KERYX BIOPHARMACEUTICALS INC
Form 10-Q
August 09, 2007

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, 2007

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

There were 43,591,153 shares of the registrant's common stock, $0.001 par value, outstanding as of August 7, 2007.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED JUNE 30, 2007

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SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations for increases or decreases in expenses;
- expectations for the development, manufacturing, regulatory approval, and commercialization of Sulonex™, Zerenex™, KRX-0401 (perifosine), and our additional product candidates or any other products we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our business strategy;
- expected losses; and
- expectations for future capital requirements.

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Balance Sheets as of June 30, 2007, and December 31, 2006

(in thousands, except share and per share amounts)

	June 30, 2007 (Unaudited)	December 31, 2006
Assets		
Current assets		
Cash and cash equivalents	$ 24,420	$ 48,736
Short-term investment securities	61,162	63,659
Accrued interest receivable	382	525
Other current assets	426	2,048
Total current assets	86,390	114,968
Long-term investment securities	2,294	12,690
Property, plant and equipment, net	11,168	8,489
Goodwill	3,208	3,208
Other assets, net	344	958
Total assets	$ 103,404	$ 140,313
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 10,212	$ 10,460
Accrued compensation and related liabilities	606	1,534
Deferred revenue	265	200
Total current liabilities	11,083	12,194
Contingent equity rights	4,004	4,004
Other liabilities	248	294
Total liabilities	15,335	16,492
Stockholders' equity		
Common stock, $0.001 par value per share (95,000,000 and 60,000,000 shares authorized, 43,661,101 and 43,516,669 shares issued, 43,581,153 and 43,460,569 shares outstanding at June 30, 2007, and December 31, 2006, respectively)	44	44
Additional paid-in capital	317,867	312,078
Treasury stock, at cost, 79,948 and 56,100 shares at June 30, 2007, and December 31, 2006, respectively	(357)	(89)
Deficit accumulated during the development stage	(229,485)	(188,212)
Total stockholders' equity	88,069	123,821
Total liabilities and stockholders' equity	$ 103,404	$ 140,313

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statements of Operations for the
Three and Six Months Ended June 30, 2007 and 2006 (Unaudited)

(in thousands, except share and per share amounts)

	Three months ended June 30,		Six months ended June 30,		Amounts accumulated during the development stage
	2007	2006	2007	2006	
Revenue:					
Diagnostic revenue	$ 36	$ 23	$ 66	$ 23	$ 169
Service revenue	14	224	26	336	1,840
Management fees from related party	--	--	--	--	300
Total revenue	50	247	92	359	2,309
Operating expenses:					
Cost of diagnostics sold	16	19	38	19	178
Cost of services	30	98	62	269	2,106
Research and development:					
Non-cash compensation	1,178	2,104	2,173	4,828	16,411
Non-cash acquired in-process research and development	--	--	--	--	18,800
Other research and development	15,685	12,352	33,131	24,685	153,164
Total research and development	16,863	14,456	35,304	29,513	188,375
Selling, general and administrative:					
Non-cash compensation	1,407	3,541	3,413	6,358	17,262
Other selling, general and administrative	2,394	1,860	5,189	4,505	39,385
Total selling, general and administrative	3,801	5,401	8,602	10,863	56,647
Total operating expenses	20,710	19,974	44,006	40,664	247,306
Operating loss	(20,660)	(19,727)	(43,914)	(40,305)	(244,997)
Interest and other income, net	1,200	1,899	2,641	2,881	16,003
Net loss before income taxes	(19,460)	(17,828)	(41,273)	(37,424)	(228,994)

Income taxes	--	--	--	--	491
Net loss	$ (19,460)	$ (17,828)	$ (41,273)	$ (37,424)	$ (229,485)
Basic and diluted loss per common share	$ (0.45)	$ (0.41)	$ (0.95)	$ (0.92)	$ (10.66)
Weighted average shares used in computing basic and diluted net loss per common share	43,556,475	43,117,656	43,531,495	40,608,571	21,530,982

