. A substantial portion of the contingent shares would be payable to related parties. The contingent equity rights have been recognized as a non-current liability on the consolidated balance sheet. We have also entered into a royalty arrangement under which our wholly-owned subsidiary may be required to pay up to a maximum of $16.1 million to AusAm on revenue from a next generation product following FDA marketing approval, as part of our acquisition of Accumin. The uncertainty relating to the timing of the commitments described in this paragraph prevents us from including them in the table above.

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 to date 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 EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." We analyze each element of our licensing agreement to determine the appropriate revenue recognition. We recognize revenue on upfront payments and milestone 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 may recognize milestone payments in revenue upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones and royalties that are deferred will be recognized when earned under the agreements.

We recognize diagnostic revenue when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured.

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.

Accounting Related to the Valuation of Intangible Assets. In accounting for acquisitions, we allocate the purchase price to the fair value of the acquired tangible and intangible assets. This allocation requires us to make several significant judgments and estimates. For example, we estimated the value of the acquired intangible assets of Accumin utilizing the income approach, which requires us to make assumptions and estimates about, among other things:

- revenue that is likely to result from the asset, including estimated selling price, estimated market share and year-over-year growth rates;
- operating margin; and
- sales and marketing and general and administrative expenses using historical and industry or other sources of market data;

The valuations are based on information that is available as of the acquisition date and the expectations and assumptions that have been deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected. For these reasons, among others, the actual results may vary from the projected results.

As of June 30, 2008, 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 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. When we perform impairment tests in future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment charges.

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. During the first quarter of 2007, management reviewed both its original and projected revenue estimates associated with the Accumin diagnostic tool. As a result of this analysis, we concluded that the asset was impaired and recorded an impairment charge of approximately $600,000 to write-down identifiable intangible long-lived assets associated with

Accumin. The charge was recorded in other selling, general and administrative expenses within the Diagnostics segment. Prior to the impairment charge taken in the first quarter of 2007, we amortized our identifiable intangible assets associated with Accumin over their estimated economic lives, which was 12 years, the life of the patents, using the straight-line method.

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, 2008, $10.1 million of our long-term investment securities were auction rate securities, which represent interests in student loan-backed securities. 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 these investments are currently rated AA or higher, we are uncertain as to when, or if, the liquidity issues relating to these investments will improve. Given the complexity of auction rate securities and the lack of readily observable market quotes related to these investments, we obtained the assistance of an independent valuation firm, Pluris Valuation Advisors LLC, to assist us in assessing the fair value of our auction rate securities portfolio. As a result of this valuation process, we recorded impairment charges of $1.8 million and $0.1 million, in the three months ended March 31, 2008, and June 30, 2008, respectively, for other-than-temporary declines in the value of our auction rate securities to an estimated fair value of $10.1 million at June 30, 2008. These other-than-temporary impairment charges were included in interest and other income (expense), net. In addition, in the first quarter of 2008, we reclassified the entire auction rate securities portfolio from short-term to long-term investments due to the uncertainty of when we will be able to sell these securities.

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 included numerous assumptions such as 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.

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 will 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 impairments 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 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 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 principal amount 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 principal amount of our investment will probably decline. As of June 30, 2008, our portfolio of financial instruments consists of cash equivalents and short-term and long-term interest bearing securities, including money market funds, government debt and auction rate securities. The average duration of all of our held-to-maturity investments held as of June 30, 2008, was less than 12 months. Due to

the short-term nature of our money market funds and held-to-maturity investments, we believe we have no material exposure to interest rate risk, and/or credit risk, arising from our money market funds and held-to-maturity investments.

As of June 30, 2008, $10.1 million of our long-term investment securities were auction rate securities, which represent interests in student loan-backed securities. 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 these investments are currently rated AA or higher, 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 will 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. Assuming a 10% adverse change in the fair value of these securities overall, the fair value would decline approximately $1.0 million. 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 lack of liquidity of our auction rate securities could have a material impact on our ability to fund our operations.

