KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 09, 2006

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, 2006

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, or a non-accelerated filer. See definition of “accelerated filer and large accelerated filer” in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer £	Accelerated filer x	Non-accelerated filer £

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

There were 43,183,871 shares of the registrant's common stock, $0.001 par value, outstanding as of August 2, 2006.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2006

TABLE OF CONTENTS

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations for increases or decreases in expenses;
- expectations for the development, manufacturing, and approval of Sulonex™, Zerenex™, KRX-0401, and our additional product candidates or any other products we may acquire or in-license;
- expectations for incurring additional 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; 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.

1

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Balance Sheets as of June 30, 2006, and December 31, 2005

(in thousands, except share and per share amounts)

	June 30, 2006 (Unaudited)	December 31, 2005*
Assets		
Current assets		
Cash and cash equivalents	$ 81,058	$ 68,175
Short-term investment securities	56,322	18,272
Accrued interest receivable	422	336
Other receivables, inventory and prepaid expenses	4,816	3,200
Total current assets	142,618	89,983
Long-term investment securities	17,309	13,950
Property, plant and equipment, net	2,766	1,004
Goodwill	3,127	--
Other assets (primarily intangible assets), net	972	160
Total assets	$ 166,792	$ 105,097
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 6,108	$ 5,054
Accrued compensation and related liabilities	401	936
Deferred revenue	184	103
Total current liabilities	6,693	6,093
Contingent equity rights	4,004	4,004
Other liabilities	288	322
Total liabilities	10,985	10,419
Stockholders' equity		
Common stock, $0.001 par value per share (60,000,000 and 60,000,000 shares authorized, 43,194,075 and 37,831,896 shares issued, 43,137,975 and 37,775,796 shares outstanding at June 30, 2006, and December 31, 2005, respectively)	43	38
Additional paid-in capital	307,725	209,177
Treasury stock, at cost, 56,100 shares at June 30, 2006, and December 31, 2005, respectively	(89)	(89)
Deficit accumulated during the development stage	(151,872)	(114,448)
Total stockholders' equity	155,807	94,678
Total liabilities and stockholders' equity	$ 166,792	$ 105,097

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

* Condensed from audited financial statements.

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Interim Unaudited Consolidated Statements of Operations for the
Three and Six Months Ended June 30, 2006 and 2005

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,		Amounts accumulated during the development stage
	2006	2005	2006	2005	
Revenue:					
Diagnostic revenue	$ 23	$ --	$ 23	$ --	$ 23
Service revenue	224	126	336	283	1,719
Management fees from related party	--	--	--	--	300
Total revenue	247	126	359	283	2,042
Operating expenses:					
Cost of diagnostics sold	19	--	19	--	19
Cost of services	98	161	269	342	1,923
Research and development:					
Non-cash compensation	2,104	137	4,828	313	12,562
Non-cash acquired in-process research and development	--	--	--	--	18,800
Other research and development	12,352	5,180	24,685	9,222	88,579
Total research and development	14,456	5,317	29,513	9,535	119,941
Selling, general and administrative:					
Non-cash compensation	3,541	168	6,358	353	11,799
Other selling, general and administrative	1,860	699	4,505	1,344	29,591
Total selling, general and administrative	5,401	867	10,863	1,697	41,390
Total operating expenses	19,974	6,345	40,664	11,574	163,273
Operating loss	(19,727)	(6,219)	(40,305)	(11,291)	(161,231)
Interest and other income, net	1,899	267	2,881	507	9,850
Net loss before income taxes	(17,828)	(5,952)	(37,424)	(10,784)	(151,381)
Income taxes	--	--	--	--	491
Net loss	$ (17,828)	$ (5,952)	$ (37,424)	$ (10,784)	$ (151,872)
	$ (0.41)	$ (0.19)	$ (0.92)	$ (0.34)	$ (7.87)

Basic and diluted loss per common share					
Weighted average shares used in computing basic and diluted net loss per common share	43,117,656	31,528,862	40,608,571	31,503,469	19,308,150

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Interim Unaudited Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2006 and 2005

(in thousands)

	Six months ended June 30,		Amounts accumulated during the development stage
	2006	**2005**	**stage**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (37,424)	$ (10,784)	$ (151,872)
Adjustments to reconcile cash flows used in operating activities:			
Acquired in-process research and development	--	--	18,800
Stock compensation expense	11,186	666	24,361
Issuance of common stock to technology licensor	--	--	359
Interest on convertible notes settled through issuance of preferred shares	--	--	253
Depreciation and amortization	120	86	2,731
Loss on disposal of property, plant and equipment	--	--	172
Impairment charges	--	--	2,482
Exchange rate differences	--	--	94
Changes in assets and liabilities, net of effects of acquisitions:			
(Increase) in other receivables, inventory and prepaid expenses	(1,524)	--	(4,353)
(Increase) in accrued interest receivable	(86)	(3)	(422)
(Increase) in security deposits	(241)	--	(249)
Increase in accounts payable and accrued expenses	625	1,194	4,366
(Decrease) in accrued compensation and related liabilities	(558)	(709)	(194)
(Decrease) increase in other liabilities	(34)	47	133
Increase (decrease) in deferred revenue	81	2	(272)
Net cash used in operating activities	(27,855)	(9,501)	(103,611)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(1,798)	(330)	(7,189)
Proceeds from disposals of property, plant and equipment	--	--	425
(Increase) in note and accrued interest receivable from related party	--	--	(356)
Decrease in accrued transaction costs	(145)	--	(145)
Decrease (increase) in other assets	27	(4)	(1,192)
(Investment in) held-to-maturity short-term securities	(4,011)	(1,103)	(48,844)
Proceeds from maturity of held-to-maturity short-term securities	1,071	5,528	44,817
(Investment in) available-for-sale short-term securities	(30,825)	(25)	(50,550)

Proceeds from sale of available-for-sale short-term securities	175	--	9,850
(Investment in) held-to-maturity long-term securities	(7,822)	(7,116)	(29,092)
Proceeds from maturity of held-to-maturity long-term securities	4	--	189
Net cash used in investing activities	(43,324)	(3,050)	(82,087)

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Interim Unaudited Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2006 and 2005
(continued)

(in thousands)

	Six months ended June 30,		Amounts accumulated during the development stage
	2006	**2005**	**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 secondary public offering, net	--	--	75,790
Proceeds from private placements, net	82,696	--	128,491
Proceeds from exercise of options and warrants	1,361	335	8,222
Purchase of treasury stock	--	--	(89)
Net cash provided by financing activities	84,057	335	266,751
Cash acquired in acquisition	5	--	99
Effect of exchange rate on cash	--	--	(94)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	12,883	(12,216)	81,058
Cash and cash equivalents at beginning of year	68,175	29,699	--
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 81,058	$ 17,483	$ 81,058
NON - CASH TRANSACTIONS			
Issuance of common stock in connection with acquisition	$ 3,310	$ --	$ 9,635
Issuance of contingent equity rights in connection with acquisition	--	--	4,004
Assumption of liabilities in connection with acquisition	347	--	9,070
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	$ --	$ --	$ 432

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Notes to Interim Consolidated Financial Statements as of June 30, 2006 (unaudited)

NOTE 1 - GENERAL

BASIS OF PRESENTATION

Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") is a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes 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. Substantially all of the Company's biopharmaceutical development and administrative operations during the six months ended June 30, 2006, and 2005, were conducted in the United States of America.

On February 5, 2004, the Company completed the acquisition of ACCESS Oncology 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.

The accompanying unaudited interim 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 interim 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, 2005. The results of operations for the three and six months ended June 30, 2006, are not necessarily indicative of the results that may be expected for the entire fiscal year or any other interim period.

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. 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.

STOCK - BASED COMPENSATION

In December 2004, the Financial Accounting Standards Board (“FASB”) issued Statement of Financial Accounting Standards No. 123R, “Share-Based Payment” (“SFAS 123R”). SFAS 123R requires all share-based payments to employees, or 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.

The Company adopted SFAS 123R using the modified prospective transition method. Under this method, compensation cost recognized in the three and six months ended June 30, 2006 includes: a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of Statement of Financial Accounting Standards No. 123 “Accounting for Stock-Based Compensation,” (“SFAS 123”), and b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS 123R. The results for prior periods have not been restated.

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 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. In the Company’s pro forma disclosures required under SFAS 123 for periods prior to 2006, the Company accounted for forfeitures as they occurred. Upon adoption of SFAS 123R, the Company elected to use the Black-Scholes model to value share-based payments granted to employees subsequent to January 1, 2006 and elected to attribute the value of stock-based compensation to expense using the straight-line single option method. These methods were previously used for the Company’s pro forma information required under SFAS 123. For additional information, see Note 2 - Stockholders' Equity.