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statement of Changes in Stockholders' Equity for the
Six Months Ended June 30, 2007 (Unaudited)

(in thousands, except share amounts)

	Common stock		Additional paid-in capital
	Shares	Amount	
Balance at December 31, 2006	43,516,669	$ 44	$ 312,078
Changes during the period:			
Cancellation of common stock held in escrow	(15,646)	(--)*	--
Issuance of restricted stock	165,000	--*	--
Forfeiture of restricted stock	(83,334)	(--)*	--
Surrender of common stock for tax withholding	--	--	--
Exercise of options	78,412	--*	203
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	--	--	5,586
Net loss	--	--	--
Balance at June 30, 2007	43,661,101	$ 44	$ 317,867

	Treasury stock		Deficit accumulated during the development Stage	Total
	Shares	Amount		
Balance at December 31, 2006	56,100	$ (89)	$ (188,212)	$ 123,821
Changes during the period:				
Cancellation of common stock held in escrow	--	--	--	(--)*
Issuance of restricted stock	--	--	--	--*
Forfeiture of restricted stock	--	--	--	(--)*
Surrender of common stock for tax withholding	23,848	(268)	--	(268)
Exercise of options	--	--	--	203
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	--	--	--	5,586
Net loss	--	--	(41,273)	(41,273)
Balance at June 30, 2007	79,948	$ (357)	$ (229,485)	$ 88,069

** Amount less than one thousand dollars.*

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2007 and 2006 (Unaudited)

(in thousands)

	Six months ended June 30,		Amounts accumulated during the development stage
	2007	**2006**	**stage**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (41,273)	$ (37,424)	$ (229,485)
Adjustments to reconcile cash flows used in operating activities:			
Acquired in-process research and development	--	--	18,800
Stock compensation expense	5,586	11,186	33,673
Issuance of common stock to technology licensor	--	--	359
Interest on convertible notes settled through issuance of preferred shares	--	--	253
Depreciation and amortization	84	120	2,919
(Gain) loss on disposal of property, plant and equipment	(1)	--	171
Impairment charges	600	--	3,082
Exchange rate differences	--	--	94
Changes in assets and liabilities, net of effects of acquisitions:			
Decrease (increase) in other current assets	1,622	(1,524)	46
Decrease (increase) in accrued interest receivable	143	(86)	(382)
(Increase) in security deposits	--	(241)	(263)
(Decrease) increase in accounts payable and accrued expenses	(248)	625	8,467
(Decrease) increase in accrued compensation and related liabilities	(928)	(558)	11
(Decrease) increase in other liabilities	(46)	(34)	93
Increase (decrease) in deferred revenue	65	81	(191)
Net cash used in operating activities	(34,396)	(27,855)	(162,353)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(2,763)	(1,798)	(15,751)
Proceeds from disposals of property, plant and equipment	15	--	440
(Increase) in note and accrued interest receivable from related party	--	--	(356)
Payments of transaction costs	--	(145)	(231)
Decrease (increase) in other assets	--	27	(1,192)
Investment in held-to-maturity short-term securities	(2,034)	(4,011)	(50,947)
Proceeds from maturity of held-to-maturity short-term securities	8,504	1,071	60,525

Investment in available-for-sale short-term securities	(10,000)	(30,825)	(68,100)
Proceeds from sale of available-for-sale short-term securities	18,750	175	35,150
Investment in held-to-maturity long-term securities	(2,329)	(7,822)	(40,276)
Proceeds from maturity of held-to-maturity long-term securities	2	4	192
Net cash provided by (used in) investing activities	10,145	(43,324)	(80,546)

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Statements of Cash Flows for the Six Months Ended June 30, 2007 and 2006 (Unaudited)
(continued)

(in thousands)