ITEM 4. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

As of June 30, 2008, management carried out, under the supervision and with the participation of our Chief Executive Officer and Principal Financial and Accounting 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 Principal Financial and Accounting Officer concluded that, as of June 30, 2008, 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, 2008, 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 July 2003, Keryx (Israel) Ltd., one of our Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of our Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, our Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount

demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,316,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. and Michael S. Weiss to vacate service of process outside of Israel was held in June 2006. On October 15, 2006, the Court held that the service of the claim against Mr. Weiss is vacated. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. However, the service against us was sustained. We appealed this holding. The appeal was denied on June 18, 2007, and the Company filed a petition for certiorari to the Supreme Court of Israel. The Company’s motion for certiorari was denied as well. We filed our testimonial affidavit along with an expert opinion contesting the interest and the accumulated debt claimed by plaintiff. The trial is scheduled for November 2008. The Court will hear the motion to dismiss parallel to the trial. We have not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

We prevailed in an arbitration proceeding with Alfa Wasserman concerning certain terms of the 1998 License Agreement between Alfa Wasserman and the Company related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. An arbitration hearing was held in October 2007 and the arbitrator issued his decision on March 25, 2008, rejecting Alfa Wasserman's claims that we were in material breach of the License Agreement. Under the terms of the License Agreement, we may be entitled to recoup a portion of our legal fees and expenses associated with the arbitration from Alfa Wasserman. Our claim for legal fees is presently before the arbitrator for determination.

In April 2008, we notified Alfa Wasserman of our intention to terminate the License Agreement. 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 are in material breach of the agreement for failing to diligently develop sulodexide by terminating the Phase 4 clinical trial. By seeking to terminate the License Agreement, Alfa Wasserman is thereby seeking to avoid reimbursing us our development costs. We intend to submit our claim for development costs and Alfa Wasserman's claim of material breach to arbitration for resolution.

In November 2007, we initiated an action in the US District Court for the Southern District of New York against Panion to enjoin Panion from improperly terminating the November 2005 License Agreement between Panion and the Company for an alleged breach of contract by us related to certain manufacturing provisions of the agreement, to enjoin Panion from interfering with our contractual relationships with certain third-parties, as well as to enforce our right with respect to the prosecution of certain patents. On November 27, 2007, the Court granted us a motion for a preliminary injunction. Panion asserted counterclaims for breach of contract relating to certain manufacturing provisions of the license agreement. On March 17, 2008, the parties agreed to settle their dispute and as a result have entered into an Amended and Restated License Agreement, which resulted in an expansion of the scope of the original license grant and granted us greater control over patent prosecution and maintenance. In consideration of these amendments and the settlement of the litigation, we paid Panion $2.5 million in March 2008, which had been accrued for in 2007. Following execution of the Amended and Restated License Agreement, the parties entered a voluntary dismissal of the action, including Panion's asserted counterclaims.

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 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, 2008, we had an accumulated deficit of approximately $320.5 million. As we continue our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug 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. Moreover, 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. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

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 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 prevents approval of such drug candidates.

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.

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 testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to 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. Moreover, if we need to change manufacturers, 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.

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 they 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. 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, has been approved to treat patients with advanced kidney disease. Biotechnology companies such as Amgen Inc., Biogen-Idec, Inc., ImClone Systems, Inc., Millennium Pharmaceuticals, Inc., 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 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, 2008, we had 21 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. Although we have an employment agreement with Mr. Weiss, this agreement does not prevent him from terminating his employment with us.

Any acquisitions we make may require a significant amount of our available cash and may not be scientifically or commercially successful.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions involve a number of operational risks, including:

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

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

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

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

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

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

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

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

government and health administration authorities;

private health insurers;

managed care programs; and

other third-party payors.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for our products. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, their market acceptance may be reduced.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the 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 the sale of Accumin, 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. 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, 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 21 full and part-time employees as of July 31, 2008. 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, interest receivable, 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, interest receivable, and investment securities as of June 30, 2008, exclusive of our holdings of auction rate securities, are sufficient to meet our anticipated working capital needs and fund our business plan for approximately the next 12 months. Our forecast of the period of time through which our cash, cash equivalents, interest receivable, 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 of completion and results from clinical trials for our drug candidates;

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

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

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

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

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

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us, if at all.

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 will 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.

Our prior restructurings may result in additional Israeli-related liabilities.