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 Emerging Issues Task Force 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 exercisable as of June 30, 2006, and 2005, which are not included in the computation of net loss per share amounts, were 6,543,578 and 4,692,742, respectively.

PATENTS

Through March 31, 2006, the Company classified its patent expenses in other research and development. Effective April 1, 2006, the Company has classified its patent expenses in other general and administrative. The results of prior periods have not been restated.

NOTE 2 - STOCKHOLDERS' EQUITY

Common Stock

On March 29, 2006, the Company completed a registered direct offering of 4,500,000 shares of its common stock to two institutional investors at $18.40 per share. Total proceeds to the Company from this public offering were approximately $82.7 million, net of offering expenses of approximately $0.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-130809) filed with the Securities and Exchange Commission, or SEC, on December 30, 2005, and 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.

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.

Stock Option Plans

The Company has in effect the following stock option plans. Options granted typically vest over a three to four year period.

a. The 1999 Stock Option Plan was adopted in November 1999. Under the 1999 Stock Option Plan, the Company's board of directors could grant stock-based awards to directors, consultants and employees. The plan authorizes grants to purchase up to 4,230,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 25 years from the date of the grant, unless otherwise authorized by the board. The plan permits the board of directors or a committee appointed by the board to administer the plan. The administrator has the authority, in its discretion, to determine the terms and conditions of any option granted to a Company service provider, including the vesting schedule. No additional shares of our common stock may be issued under the 1999 Stock Option Plan.

b. The 2000 Stock Option Plan was adopted in June 2000. Under the 2000 Stock Option Plan the compensation committee of the Company's board of directors could grant stock-based awards to directors, consultants and employees. The 2000 plan authorizes grants to purchase up to 4,455,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 10 years from the date of the grant, unless authorized by the board. As of June 30, 2006, up to 52,318 additional shares may be issued under the 2000 Stock Option Plan.

c. The Non-Plan was adopted in February 2000. Under the Non-Plan, the Company's board of directors granted options, which are not part of any plan, to non-employee directors of the Company to purchase up to 240,000 shares of authorized but unissued common stock. The options issued by the board of directors pursuant to the Non-Plan have a life of 10 years from the date of their grant. No additional shares of our common stock may be issued under the Non-Plan.

d. The 2002 CEO Incentive Stock Option Plan was adopted in December 2002. Under the 2002 CEO Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed Chief Executive Officer of the Company to purchase up to 2,002,657 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Executive Officer was part of a total grant of options issued pursuant to the 1999 Stock Option Plan, the 2000 Stock Option Plan and the 2002 CEO Incentive Stock Option Plan, to purchase a total of 4,050,000 shares of the Company's common stock. As of June 30, 2006, all of the options granted under the 2002 CEO Incentive Stock Option Plan have vested. In the event of a merger, acquisition or other change of control or in the event that the Company terminates the Chief Executive Officer's employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or December 24, 2012. No additional shares of our common stock may be issued under the 2002 CEO Incentive Stock Option Plan.

e. The 2004 President Incentive Stock Option Plan was adopted in February 2004. Under the 2004 President Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed President of the Company to purchase up to 1,000,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed President was made pursuant to an employment agreement following the acquisition of ACCESS Oncology in February 2004. Of these options, 166,667 vest over a three-year period and 833,333 vest upon the earlier of the achievement of certain performance-based milestones or February 5, 2011. As of June 30, 2006, 458,333 options have vested under this plan. In addition, in the event of a merger, acquisition or other change of control or in the event that the Company terminates the President's

employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the exercisability of any of the options described in this paragraph that are unexercisable at the time of such event or termination shall accelerate and the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or February 5, 2014. Additionally, the Company's board of directors shall have the discretion to accelerate all or a portion of these options at any time. No additional shares of our common stock may be issued under the 2004 President Incentive Stock Option Plan.

f. The 2004 Long-Term Incentive Plan was adopted in June 2004 by our stockholders. Under the 2004 Long-Term Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants and employees. The 2004 plan authorizes grants to purchase up to 4,000,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 10 years from the date of their grant. As of June 30, 2006, up to an additional 687,040 shares may be issued under the 2004 Long-Term Incentive Plan.

g. The 2006 CFO Incentive Plan was adopted in February 2006. Under the 2006 CFO Incentive Plan the Company's board of directors granted an option to the newly-appointed Chief Financial Officer of the Company to purchase up to 500,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Financial Officer was made pursuant to an employment agreement. Of these options, 55,556 vest on the one-year anniversary of employment and 13,889 vest every three months following the one-year anniversary of employment until the 36th month of employment; and 333,333 vest after seven years, provided that the newly appointed Chief Financial Officer remains employed by the Company on such date. The 333,333 stock options may vest earlier upon the achievement of certain milestones, of which 111,111 have vested as of June 30, 2006. No additional shares of our common stock may be issued under the 2006 CFO Incentive Plan.

The following table summarizes activity for the Company's stock option plans during the six months ended June 30, 2006:

	Number of options	Weighted-average exercise price	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at January 1, 2006	8,024,652	$ 4.35	7.2	$ 119,097,000
Granted	3,185,460	$ 14.26		
Exercised	(517,155)	$ 2.63		$ 5,983,000
Forfeited and expired	(97,996)	$ 2.42		
Outstanding at June 30, 2006	10,594,961	$ 7.43	7.9	$ 74,097,000
Exercisable at June 30, 2006	6,221,602	$ 3.52	7.1	$ 66,516,000

The aggregate intrinsic value in the table above represents the total intrinsic value (the difference between the Company's closing common stock price of $14.20 on June 30, 2006 and the exercise price, multiplied by the number of in-the-money options) that would have been received by the option holders had all option holders exercised their options as of that date. Upon the exercise of outstanding options, the Company intends to issue new shares.

As of June 30, 2006, there were 100,000 shares of restricted stock outstanding. All 100,000 shares were granted to the Company's newly-appointed Chief Financial Officer on February 14, 2006, at a grant-date fair value of $15.30 per share. 50,000 of the restricted shares will vest in three equal installments on the first, second and third anniversary of the grant date. For the remaining 50,000 restricted shares, vesting is contingent upon meeting a certain performance goal. As of June 30, 2006, the Company has recorded $159,000 of expense associated with the restricted stock.

Stock-based Compensation

The Company incurred additional non-cash compensation expense during the three months ended June 30, 2006, of $1,697,000, relating to a former officer and two former directors who are no longer employees as defined by the terms of their option agreements. The Board of Directors agreed to modify their option agreements such that their vesting and exercisability has been extended beyond the terms of their original agreements.

The application of SFAS 123R had the following effect on reported amounts, for the three and six months ended June 30, 2006, relative to amounts that would have been reported using the intrinsic value method under previous accounting:

(in thousands, except per share amounts)	Three months ended June 30, 2006	Six months ended June 30, 2006
Net loss, using previous accounting method	$ (14,147)	$ (28,632)
Basic and diluted loss per ordinary share, using previous method	(0.33)	(0.71)
Impact of the adoption of SFAS No. 123R	(3,681)	(8,792)
Net loss, as reported	(17,828)	(37,424)
Basic and diluted loss per ordinary share, as reported	$ (0.41)	$ (0.92)

The value of these options has been estimated 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 for the foreseeable future.

The weighted average fair market value of options and restricted stock granted during the six months ended June 30, 2006, as of the date of the grant, was $7.83 and $15.30, respectively. The assumptions used in the calculation of the fair value of options granted during the six months ended June 30, 2006 were a weighted average expected term of 3.0 years, a weighted average expected volatility rate of 79.17% and a weighted average risk-free interest rate of 4.76%. The Company used historical information to estimate forfeitures within the valuation model. As of June 30, 2006, there was $30.9 million of total unrecognized compensation cost, related to nonvested stock options and restricted stock, which is expected to be recognized over a weighted-average period of 3.5 years.