	Six months ended June 30,		Amounts accumulated during the development stage
	2007	**2006**	
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from short-term loans	$ --	$ --	$ 500
Proceeds from long-term loans	--	--	3,251
Payment of assumed notes payable and accrued interest in connection with the ACCESS Oncology acquisition	--	--	(6,322)
Issuance of convertible note, net	--	--	2,150
Issuance of preferred shares, net	--	--	8,453
Receipts on account of shares previously issued	--	--	7
Proceeds from initial public offering, net	--	--	46,298
Proceeds from subsequent public offerings, net	--	82,696	158,487
Proceeds from private placements, net	--	--	45,795
Proceeds from exercise of options and warrants	203	1,361	9,052
Purchase of treasury stock	(268)	--	(357)
Net cash (used in) provided by financing activities	(65)	84,057	267,314
Cash acquired in acquisition	--	5	99
Effect of exchange rate on cash	--	--	(94)
NET (DECREASE) INCREASE IN CASH AND CASH EQUIVALENTS	(24,316)	12,883	24,420
Cash and cash equivalents at beginning of year	48,736	68,175	--
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 24,420	$ 81,058	$ 24,420
NON - CASH TRANSACTIONS			
Issuance of common stock in connection with acquisition	$ --	$ 3,310	$ 9,635
Contingent equity rights in connection with acquisition	--	--	4,004
Assumption of liabilities in connection with acquisition	--	347	9,068
Conversion of short-term loans into contributed capital	--	--	500
Conversion of long-term loans into contributed capital	--	--	2,681
Conversion of long-term loans into convertible notes of Partec	--	--	570
	--	--	2,973

Conversion of convertible notes of Partec and accrued interest into stock in Keryx						
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 Consolidated Financial Statements (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 medically important, 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. Most of the Company's biopharmaceutical development and substantially all of its administrative operations during the six months ended June 30, 2007, and 2006, were conducted in the United States of America.

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

On April 6, 2006, Accumin Diagnostics, Inc., a wholly-owned subsidiary of the Company, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. The transaction was accounted for under the purchase method of accounting. The assets and liabilities of Accumin that the Company acquired and assumed pursuant to the acquisition have been included in the Company's consolidated financial statements as of April 6, 2006. (See Note 4).

The accompanying unaudited consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles (“GAAP”) for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the consolidated financial statements have been included. Nevertheless, these financial statements should be read in conjunction with the Company's audited consolidated financial statements contained in its Annual Report on Form 10-K for the year ended December 31, 2006. The results of operations for the three and six months ended June 30, 2007 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

The Company adopted Statement of Financial Accounting Standards No. 123R, “Share-Based Payment” (“SFAS 123R”) on January 1, 2006 using the modified prospective transition method. 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. 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.

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 outstanding as of June 30, 2007, and 2006, which are not included in the computation of net loss per share amounts, were 10,859,094 and 10,816,937, 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 reclassified because they were not significant.

ACCOUNTING FOR MANUFACTURING SUITE

As of June 30, 2007, the Company has spent approximately $10.8 million in capital expenditures building its manufacturing suite for Sulonex. The Company anticipates that in the second half of 2007, after equipment validation has been completed, the facility will be ready for its intended use, and the Company will begin to depreciate this asset at that time.

INCOME TAXES

On January 1, 2007, the Company adopted FIN 48, Accounting for Uncertainty in Income Taxes. FIN 48 clarifies the criteria for recognizing tax benefits related to uncertain tax positions under SFAS No. 109, Accounting for Income Taxes, and requires additional financial statement disclosure. FIN 48 requires that the Company recognize, in its consolidated financial statements, the impact of a tax position if that position is more likely than not to be sustained upon examination, based on the technical merits of the position. Adoption of FIN 48 had no impact on the Company’s consolidated results of operations and financial position.

Upon adoption, the Company believes there are no uncertain tax positions that fail to meet the more likely than not recognition threshold under FIN 48 to be sustained upon examination.

Prior to the adoption of FIN 48, the Company included interest accrued on the underpayment of income taxes, if any, in selling, general and administrative expense. The Company continued to follow this policy following the adoption of FIN 48.