In July 2003, Keryx (Israel) Ltd., one of our Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of our Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, our Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,316,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. to vacate service of process outside of Israel was held in September 2006. On October 15, 2006, the Circuit Court of Jerusalem held that the service of process on Keryx was sustained. We appealed this holding. The appeal was denied on September 18, 2007, and we filed a petition for certiorari to the Supreme Court of Israel. Our motion for certiorari was denied as well. We filed our testimonial affidavit along with an expert opinion contesting the interest and the accumulated debt claimed by plaintiff. The trial is scheduled for November 2008. The Court will hear the motion to dismiss parallel to the trial. We have not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

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.

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 obtain patents in the future and claim that our drug products or technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to our drug products or technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use our drug products or technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Risks Related to Our Common Stock

Future sales or other issuances of our common stock could depress the market for our common stock.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future. On December 30, 2005, we filed with the SEC a shelf registration statement on Form S-3, that was declared effective by the SEC on January 13, 2006, providing for the offering of up to $150 million of our common stock. Following our registered direct offering of common stock to two institutional investors that was completed in March 2006, there remains approximately $67 million available for sale on this shelf registration statement. Future sales pursuant to this registration statement could depress the market for our common stock.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders 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 2008 if we reach the first milestone, or we may 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. A substantial portion of the contingent shares would be payable to related parties.

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;

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.

We may not be able to continue to meet the minimum listing requirements of the NASDAQ Capital Market, and as a result may be de-listed which would significantly and adversely affect the liquidity of the market for our common stock.

On April 22, 2008, we received notice from the NASDAQ Stock Market that we were not in compliance with the $1.00 minimum bid price requirement for continued inclusion on the applicable NASDAQ market. This notification is a standard communication when the bid price of a NASDAQ-listed company closes below the minimum $1.00 per share requirement for 30 consecutive business days. In accordance with NASDAQ rules, we will be provided 180 calendar days (until October 20, 2008) to regain compliance by having the bid price of our common stock close at $1.00 per share or more for a minimum of 10 consecutive business days.

We cannot provide assurance that in the future we will continue to meet the listing requirements of the NASDAQ Capital Market, including, without limitation, bid price, stockholders’ equity and/or market value of listed securities minimum requirements. Under the rules of the NASDAQ Capital Market, the Company has until October 20, 2008 to comply with the $1.00 minimum closing bid price requirement, and may have an additional 180-calendar day compliance period through April 17, 2009 to comply with the $1.00 minimum closing bid price requirement, provided the Company otherwise meets the initial listing requirements for the NASDAQ Capital Market on the 180th day of the first 180-calendar day compliance period (October 20, 2008).

ITEM 4. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

On June 17, 2008, we held our annual meeting of stockholders. The following matters were voted on by the stockholders: the election of directors, and the approval of an amendment to our certificate of incorporation to provide the Board of Directors with the authority to issue series of preferred stock. At the meeting, Kevin J. Cameron, Wyche Fowler, Jr., Malcolm Hoenlein, Jack Kaye, Eric Rose, Michael P. Tarnok and Michael S. Weiss were re-elected to our board of directors.
The vote with respect to each nominee is set forth below:

Nominee	Total Votes For	Total Votes Withheld
Kevin J. Cameron	27,657,806	2,040,434
Wyche Fowler, Jr.	27,610,045	2,088,195
Malcolm Hoenlein	27,613,104	2,085,136
Jack Kaye, CPA	27,524,902	2,173,338
Eric Rose, M.D.	27,618,865	2,079,375
Michael P. Tarnok	27,657,690	2,040,550
Michael S. Weiss	26,017,050	3,681,190

The vote with respect to the approval of an amendment to our certificate of incorporation to authorize the Board of Directors to issue preferred stock is set forth below.

Total Votes For	Total Votes Against	Abstention and Broker Non-Votes
1,541,526	5,233,440	22,923,270

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.
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 11, 2008.

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 11, 2008.
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 11, 2008.
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 11, 2008.

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 11, 2008	By:	/s/ James F. Oliviero Vice President, Finance Principal Financial and Accounting Officer

EXHIBIT INDEX

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

31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 11, 2008.
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 11, 2008.
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