Prior to January 1, 2006, the Company applied the intrinsic value-based method of accounting prescribed by the Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations, including Financial Accounting Standards Board ("FASB") Interpretation 44, "Accounting for Certain Transactions involving Stock Compensation, an Interpretation of APB Opinion No. 25," to account for its fixed-plan stock options for employees and non-employee directors. Under this method, compensation expense was recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price. Prior to January 1, 2006, the Company provided pro forma disclosure amounts in accordance with SFAS 123, as amended by Statement of Financial Accounting Standards No. 148 "Accounting for Stock-Based Compensation — Transition and Disclosure," ("SFAS 148"). As compensation expense was disclosed but not recognized in periods prior to January 1, 2006, no cumulative adjustment for forfeitures was recorded in 2006. The following is a pro forma unaudited presentation illustrating the effect on net loss and net loss per share if the Company had applied the fair value recognition provisions of SFAS 123 to stock-based employee compensation in the prior three- and six-month period ended June 30, 2005:

(in thousands, except per share amounts)	Three months ended June 30, 2005	Six months ended June 30, 2005
Net loss, as reported	$ (5,952)	$ (10,784)
Add: Stock-based compensation expense to employees and directors determined under the intrinsic value-based method, as included in reported net loss	112	223
Deduct: Stock-based compensation expense to employees and directors determined under fair value based method	(1,049)	(1,922)
Pro forma net loss	$ (6,889)	$ (12,483)

Basic and diluted loss per common share:				
As reported	$	(0.19)	$	(0.34)
Pro forma	$	(0.22)	$	(0.40)

The value of these options had been estimated using the Black-Scholes model. The weighted average fair market value of options granted during the three and six months ended June 30, 2005, as of the date of the grant, was $7.85 and $7.75, respectively. The assumptions used in the calculation of the fair value of options granted during the three and six months ended June 30, 2005 were a weighted average expected term of 4.3 years and 4.9 years, respectively, a weighted average expected volatility rate of 83.43% and 85.00%, respectively, and a weighted average risk-free interest rate of 3.77% and 3.71%, respectively.

Review of Stock Option Grant Procedures

At the direction of the Company's Board of Directors, the Company commenced an internal review into the Company's historical stock option practices from the date of its initial public offering to the present under the Company's stock option plans in effect during this period, including a review of the underlying option grant documentation and procedures. This internal review has been completed as of the date of this filing and is discussed below.

In addition to this review, the Board of Directors conducted a review led by one of the independent members of the Board of the facts and circumstances surrounding a stock option grant in the first quarter of 2004 and a May 1, 2003 grant to employees. With the assistance of outside counsel, the review included interviews and a review of contemporaneous documents relevant to these grants. The availability of contemporaneous documents may have been limited to some extent by the fact that the grants occurred over two years ago. The review did not discover any evidence of intentional fraud or wrongdoing in connection with these option grants.

During the Company's early history as a public company, the Company generally utilized meetings or unanimous written consents signed by all members of the applicable committee to approve multiple option grants, the effective dates of which preceded the date of the meeting or written consent. The Company has determined that the proper measurement date, for accounting purposes, may differ from the legal effective date. The Company also historically considered the effective date specified in the written consents as the accounting measurement date for determining stock-based compensation expense. However, the Company has concluded that in some instances the proper measurement date for accounting purposes may not be the effective date of the grant, if the terms of the stock option grant were not communicated to the optionee within a reasonable period of time after the grant was effective. In such instance, the measurement date may be such later date on which the terms were actually communicated.

Based on the results of the Company's review of its historical stock option practices, including its underlying option grant documentation and procedures, the Company determined that the additional compensation expense resulting from revised measurement dates was not material for any period and has not been recorded.

Additionally, in connection with the Company's acquisition of ACCESS Oncology, Inc. (ACCESS), which was completed in February 2004, the Board of Directors considered during board meetings convened for the purpose of approving the acquisition the proposed stock option component that would be designated to the ACCESS management team. The disclosure of the stock option grant to one member of the ACCESS management team, Dr. Craig Henderson, in the Company's proxy statements following the acquisition date, did not, however, agree with the final terms of the stock option grant as evidenced in Dr. Henderson's employment agreement. Dr. Henderson's stock options, 1,000,000 in total, carry an exercise price equal to the closing price of the Company's common stock on the date immediately prior to the date of his employment, or February 5, 2004, according to the terms of his employment agreement. Dr. Henderson's stock options have an exercise price of $9.25, and not the price of $4.59 previously disclosed by the Company. This discrepancy did not have an accounting impact for the periods prior to the first quarter of fiscal 2006. For the first quarter of 2006, however, with the adoption of SFAS 123(R), the value attributed to Dr. Henderson's stock options was incorrectly calculated, and as a result an additional compensation charge of $565,000 has been recorded in the three months ended June 30, 2006, to expense the additional compensation attributable to the incorrect calculation.

In addition, the Company has determined that the cumulative pretax stock-based compensation charge upon the adoption of SFAS 123(R), resulting from the change in grant date fair value of stock options granted, excluding Dr. Henderson's stock option grant, is $117,000, which amount has been recorded in the three months ended June 30, 2006. The impact of this compensation charge, together with Dr. Henderson's compensation charge, is not material to the Company's first or second quarter 2006 financials, and there is no impact on net cash used in operating activities as a result of the additional compensation charges.

11

NOTE 3 - BONUS TO OFFICER

Pursuant to his employment agreement, the Chief Executive Officer of the Company was entitled to receive a one-time $2 million cash bonus due to the achievement of a corporate milestone that occurred, and was expensed, in the first quarter of 2006 and paid in the second quarter of 2006. Of this amount, $1,000,000 was included in other research and development expenses and $1,000,000 was included in other selling, general and administrative expenses for the six months ended June 30, 2006.

NOTE 4 - ACCUMIN TRANSACTION

On April 6, 2006, Accumin Diagnostics, Inc. ("ADI"), 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. ("AusAm"). We believe that the acquisition of Accumin will help leverage the Company's exposure to physicians that treat diabetes, the target market for Sulonex, by emphasizing the importance of detecting microalbuminuria earlier.

The purchase price was $3,907,000, which included the issuance of 245,024 shares of the Company's common stock, the assumption of certain liabilities of AusAm equal to approximately $347,000 and transaction costs of approximately $250,000. ADI also entered into a royalty arrangement under which ADI may be required to pay up to a maximum of $16.1 million to AusAm. Keryx filed a registration statement on Form S-3 with the SEC on April 6, 2006 with respect to the shares issued to AusAm which was declared effective on June 23, 2006 (the "Effective Date"). At closing, 300,000 shares were issued to AusAm by Keryx, but were held in escrow until the Effective Date. On the Effective Date, 245,024 shares were released from escrow to AusAm.

The Accumin transaction has been accounted for as a purchase by the Company under GAAP. Under the purchase method of accounting, the assets and liabilities assumed from AusAm are recorded at the date of acquisition at their respective fair values. The consolidated financial statements and reported results of operations of the Company issued after completion of the transaction reflect these values but will not be restated retroactively to reflect the historical financial position or results of operations of AusAm.

The following represents the purchase price for Accumin:

(in thousands, except share and per share amounts)

Assumed liabilities			347
Number of shares of Keryx common stock issued	245,024		
Multiplied by Keryx's average closing bid price per share as quoted on NASDAQ over a period of 5 trading days (2 days prior to the Effective Date, the Effective Date, and 2 days after the Effective Date	$ 13.51		3,310
Other transaction costs			250
Total purchase price		$	3,907

The excess of the purchase price over the net assets acquired represented goodwill of approximately $3,127,000, which has been allocated to our Products segment, which is expected to benefit from the synergies of the Accumin acquisition.

The above estimated purchase price has been preliminarily allocated based on an estimate of the fair value of net assets acquired. The final valuation of net assets is expected to be completed as soon as possible but no later than one year from the acquisition date. To the extent that these estimated amounts need to be adjusted, the Company will do so.

(in thousands)

Allocation of purchase price:		
Tangible assets acquired	$	124
Amortizable intangibles (over 12 years - patent life)		656
Goodwill		3,127
Purchase price	$	3,907

A valuation using the guidance in SFAS No. 141, “Business Combinations” was performed with the assistance of independent valuation specialists to determine the fair value of certain identifiable intangible assets of Accumin.

The fair value of certain identifiable intangible assets was determined using the income approach. This method starts with a forecast of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the risk of achieving the asset’s projected cash flows. The present value of the estimated cash flows are then added to the present value equivalent of the residual value of the asset, if any, at the end of the discrete projection period to estimate the fair value.

The forecast of future cash flows required the following assumptions to be made:

- 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.

NOTE 5 - 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 novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer.