The Company files income tax returns in the U.S. and the statue of limitations has expired for years prior to 2003. In 2006, the Internal Revenue Service commenced an examination of the Company's U.S. Federal income tax returns for tax years 2004 and 2005. The Company has filed inactive returns in Israel for its subsidiaries in Israel since 2004. These subsidiaries in Israel had ceased operations and are currently in the process of being closed down. In 2007, the Israeli tax authorities commenced an examination of the Israeli tax returns of one of the Company's subsidiaries in Israel for the tax years 2003 through 2006.

The Company and its subsidiaries file income tax returns in the U.S. federal jurisdiction and in various states. The Company has tax net operating loss carryforwards that are subject to examination for a number of years beyond the year in which they are utilized for tax purposes. Since a portion of these carryforwards may be utilized in the future, many of these carryforwards will remain subject to examination.

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.

On June 20, 2007, at the 2007 Annual Meeting of Stockholders, the Company's stockholders approved an amendment to the Company's amended and restated certificate of incorporation increasing the shares of authorized common stock from 60,000,000 shares to 95,000,000 shares. The number of authorized shares of preferred stock remains unchanged at 5,000,000 shares.

TREASURY STOCK

On February 14, 2007, our former Chief Financial Officer surrendered to the Company 5,973 shares of common stock in order to satisfy his tax withholding obligation upon the vesting of 16,666 shares of restricted stock. The 5,973 shares of common stock are being held by the Company in Treasury, at a cost of approximately $70,000, representing the fair market value on the date the shares were surrendered.

On April 25, 2007, our President surrendered to the Company 17,875 shares of common stock in order to satisfy his tax withholding obligation upon the vesting of 50,000 shares of restricted stock. The 17,875 shares of common stock are being held by the Company in Treasury, at a cost of approximately $198,000, representing the fair market value on the date the shares were surrendered.

STOCK OPTIONS, RESTRICTED STOCK AND WARRANTS

In March 2007, the Company adopted the 2007 Chief Accounting Officer Inducement Stock Option Plan (the "2007 CAO Plan"). Under the 2007 CAO Plan, the Company's board of directors granted an option to the newly-appointed Chief Accounting Officer of the Company to purchase up to 100,000 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 Accounting Officer was made pursuant to an employment arrangement. Of these options, 25,000 vest on the one-year anniversary of employment and 6,250 vest every three months following the one-year anniversary of employment, until the 48th month of employment. No additional shares of our common stock may be issued under the 2007 CAO Plan.

In April 2007, the Company adopted the 2007 General Counsel Incentive Stock Option Plan (the "2007 GC Plan"). Under the 2007 GC Plan, the Company's board of directors granted an option to the newly-appointed General Counsel of the Company to purchase up to 150,000 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 General Counsel was made pursuant to an employment arrangement. Of these options, 37,500 vest on the one-year anniversary of employment and 9,375 vest every three months following the one-year anniversary of employment, until the 48th month of employment. No additional shares of our common stock may be issued under the 2007 GC Plan.

The 2007 Incentive Plan was adopted in June 2007 by our stockholders. Under the 2007 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2007 Incentive Plan authorizes grants to purchase up to 6,000,000 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, 2007, up to an additional 6,000,000 shares may be issued under the 2007 Incentive Plan.

The following table summarizes equity awards authorized by the Company as of June 30, 2007.

Plan	Exercise price	Authorized	Outstanding	Exercised	Restricted stock vested	Exercisable	Available for grant
1999 Stock Option Plan	$ 0.10 - 1.30	4,230,000	617,995	3,506,505	--	617,995	--
2000 Stock Option Plan	1.10 - 14.64	4,455,000	2,819,465	1,581,156	--	2,291,455	54,379
Non Plan	0.33	240,000	60,000	157,500	--	60,000	--
2002 CEO Incentive Stock Option Plan	1.30	2,002,657	2,002,657	--	--	2,002,657	--
2004 President Incentive Plan	9.25	1,000,000	1,000,000	--	--	500,000	--
2004 Long-Term Incentive Plan	7.13 - 18.06*	4,000,000	3,721,445	131,037	66,666	1,444,615	80,852
2006 CFO Incentive Plan	15.30	500,000	180,556	--	--	180,556	--
2007 CAO Inducement Plan	11.11	100,000	100,000	--	--	--	--
2007 General Counsel Incentive Stock Option Plan	11.02	150,000	150,000	--	--	--	--
2007 Incentive Plan	--	6,000,000	--	--	--	--	6,000,000
		22,677,657	10,652,118	5,376,198	66,666	7,097,278	6,135,231

* Exercise price range excludes restricted stock.