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

	Revenue				
	Three months ended June 30,		Six months ended June 30,		Amounts accumulated during the development Stage
(in thousands)	2006	2005	2006	2005	
Diagnostics	$ 23	$ --	$ 23	$ --	$ 23
Services	224	126	336	283	1,719
Products	--	--	--	--	--
Total	$ 247	$ 126	$ 359	$ 283	$ 1,742

	Operating loss				
(in thousands)	Three months ended June 30, 2006	2005	Six months ended June 30, 2006	2005	Amounts accumulated during the development Stage
Diagnostics	$ (414)	$ --	$ (414)	$ --	$ (414)
Services	126	(35)	67	(59)	(204)
Products	(19,439)	(6,184)	(39,958)	(11,232)	(160,613)
Total	$ (19,727)	$ (6,219)	$ (40,305)	$ (11,291)	$ (161,231)

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, 2006	2005	Six months ended June 30, 2006	2005	Amounts accumulated during the development Stage
Operating loss of reportable segments	$ (19,727)	$ (6,219)	$ (40,305)	$ (11,291)	$ (161,231)
Interest and other income	1,899	267	2,881	507	9,850
Income taxes	--	--	--	--	491
Consolidated net loss	$ (17,828)	$ (5,952)	$ (37,424)	$ (10,784)	$ (151,872)

All long-lived assets, other than the acquired intangibles for Accumin and other immaterial assets, reside in the Products segment.

The excess of the purchase price over the net assets acquired in the Accumin transaction represented goodwill of approximately $3,127,000, which has been allocated to our Products segment, which is expected to benefit from the synergies of the acquisition. The carrying amount of goodwill by reportable segment as of June 30, 2006 and December 31, 2005 was as follows:

	Goodwill	
(in thousands)	June 30, 2006	December 31, 2005
Diagnostics	--	--
Services	--	--
Products	$ 3,127	--
Total	$ 3,127	-

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 respective 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, 2005.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Our lead compound under development is Sulonex™ (sulodexide), which we previously referred to as KRX-101, a first-in-class, oral heparinoid compound for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes. Sulonex is in a pivotal Phase III and Phase IV clinical program under a Special Protocol Assessment, or SPA, with the Food & Drug Administration, or FDA. Additionally, we are developing Zerenex™, an oral, inorganic, iron-based compound that has the capacity to bind to phosphorous and form non-absorbable complexes. Zerenex is currently in Phase II 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, a novel, first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth, and 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 II clinical development for multiple tumor types. We also have an active 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 revenues from our drug candidates.

The table below summarizes the status of our product pipeline.

Product candidate	Target indication	Development status
Endocrine/Renal		
Sulonex™	Diabetic nephropathy	Phase III & Phase IV
Zerenex™	Hyperphosphatemia in patients with end-stage renal disease	Phase II
Oncology		
KRX-0401	Multiple forms of cancer	Phase II
KRX-0402	Brain cancer	Phase II
KRX-0404	Multiple forms of cancer	Pre-clinical
Neurology		
KRX-0501	Neurological disorders	Pre-clinical

Recent Developments

Zerenex

In June 2006, we announced positive final results from the Phase II multi- center study entitled: “A randomized, double-blind, placebo-controlled, dose ranging study of the effects of Zerenex on serum phosphate in patients with end stage renal disease (ESRD).” This Phase II study was conducted under an Investigational New Drug, or IND, sponsored our licensors in both the United States and Taiwan.

From this Phase II study, the investigators concluded that Zerenex appeared to have an acceptable safety and tolerability profile at the 2, 4, and 6g/day dose. The optimum dose of Zerenex in this study was 6g/day at which dose it appeared to be efficacious, safe and well tolerated as treatment for hyperphosphatemia in hemodialysis patients. Additionally, the investigators found that Zerenex therapy for up to 28 days had no statistically significant effect on serum iron, ferritin, transferrin saturation, or total iron binding capacity.

The Phase II study was designed to determine the safety and efficacy of several doses of Zerenex in patients with end stage renal disease who were undergoing hemodialysis. In this study, each of three Zerenex doses (2g, 4g and 6g) administered daily with meals was compared to placebo. Patients who had been on other phosphate binders prior to enrolling in this study underwent a 1-2-week washout period prior to randomization. Patients who had a serum phosphorous level greater than or equal to 5.5 mg/dl and less than or equal to 10 mg/dl by the end of this washout period were eligible to be randomized to one of four treatment groups at a ratio of 2:2:2:1, (Zerenex 2g, 4g, 6g and placebo, respectively) and were treated for 28 days. The primary endpoint for this study was the change in serum phosphorous concentration at day 28 relative to baseline.

Of the 116 patients randomized in the study, 111 patients were evaluable for efficacy at 28 days and were included in the analysis. At day 28, there was a statistically significant dose response to Zerenex in reducing serum phosphorous concentration (p=0.0073). In the 6g/day Zerenex group the mean decrease in serum phosphorous concentration was statistically significant when compared with placebo (p=0.0119) (see Table 1). There was also a statistically significant dose response to Zerenex in the calcium x phosphorous (Ca x P) product at day 28 (p=0.0158). In the 6g/day Zerenex group the mean decrease in Ca x P product when compared with placebo was statistically significant (p=0.0378) (See Table 2).

Table 1: Changes in Serum Phosphorous Concentration (mg/dL) on day 28 compared to day 0 (baseline) at Zerenex doses of 2, 4 and 6 g/day.

	Placebo (n=16)	2g/day (n=31)	4g/day (n=32)	6g/day (n=32)
Day 0 (Baseline)*	7.2 (1.4)	7.2 (1.2)	7.1 (1.3)	7.3 (1.3)
Day 28 (End of Treatment Period)*	7.2 (1.2)	6.9 (2.2)	6.0 (1.3)	5.8 (1.8)
Placebo Comparison:				
Mean Difference from Placebo		-0.02	-1.1	-1.5
P-value		NS	0.06	0.0119
Baseline Comparison:				
Mean Difference from Baseline	-0.1	-0.3	-1.1	-1.5
P-value	NS	NS	NS	<0.01

*mean (standard deviation)

Table 2: Changes in the Calcium x Phosphorous (mg/dL) on day 28 compared to day 0 (baseline) at Zerenex doses of 2, 4 and 6 g/day.

	Placebo (n=16)	2g/day (n=31)	4g/day (n=32)	6g/day (n=32)
Day 0 (Baseline)*	62.8 (13.9)	62.9 (13.2)	63.5 (10.7)	65.8 (12.2)
Day 28 (End of Treatment Period)*	63.2 (12.6)	61.7 (21.3)	55.4 (13.4)	54.1 (17.7)
Placebo Comparison:				
Mean Difference from Placebo		-0.9	-7.91	-11.4
P-value		0.8950	0.1375	0.0378
Baseline Comparison:				
Mean Difference from Baseline	-0.3	-1.1	-8.1	-11.7
P-value	NS	NS	NS	<0.01

*mean (standard deviation)

There were no deaths over the course of the 28-day study and there were no serious adverse events, or SAEs, that were deemed by the investigators to be definitely related to Zerenex. The majority of adverse events were of mild severity. Seven (43.8%), 13 (39.4%), 9 (26.5%), and 14 (42.4%) patients in the placebo, 2, 4, and 6g treatment groups, respectively, experienced no adverse events more severe than mild and 1 (6.3%), 0 (0.0%), 2 (5.9%), 1 (3.0%), of the placebo, 2,4, and 6 grams per day groups, respectively, experienced at least one severe AE. Possibly or probably related AEs occurred in 4 (25.0%), 7 (21.2%), 8 (23.5%), and 7 (21.2%) of the placebo, 2, 4, and 6 grams per day groups, respectively.

KRX-0401

In June 2006, we announced positive data of KRX-0401 in patients with advanced renal cell carcinoma, or advanced RCC. These patients were a cohort of a phase II, multi-center trial of KRX-0401 that included multiple tumor types. All patients in this study were to have had prior standard therapy. Although the extent of prior treatment varied with tumor type, most patients had received two chemotherapy regimens for metastatic disease. An interim analysis was performed at the end of the first year of accrual, and the results in the renal group met protocol requirements for expansion of this cohort. The study is ongoing.

Thirteen patients with advanced RCC were enrolled in the study and seven were evaluable for response. Three of these (43%) had a partial response and an additional two patients (29%) achieved long-term stable disease. Two progressed. Four patients were inevaluable because they stopped treatment early (42-62 days) and their disease was not evaluated at the time drug was stopped. Two patients have not been on study long enough to reach the first point of evaluation. Responses were scored using RECIST criteria.