A summary of the status of the Company's equity awards as of June 30, 2007 and December 31, 2006, and changes during the period is presented in the table below.

		Outstanding equity awards	
	Shares available	Number of shares	Weighted-average exercise price
Balance, December 31, 2006	152,158	10,849,713	$ 7.82

Authorized	6,250,000	--		--
Granted	(651,200)	651,200		8.05
Exercised	--	(78,412)		2.59
Restricted stock vested	--	(66,666)		--
Canceled	(319,444)	--		--
Forfeited and expired	703,717	(703,717)		12.18
Balance, June 30, 2007	6,135,231	10,652,118	$	7.64
Exercisable at December 31, 2006		6,178,994	$	3.92
Exercisable at June 30, 2007		7,097,278	$	5.36

As of June 30, 2007, there were 115,000 shares of restricted stock outstanding under the 2004 Long-Term Incentive Plan (included in the tables above).

A summary of share-based compensation activity for the six months ended June 30, 2007 is presented below:

Stock Options

	Number of options	Exercise price per share	Weighted-average exercise price	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at December 31, 2006	10,749,713	$ 0.10 - 18.06	$ 7.90	7.6	$ 58,048,000
Granted	486,200	10.12 - 11.11	10.78		
Exercised	(78,412)	0.10 - 9.25	2.59		
Forfeited and expired	(620,383)	1.92 - 18.00	13.82		
Outstanding at June 30, 2007	10,537,118	$ 0.10 - 18.06	$ 7.72	7.0	$ 21,601,000
Vested and expected to vest at June 30, 2007	10,441,030	$ 0.10 - 18.06	$ 7.68	7.0	$ 21,822,000
Exercisable at June 30, 2007	7,097,278	$ 0.10 - 18.06	$ 5.36	6.4	$ 31,299,000

The aggregate intrinsic value of options exercised for the six months ended June 30, 2007 and 2006 was approximately $735,000 and $7,538,000, respectively. Upon the exercise of outstanding options, the Company issues new shares.

As of June 30, 2007, 3,604,944 options issued to directors and employees, and 93,000 options issued to consultants, are milestone-based, of which 3,379,944 options issued to directors and employees, and 43,000 options issued to consultants, are vested and exercisable.

Restricted Stock

	Number of shares	Average grant date fair value
Nonvested at December 31, 2006	100,000	$ 15.30
Granted	165,000	10.50
Vested	(66,666)	12.09
Forfeited	(83,334)	15.30
Nonvested at June 30, 2007	115,000	$ 10.28

Warrants

	Warrants	Weighted-average exercise price
Outstanding at December 31, 2006	321,976	$ 4.65
Issued	--	--
Exercised	--	--
Canceled	--	--
Outstanding at June 30, 2007	321,976	$ 4.65

Stock-based Compensation

The value of options granted 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 granted during the three months ended June 30, 2007, and 2006, as of the date of the grant, was $6.25 and $6.63, respectively. The assumptions used in the calculation of the fair value of options granted during the three months ended June 30, 2007, and 2006, were a weighted average expected term of 4.4 and 2.6 years, respectively, a weighted average expected volatility rate of 71.36% and 77.14%, respectively, and a weighted average risk-free interest rate of 4.73% and 5.04%, respectively.

The weighted average fair market value of options granted during the six months ended June 30, 2007, and 2006, as of the date of the grant, was $6.42 and $7.83, respectively. The assumptions used in the calculation of the fair value of options granted during the six months ended June 30, 2007, and 2006, were a weighted average expected term of 4.5 and 3.0 years, respectively, a weighted average expected volatility rate of 71.58% and 79.17%, respectively, and a weighted average risk-free interest rate of 4.67% and 4.76%, respectively.