Response	**N (%)**	**Duration (months)**
Partial Response	3 (43%)	4, 4+, 9
Stable Disease	2 (29%)	8+, 11
Progression	2 (29%)	2, 3
Too Early	2	
Not Evaluable	4	

Times with '+' meaning patient still stable or responding at time of analysis.

Accumin Transaction

On April 6, 2006, Accumin Diagnostics, Inc., our wholly-owned subsidiary, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. See Note 4 - “Accumin Transaction.”

General Corporate

We were incorporated in Delaware in October 1998. We commenced operations in November 1999, following our acquisition of substantially all of the assets and certain of the liabilities of Partec Ltd., our predecessor company that began operations in January 1997. Since commencing operations, our activities have been primarily devoted to developing our technologies and drug candidates, acquiring clinical-stage compounds, raising capital, purchasing assets for our facilities, and recruiting personnel.

We are a development stage company and have no product sales to date. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, and from public offerings of our common stock. We have devoted substantially all of our efforts to the discovery, 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 service revenues consist entirely of clinical trial management and site recruitment services. Revenues from providing these services are recognized as the services are provided. Deferred revenue is recorded when we receive a deposit or prepayment for services to be performed at a later date.

Our diagnostic revenue is based on the sale of diagnostic products 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.

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

Our cost of services consist 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 systems and other support facilities associated with delivering services to our clients. Cost of services are recognized as services are performed.

Our cost of diagnostics sold consist specifically of costs associated with the manufacture of the diagnostic products such as payments to third-party vendors and systems, 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 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 product 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 and warrants. Compensation expense for awards of options 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 statement of operations. For awards of options and warrants to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. These awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. We expect to incur significant non-cash compensation as a result of adopting SFAS No. 123R, which we adopted on January 1, 2006. In addition, because some of the options and warrants issued to employees, consultants and other third-parties either do not vest immediately or vest upon the achievement of certain milestones, the total expense is uncertain.

For periods presented prior to our adoption of SFAS 123R, compensation expense for fixed award options and warrants granted to employees and directors represents the intrinsic value (the difference between the stock price of the common stock and the exercise price of the options or warrants) of the options and warrants at the date of grant. For variable awards, we considered the difference between the stock price at reporting date and the exercise price, in the case where a measurement date has not been reached. The compensation cost was recorded over the respective vesting periods of the individual stock options and warrants. The expense was included in the respective categories of expense in the statement of operations.

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 product 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 will 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.

Stock Option Review

At the direction of our Board of Directors, we commenced an internal review into our historical stock option practices from the date of our initial public offering to the present under the stock option plans in effect during this period, including a review of the underlying option grant documentation and procedures. This internal review has been completed as of the date of this filing and is discussed below.

In addition to this review, the Board of Directors conducted a review led by one of the independent members of the Board of the facts and circumstances surrounding a stock option grant in the first quarter of 2004 and a May 1, 2003 grant to employees. With the assistance of outside counsel, the review included interviews and a review of contemporaneous documents relevant to these grants. The availability of contemporaneous documents may have been limited to some extent by the fact that the grants occurred over two years ago. The review did not discover any evidence of intentional fraud or wrongdoing in connection with these option grants.

During our early history as a public company, we generally utilized meetings or unanimous written consents signed by all members of the applicable committee to approve multiple option grants, the effective dates of which preceded the date of the meeting or written consent. We have determined that the proper measurement date, for accounting purposes, may differ from the legal effective date. We also historically considered the effective date specified in the written consents as the accounting measurement date for determining stock-based compensation expense. However, we have concluded that in some instances the proper measurement date for accounting purposes may not be the effective date of the grant, if the terms of the stock option grant were not communicated to the optionee within a reasonable period of time after the grant was effective. In such instance, the measurement date may be such later date on which the terms were actually communicated.

Based on the results of the Company's review of its historical stock option practices, including its underlying option grant documentation and procedures, the Company determined that the additional compensation expense resulting from revised measurement dates was not material for any period and has not been recorded. The following illustrates the effect on net loss per share had this compensation charge been reflected, as and when incurred, in our results of operations in prior years:

Net loss per share:	**2005**	**2004**	**2003**	**2002**	**2001**
As reported	$ (0.78)	$ (1.10)	$ (0.43)	$ (0.59)	$ (0.50)
As adjusted	$ (0.79)	$ (1.10)	$ (0.44)	$ (0.60)	$ (0.50)

Additionally, in connection with our acquisition of ACCESS Oncology, Inc., which was completed in February 2004, the Board of Directors considered during board meetings convened for the purpose of approving the acquisition the proposed stock option component that would be designated to the ACCESS management team. The disclosure of the stock option grant to one member of the ACCESS management team, Dr. Craig Henderson, in our proxy statements following the acquisition date, did not, however, agree with the final terms of the stock option grant as evidenced in Dr. Henderson's employment agreement. Dr. Henderson's stock options, 1,000,000 in total, carry an exercise price equal to the closing price of our common stock on the date immediately prior to the date of his employment, or February 5, 2004, according to the terms of his employment agreement. Dr. Henderson's stock options have an exercise price of $9.25, and not the price of $4.59 we previously disclosed. This discrepancy did not have an accounting impact for the periods prior to the first quarter of fiscal 2006. For the first quarter of 2006, however, with the adoption of SFAS 123(R), the value attributed to Dr. Henderson's stock options was incorrectly calculated, and as a result an additional compensation charge of $565,000 has been recorded in the three months ended June 30, 2006, to expense the additional compensation attributable to the incorrect calculation.

In addition, we have determined that the cumulative pretax stock-based compensation charge upon the adoption of SFAS 123(R), resulting from the change in grant date fair value of stock options granted, excluding Dr. Henderson's stock option grant, is $117,000, which amount has been recorded in the three months ended June 30, 2006. Had this compensation charge together with Dr. Henderson's been reflected, as and when incurred, in our results of operations in the first quarter of fiscal 2006, the impact on our net loss for the period would have been an increase in net loss of $0.02 per share. The impact is not material to our first or second quarter 2006 financials, and there is no impact on net cash used in operating activities as a result of the additional compensation charges.

RESULTS OF OPERATIONS

Three months ended June 30, 2006 and June 30, 2005

Diagnostic Revenue. Diagnostic revenue for the three months ended June 30, 2006 was $23,000 as compared to no diagnostic revenue for the three months ended June 30, 2005. Diagnostic revenue for the three months ended June 30, 2006 was a result of our acquisition of Accumin during the second quarter of 2006. We do not expect our diagnostic revenue to have a material impact on our financial results during the remainder of 2006.

Service Revenue. Service revenue increased by $98,000 to $224,000 for the three months ended June 30, 2006, as compared to service revenue of $126,000 for the three months ended June 30, 2005. The increase in service revenue was primarily due to the timing of services performed in accordance with our service contracts. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2006.

Cost of Diagnostics Sold Expense. Cost of diagnostics sold expense for the three months ended June 30, 2006 was $19,000 as compared to no cost of diagnostics sold expense for the three months ended June 30, 2005. Cost of diagnostics sold expense for the three months ended June 30, 2006 was a result of our acquisition of Accumin during the second quarter of 2006. We do not expect our cost of diagnostics sold expense to have a material impact on our financial results during the remainder of 2006.

Cost of Services Expense. Cost of services expense decreased by $63,000 to $98,000 for the three months ended June 30, 2006, as compared to an expense of $161,000 for the three months ended June 30, 2005. The decrease in cost of services was primarily due to a reduction in the amount of time necessary to service client contracts. We do not expect our cost of service expense to have a material impact on our financial results during the remainder of 2006.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants was $2,104,000 for the three months ended June 30, 2006, as compared to an expense of $137,000 for the three months ended June 30, 2005. The increase in non-cash compensation expenses was due primarily to the adoption of SFAS 123R on January 1, 2006, and the $620,000 charge relating to our review of historical stock option grants described above. In addition, expenses during the three months ended June 30, 2006, and June 30, 2005, of $86,000 and $137,000, respectively were due to the adjustment to fair market value of previously-issued options to consultants.

Other Research and Development Expenses. Other research and development expenses increased by $7,172,000 to $12,352,000 for the three months ended June 30, 2006, as compared to an expense of $5,180,000 for the three months ended June 30, 2005. The increase in other research and development expenses was due primarily to a $5,556,000 increase in expenses related to our Sulonex pivotal Phase III and Phase IV clinical program, and due to a $1,350,000 increase in expenses related to our other clinical compounds (including a $500,000 milestone expense relating to Zerenex).

We expect our other research and development costs to increase during the remainder of 2006 as a result of the pivotal Phase III and Phase IV clinical program for Sulonex and the expansion of the clinical program for KRX-0401, including the planned commencement of additional single agent and combination trials, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense related to stock option grants and warrant issuances was $3,541,000 for the three months ended June 30, 2006, as compared to an expense of $168,000 for the three months ended June 30, 2005. The increase in non-compensation expenses was primarily associated with the adoption of SFAS 123R on January 1, 2006 and the $62,000 charge relating to our review of historical stock option grants described above. In addition, modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second quarter resulted in expenses of $1,697,000 during the

three months ended June 30, 2006. Additionally, expenses during the three months ended June 30, 2006, and June 30, 2005, of $194,000 and $57,000, respectively were due to the adjustment to fair market value of previously-issued options to consultants.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $1,161,000 to $1,860,000 for the three months ended June 30, 2006, as compared to an expense of $699,000 for the three months ended June 30, 2005. The increase in selling, general and administrative expenses was due primarily to an increase of $493,000 in legal expenses and due to $245,000 of sales and marketing expenses associated with Accumin, which was acquired in April 2006.

We expect our other selling, general and administrative costs to increase modestly over the remainder of 2006 primarily as a result of our clinical development programs.

Interest and Other Income, Net. Interest and other income, net, increased by $1,632,000 to $1,899,000 for the three months ended June 30, 2006, as compared to income of $267,000 for the three months ended June 30, 2005. The increase resulted from a higher level of invested funds due to the completion of a public offering that closed in July 2005, the registered direct offering that closed in March 2006, as well as due to the general increase in short-term market interest rates when compared to the comparable period last year.

Six months ended June 30, 2006 and June 30, 2005

Diagnostic Revenue. Diagnostic revenue for the six months ended June 30, 2006 was $23,000 as compared to no diagnostic revenue for the six months ended June 30, 2005. Diagnostic revenue for the six months ended June 30, 2006 was a result of our acquisition of Accumin during the second quarter of 2006. We do not expect our diagnostic revenue to have a material impact on our financial results during the remainder of 2006.

Service Revenue. Service revenue increased by $53,000 to $336,000 for the six months ended June 30, 2006, as compared to service revenue of $283,000 for the six months ended June 30, 2005. The increase in service revenue was primarily due to the timing of services performed in accordance with our service contracts. We do not expect our service revenue to have a material impact on our financial results during the remainder of 2006.

Cost of Diagnostics Sold Expense. Cost of diagnostics sold expense for the six months ended June 30, 2006 was $19,000 as compared to no cost of diagnostics sold expense for the six months ended June 30, 2005. Cost of diagnostics sold expense for the six months ended June 30, 2006 was a result of our acquisition of Accumin during the second quarter of 2006. We do not expect our cost of diagnostics sold expense to have a material impact on our financial results during the remainder of 2006.

Cost of Services Expense. Cost of services expense decreased by $73,000 to $269,000 for the six months ended June 30, 2006, as compared to an expense of $342,000 for the six months ended June 30, 2005. The decrease in cost of services was primarily due to a reduction in the amount of time necessary to service client contracts. We do not expect our cost of service expense to have a material impact on our financial results during the remainder of 2006.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants was $4,828,000 for the six months ended June 30, 2006, as compared to an expense of $313,000 for the six months ended June 30, 2005. The increase in non-cash compensation expenses was due primarily to the adoption of SFAS 123R on January 1, 2006. In addition, expenses during the six months ended June 30, 2006, and June 30, 2005, of $336,000 and $228,000, respectively were due to the adjustment to fair market value of previously-issued options to consultants.

Other Research and Development Expenses. Other research and development expenses increased by $15,463,000 to $24,685,000 for the six months ended June 30, 2006, as compared to an expense of $9,222,000 for the six months ended June 30, 2005. The increase in other research and development expenses was due primarily to a $13,091,000 increase in expenses related to our Sulonex pivotal Phase III and Phase IV clinical program, and includes one-half, or $1,000,000, of a one-time bonus to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone, and due to a $2,175,000 increase in expenses related to our other clinical compounds (including a $500,000 milestone expense relating to Zerenex).

We expect our other research and development costs to increase during the remainder of 2006 as a result of the pivotal Phase III and Phase IV clinical program for Sulonex and the expansion of the clinical program for KRX-0401, including the planned commencement of additional single agent and combination trials, as well as possible development programs for our other drug candidates.

21

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense related to stock option grants and warrant issuances was $6,358,000 for the six months ended June 30, 2006, as compared to an expense of $353,000 for the six months ended June 30, 2005. The increase in non-compensation expenses was associated with the adoption of SFAS 123R on January 1, 2006. In addition, modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second quarter resulted in expenses of $1,697,000 during the three months ended June 30, 2006. Additionally, expenses during the six months ended June 30, 2006, and June 30, 2005, of $231,000 and $131,000, respectively were due to the adjustment to fair market value of previously-issued options to consultants.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $3,161,000 to $4,505,000 for the six months ended June 30, 2006, as compared to an expense of $1,344,000 for the six months ended June 30, 2005. The increase in selling, general and administrative expenses was due primarily to one-half, or $1,000,000, of a one-time bonus to our Chief Executive Officer for the achievement of a corporate milestone pursuant to his employment agreement. The compensation of our Chief Executive Officer is allocated equally between other research and development expenses and other general and administrative expenses to reflect the allocation of his responsibilities and activities for Keryx. The increase was also due to an increase of $677,000 in legal expenses, $470,000 of expenses incurred in the first quarter of 2006 related to the acquisition of Accumin, which closed on April 6, 2006, and $245,000 of sales and marketing expenses associated with Accumin.

We expect our other selling, general and administrative costs to increase modestly over the remainder of 2006 primarily as a result of our clinical development programs.

Interest and Other Income, Net. Interest and other income, net, increased by $2,374,000 to $2,881,000 for the six months ended June 30, 2006, as compared to income of $507,000 for the six months ended June 30, 2005. The increase resulted from a higher level of invested funds due to the completion of a public offering that closed in July 2005, the registered direct offering that closed in March 2006, as well as due to the general increase in short-term market interest rates when 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, and option and warrant exercises. This includes net proceeds of $82.7 million from our March 2006 registered direct offering and $75.8 million from our July 2005 public offering.

As of June 30, 2006, we had $155.1 million in cash, cash equivalents, interest receivable, and short-term and long-term securities, an increase of $54.4 million from December 31, 2005. Cash used in operating activities for the six months ended June 30, 2006 was $27.9 million, as compared to $9.5 million for the six months ended June 30, 2005. This increase in cash used in operating activities was due primarily to increased expenditures associated with the execution of our business plan, including costs associated with our pivotal Phase III and Phase IV clinical program for Sulonex and the expansion of our other clinical programs. For the six months ended June 30, 2006, net cash used in investing activities of $43.3 million was primarily the result of the investment of a portion of the proceeds of our registered direct offering that closed in March 2006 in marketable securities. For the six months ended June 30, 2006, net cash provided by financing activities of $84.1 million was the result of our $82.7 million registered direct offering of our common stock completed in March 2006, and $1.4 million of proceeds from the exercise of options and warrants.

In March 2006, we completed a registered direct offering of 4,500,000 shares of our common stock to two institutional investors at $18.40 per share. We received approximately $82.7 million in proceeds, net of offering expenses of approximately $0.1 million.

We believe that our $155.1 million in cash, cash equivalents, interest receivable and investment securities as of June 30, 2006 will be sufficient to enable us to meet our planned operating needs and capital expenditures for at least the next 24 months. Additionally, we also believe that our cash position provides us with added flexibility in our in-licensing and product acquisition program to potentially strengthen our portfolio with additional clinical-stage drug candidates.

Our cash and cash equivalents and investment securities as of June 30, 2006 are invested in highly liquid investments such as cash, money market accounts and short-term and long-term U.S. corporate and government debt and auction note securities. As of June 30, 2006, we are unaware of any known trends or any known demands, commitments, events, or uncertainties that will, or that are reasonably likely to, result in a material increase or decrease in our required liquidity. We expect that our liquidity needs throughout 2006 will continue to be funded from existing cash, cash equivalents, and short-term marketable securities.

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 $67.2 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 the company and our stockholders. We believe that the availability to conduct such offerings enhances our ability to raise additional capital to finance our operations.

OFF-BALANCE SHEET ARRANGEMENTS

We have not entered into any transactions with unconsolidated entities whereby we have financial guarantees, subordinated retained interests, derivative instruments or other contingent arrangements that expose us to material continuing risks, contingent liabilities, or any other obligations under a variable interest in an unconsolidated entity that provides us with financing, liquidity, market risk or credit risk support.

CRITICAL ACCOUNTING POLICIES

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

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

Stock Compensation. We have granted options to employees, directors and consultants, as well as warrants to other third parties. In December 2004, the FASB issued SFAS 123R. This SFAS 123R is a revision of SFAS 123 “Accounting for Stock-Based Compensation” and amends SFAS No. 95 “Statement of Cash Flows.” SFAS 123R supersedes APB Opinion No. 25 “Accounting for Stock Issued to Employees,” and its related implementation guidance. SFAS 123R covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. The new standard is effective as of the beginning of the first interim or annual reporting period that begins after December 15, 2005. We adopted SFAS 123R effective January 1, 2006. See Note 1 - “Stock Based Compensation.”

In applying SFAS 123R, 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, this estimate is 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 options 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 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 issued to consultants is determined at the “measurement date.” The expense is recognized over the vesting period for the options. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record option compensation based on the fair value of the options at the reporting date. These options 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 option grant, and additional expense or a negative 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 in any accounting period. In addition, administrative costs related to external CROs are recognized on a straight-line basis over the estimated contractual period.

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, 2006, there was approximately $3.1 million of net goodwill and $0.6 million of net other intangible assets on our consolidated balance sheet. We amortize our identifiable intangible assets over their estimated economic lives, which is 12 years, the life of the patents, using the straight-line method.

Impairment. SFAS No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets,” or SFAS No. 144, requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. 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. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

SFAS No. 142 requires periodic tests of goodwill for impairment and that other intangible assets be amortized over their useful lives unless these lives are determined to be indefinite. 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 determine the implied fair value by discounting, to present value, the estimated future cash flow of the reporting unit, which includes various analyses, assumptions and estimates including discount rates, projected results and estimated cash flows.

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.

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 U.S. 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 establishing the valuation allowance. In prior periods, our wholly-owned Israeli subsidiaries had generated taxable income in respect of services provided within the group, and therefore we believed in the past that our deferred tax assets relating to the Israeli subsidiaries would be realized. With the cessation of operating activities in Israel during 2003 and the resulting absence of taxable income from the Israeli subsidiaries, the deferred tax asset was written off in 2003.

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 note securities in accordance with our investment policy. Some of the securities in which we invest may have market risk. This means that a change in prevailing interest rates 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, 2006, our portfolio of financial instruments consists of cash equivalents and short-term and long-term interest bearing securities, including corporate debt, money market funds, government debt and auction note securities. The average duration of all of our held-to-maturity investments held as of June 30, 2006, was less than 12 months. Additionally, the re-pricing of our auction notes within thirty days allows these securities to function as short-term investments. Due to the short-term nature of our investments, we believe we have no material exposure to interest rate risk arising from our investments.

ITEM 4. CONTROLS AND PROCEDURES

Review of Stock Option Granting Practices

At the direction of our Board of Directors, we commenced an internal review into our historical stock option practices from the date of our initial public offering to the present under the stock option plans in effect during this period, including a review of the underlying option grant documentation and procedures. This internal review has been completed as of the date of this filing and is discussed elsewhere in this report. Our review of stock option grant procedures concluded that there were historical documentation problems.

In addition to this review, the Board of Directors conducted a review led by one of the independent members of the Board of the facts and circumstances surrounding a stock option grant in the first quarter of 2004 and a May 1, 2003

grant to employees. With the assistance of outside counsel, the review included interviews and a review of contemporaneous documents relevant to these grants. The availability of contemporaneous documents may have been limited to some extent by the fact that the grants occurred over two years ago. The review did not discover any evidence of intentional fraud or wrongdoing in connection with these option grants.

Evaluation of Disclosure Controls and Procedures

As of June 30, 2006, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934). Our disclosure controls and procedures are designed to provide reasonable assurance that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, which took into account the matters discussed below, our Chief Executive Officer and Chief Financial Officer concluded that, as of June 30, 2006, our disclosure controls and procedures were effective.

We have identified historical deficiencies in our controls relating to stock option plan administration and accounting for and disclosure of stock option grants from the period beginning at our initial public offering through the beginning of 2004. While the issues encountered in early periods no longer exist, in the second half of 2006 we intend to take the following actions to strengthen our controls in this area, including:

- Improve communication between our legal counsel and our finance department relating to stock option grants and administrative practices, including related documentation requirements;
- Improve training and education designed to ensure that all relevant personnel involved in the administration of stock option grants understand the terms of our stock option plans and the relevant accounting guidance under generally accepted accounting principles for stock options and other share-based payments; and
- Add additional personnel with accounting experience in the area of compensation generally.

In addition, on August 7, 2006, the Board of Directors took action to further strengthen our controls by establishing the following policies relating to stock option grants:

- All stock option grants to employees are to be made by the Compensation Committee or the Board of Directors, and no authority to grant stock options is delegated to management;
- All stock option grants to newly hired, promoted or special recognition employees are to be made at the next meeting of the Compensation Committee or Board of Directors immediately following the date of their hiring, promotion or recognition;
- All other stock option grants are to be made one time each year, at the meeting of the Compensation Committee or Board of Directors held during the fourth fiscal quarter; and
- The exercise price of all employee stock options is to be equal to the closing price of the Company's common stock, as reported by The Nasdaq Stock Market, on the date of grant by the Compensation Committee or Board of Directors.

Internal Control Over Financial Reporting

Except as described above, there were no significant changes in our internal control over financial reporting that occurred during the Company's quarter ended June 30, 2006, 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.

26

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 $973,000 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 and a hearing date has been set by the Circuit Court of Jerusalem. A hearing on a motion by Keryx Biopharmaceuticals, Inc. to vacate service of process outside of Israel and dismiss the lawsuit was held in June 2006, but the Circuit Court of Jerusalem has not ruled with respect to the motion at this time. To date, 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.

In April 2006, we acquired the assets of the diagnostics business of AusAm Biotechnologies, Inc., a debtor in a pending Chapter 11 proceeding, in a court-approved transaction. Subsequent to the closing, disputes arose between the debtor and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, the debtor filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145. (In re: AusAm Biotechnologies, Inc., Chapter 11 Case No. 06-10214 (RDD) (Bankr. S.D.N.Y.)). We intend to defend this action vigorously and do not believe that it will have a material adverse effect on Keryx.

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, 2006, we had an accumulated deficit of approximately $151.9 million. As we expand 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. 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. In addition, one of our current trials for Sulonex is 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 U.S. For instance, we have clinical trial sites for both our Phase III and Phase IV clinical trials in Israel. If the conflict in Israel continues and/or expands and these sites are unable to recruit additional patients or are unable to follow patients already enrolled in these trials, this may affect our timelines for completion of these trials.

Additionally, we have finalized an SPA agreement with the FDA for the Phase III and Phase IV clinical trials of Sulonex. The clinical plan to support a new drug application, or NDA, approval for Sulonex under subpart H, as agreed upon with the FDA under an SPA, consists of: (i) a single Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; (ii) supportive data from previously conducted clinical studies; and (iii) substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. The subpart H process is complex and requires careful execution. No assurance can be given that we will be able to meet the requirements set forth in the SPA. Even if we meet those requirements, the FDA is not obligated to grant approval of our NDA for Sulonex. If the FDA approves Sulonex for marketing on the basis of our Phase III trial, our Phase IV clinical trial may yield insufficient efficacy data or give rise to safety concerns, which could result in withdrawal of such approval or could cause us to withdraw the product from the market. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to 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.

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. 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. There can be no assurance that the results from the Phase III study will track the data from the Phase II study, or that

the results from the Phase IV study will yield sufficient efficacy data. With respect to Sulonex, the recommendation to move into our pivotal program, as well as the announced Phase II data, may not be indicative of results from future clinical trials and the risk remains that the pivotal program for Sulonex 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.

Clinical trials also 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 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.

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 patent rights to these drugs candidates from others. These license agreements require us to meet development or financing 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.

We rely on third parties to manufacture our products. If these third parties do not successfully manufacture our products, our business will be harmed.

We have no experience in manufacturing products for clinical or commercial purposes and do not have any manufacturing facilities. We intend to continue, in whole or in part, to use third parties to manufacture our products for use in clinical trials and for future sales. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms to us, if at all.

Contract manufacturers often encounter difficulties in scaling up production, including problems involving 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. 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, unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple manufacturers may be difficult because the number of potential manufacturers is limited and, particularly in the case of Sulonex, 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 third-party manufacturers fail to deliver the required quantities of our drug candidates on a timely basis and at commercially reasonable prices, we will not be able to commercialize our products as planned.

We have entered into a relationship with a U.S.-based contract manufacturer for Sulonex which we believe will be adequate to satisfy our current clinical supply needs; however, as we scale-up for commercial manufacturing, we will need to ensure that we accurately reproduce the established process on a larger scale. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, as we scale-up, reproducibility will be required for the successful commercialization of Sulonex. There can be no assurance that we will be successful in this endeavor. Additionally, as we scale-up, we will incur capital expenditures to enable larger scale production.

If we are not able to obtain the raw materials required for the manufacture of our lead product candidate, Sulonex, our ability to develop and market this product candidate will be substantially harmed.

Source materials for Sulonex, our lead product candidate, are derived from porcine mucosa. Long-term supplies for Sulonex could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products, over which we will have no control. Additionally, diseases affecting the world supply of pigs could have an actual or

perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell Sulonex. Such negative impact could materially affect the commercial success of Sulonex.

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 are an emerging company and 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.

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. Because we have engaged and intend to continue to engage CROs to help us obtain market approval for our drug candidates, many important aspects of this process have been and will be out of our direct control. 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 Sulonex is approved by the FDA, we currently plan to conduct our own sales and marketing effort to support the drug, and we may adopt this strategy with respect to future drug products. We currently have no 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 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.

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. In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

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

As of August 2, 2006, we had 40 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. In addition, 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 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 40 full and part-time employees. We also have significantly fewer employees than many other companies that have a product candidate in late-stage clinical development, and we rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices, 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 stock option granting practices were the subject of a comprehensive review including one conducted by an independent director. The Securities and Exchange Commission or other legal or regulatory body could initiate an inquiry into our stock option practices, which could require significant attention by management and could result in significant legal expenses.

At the direction of our Board of Directors, we commenced an internal review into our historical stock option practices from the date of our initial public offering to the present under the stock option plans in effect during this period, including a review of the underlying option grant documentation and procedures. This internal review has been completed as of the date of this filing and is discussed elsewhere in this report. Certain historical documentation and procedural deficiencies were noted. We have determined that the compensation expense adjustments resulting from those deficiencies are immaterial, however there can be no assurance that the Securities and Exchange Commission or any other regulatory body would agree with this finding.

In addition to this review, the Board of Directors conducted a review led by one of the independent members of the Board of the facts and circumstances surrounding a stock option grant in the first quarter of 2004 and a May 1, 2003 grant to employees. The review did not discover any evidence of intentional fraud or wrongdoing in connection with these option grants, howerver, there can be no assurance that the SEC or another regulatory body would agree with this finding. As of the date of this filing, we have not been contacted by the Securities and Exchange Commission or any other regulatory body or by The Nasdaq Stock Market regarding our stock option practices. We cannot, however, provide any assurance that we will not be the subject of such an inquiry, or other legal or regulatory action. If that occurs, it could result in the need to devote a significant amount of management's time in responding to such an inquiry and could also result in significant legal expenses, regulatory fines or penalties or other contingent liabilities.

Our current cash, cash equivalents and investment securities may not be adequate to support our operations for the next 24 months as we have estimated.

We believe that our $155.1 million in cash, cash equivalents, interest receivable and investment securities as of June 30, 2006 will be sufficient to enable us to meet our planned operating needs and capital expenditures for at least the next 24 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 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 we are unable to obtain additional funds on terms favorable to us, or at all, our business would be harmed.

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash, cash equivalents, interest receivable and investment securities will be sufficient to fund

our operating expenses and capital requirements for at least the next 24 months; however, the actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate, depending upon:

the progress of our development activities;

the progress of our research activities;

the number and scope of our development programs;

the costs associated with commercialization activities, including manufacturing, marketing and sales;

our ability to establish and maintain current and new licensing or acquisition arrangements;

our ability to achieve our milestones under our licensing arrangements;

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

the costs and timing of regulatory approvals.

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.

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

In July 2003, our Israeli subsidiary vacated its Jerusalem facility, after giving advance notice to the landlord. On May 1, 2005, the landlord of the Jerusalem facility filed suit in Israel claiming that we were liable as a result of the alleged breach of the lease agreement by our subsidiary. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels or approximately $973,000, 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 also filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer and a hearing date has been set by the Circuit Court of Jerusalem. A hearing on a motion by Keryx Biopharmaceuticals, Inc. to vacate service of process outside of Israel and dismiss the lawsuit was held in June 2006, but the Circuit Court of Jerusalem has not ruled with respect to the motion at this time. To date, 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.

In September 2001, one of our Israeli subsidiaries received the status of an "Approved Enterprise," a status which grants certain tax benefits in Israel in accordance with the "Law for the Encouragement of Capital Investments, 1959." Through December 31, 2003, our Israeli subsidiary, which ceased operations in 2003, has received tax benefits in the form of exemptions of approximately $744,000 as a result of our subsidiary's status as an "Approved Enterprise." As part of the restructuring implemented during 2003, we closed down our Jerusalem laboratory facility. In October 2003, the subsidiary received a letter from the Israeli Ministry of Industry and Trade that its Approved Enterprise status was cancelled as of July 2003 and that past benefits would not need to be repaid. The Israeli tax authorities have yet to confirm this position; however, we believe that, based on the letter received from the Ministry of Industry and Trade, it is unlikely that past benefits will need to be repaid, and therefore, we have not recorded any charge with

respect to this potential liability. There can be no assurances that the Israeli tax authorities will confirm this position. As a result, we may be liable to repay some or all of the tax benefits received to date, which could adversely affect our cash flow and results of operations.

We are party to a motion filed by AusAm Biotechnologies, Inc. in Bankruptcy Court that may result in us making an additional payment to AusAm Biotechnologies, Inc.

We acquired the assets of the diagnostics business of AusAm Biotechnologies, Inc., a debtor in a pending Chapter 11 bankruptcy proceedings, in a court-approved transaction. Subsequent to the closing, disputes arose between the debtor and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, the debtor filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145.

Risks Related to Our Intellectual Property

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 of intellectual property infringement could require us to spend substantial time and money defending such claims and adversely affect our ability to develop and commercialize our products.

Third parties may assert that we are using their proprietary intellectual property without authorization. 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 patent suits brought by third parties, or if we sue third parties to protect our patent 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 the affected 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 the affected 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

Concentration of ownership of our common stock among our existing executive officers and directors may prevent new investors from influencing significant corporate decisions.

As of June 30, 2006, our executive officers and directors (including their affiliates) beneficially owned, in the aggregate, approximately 18.06% of our outstanding common stock, including, for this purpose, currently exercisable options and warrants held by our executive officers and directors. As a result, these persons, acting together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of 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 $67.2 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, your equity in us may be significantly diluted. 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. 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.

As of June 30, 2006, our executive officers and directors, beneficially own, in the aggregate, approximately 18.06% of our common stock, including currently exercisable warrants and options held by them. If some or all of them should decide to sell a substantial number of their holdings, it could have a material adverse effect on the market for our common stock.

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 rights senior to those of the common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

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

On June 8, 2006, we held our annual meeting of stockholders. The only matters before the stockholders were the election of directors and the ratification of auditors. At the meeting, I. Craig Henderson, Malcolm Hoenlein, Eric Rose, Lindsay Rosenwald, Jonathan Spicehandler, 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
Michael S. Weiss	34,204,163	2,492,339
I. Craig Henderson, M.D.	36,347,670	348,832
Malcolm Hoenlein	36,652,180	44,322
Eric Rose, M.D.	36,652,180	44,322
Lindsay A. Rosenwald, M.D.	36,653,333	43,169
Jonathan Spicehandler, M.D.	36,651,723	44,779

The vote with respect to the ratification of the appointment of KPMG LLP as our independent registered accounting firm is as follows:

Total Votes For	Total Votes Against	Abstention and Broker Non-Votes
36,435,920	191,932	68,650

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 June 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 (File No. 000-30929), and incorporated herein by reference.
10.1	Amendment to the Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan dated April 11, 2006.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2006.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 8, 2006.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2006.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 8, 2006.

SIGNATURES

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

KERYX BIOPHARMACEUTICALS, INC.

Date: August 8, 2006	By:	/s/ Ronald C. Renaud, Jr Senior Vice President, Chief Financial Officer, Secretary and Treasurer (Principal Financial and Accounting Officer)

EXHIBIT INDEX

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

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