The Company used historical information to estimate forfeitures within the valuation model. As of June 30, 2007, there was $20.7 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 2.5 years.

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 million 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”). The Company believes that the acquisition of Accumin could help increase the Company’s exposure to physicians that treat diabetes, the target market for Sulonex, by, among other things highlighting the need for and importance of early detection of microalbuminuria, which, if successful, could ultimately improve market perception and utilization of Sulonex. This acquisition also provided the Company with an incidental revenue stream associated with Accumin’s diagnostic tool.

The purchase price of Accumin was $3,996,000, which included the issuance of 245,024 shares of the Company’s common stock, the assumption of certain liabilities of AusAm equal to approximately $345,000 and transaction costs and cash settlement costs of approximately $341,000. 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 on revenue from a next generation product following Food and Drug Administration marketing approval. 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”). On the Effective Date, 245,024 shares were released from escrow to AusAm.

The excess of the purchase price over the net assets acquired in the Accumin transaction represented goodwill of approximately $3,208,000, which has been allocated to our Products segment based on the proposed synergies associated with Sulonex.

Subsequent to the closing, disputes arose between AusAm and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, AusAm 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.)). The matter has been settled pursuant

to a settlement agreement approved by the Bankruptcy Court on April 10, 2007. In April 2007, under the settlement, Keryx paid AusAm $110,075 in full settlement of all claims made by AusAm in the action. Following completion of the settlement, 15,646 shares of the Company's common stock, which were issued and outstanding and held in escrow, were canceled.

In accordance with Statement of Financial Accounting Standards No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," the Company recognizes an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management reviews various quantitative and qualitative factors in determining whether an impairment indicator exists, a triggering event. If an analysis is necessitated by the occurrence of a triggering event, the Company makes certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized. The Company continues to derive incidental revenue from the sale of the Accumin diagnostic tool. During the first quarter of 2007, management reviewed both its original and projected revenue estimates associated with the diagnostic tool. As a result of the projected cash flows of the diagnostic tool, the Company concluded that the intangible asset was impaired and recorded an impairment charge of approximately $600,000 to write-down identifiable intangible long-lived assets associated with Accumin. The charge was recorded in other selling, general and administrative expenses within the Diagnostics segment.

Unaudited pro forma financial information has not been presented as the AusAm information is immaterial to our results of operations.

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 medically important, 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				
(in thousands)	Three months ended June 30, 2007	2006	Six months ended June 30, 2007	2006	Amounts accumulated during the development stage
Diagnostics	$ 36	$ 23	$ 66	$ 23	$ 169
Services	14	224	26	336	1,840
Products	--	--	--	--	--
Total	$ 50	$ 247	$ 92	$ 359	$ 2,009

	Operating loss				
(in thousands)	Three months ended June 30, 2007	2006	Six months ended June 30, 2007	2006	Amounts accumulated during the development stage
Diagnostics	$ (21)	$ (414)	$ (695)	$ (414)	$ (1,712)
Services	(16)	126	(36)	67	(266)
Products	(20,623)	(19,439)	(43,183)	(39,958)	(243,019)

Total	$ (20,660)	$ (19,727)	$ (43,914)	$ (40,305)	$ (244,997)

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, 2007	2006	Six months ended June 30, 2007	2006	Amounts accumulated during the development stage
Operating loss of reportable segments	$ (20,660)	$ (19,727)	$ (43,914)	$ (40,305)	$ (244,997)
Interest and other income	1,200	1,899	2,641	2,881	16,003
Income taxes	--	--	--	--	(491)
Consolidated net loss	$ (19,460)	$ (17,828)	$ (41,273)	$ (37,424)	$ (229,485)

The carrying amount of goodwill by reportable segment as of June 30, 2007 and December 31, 2006 was as follows:

	Goodwill	
(in thousands)	June 30, 2007	December 31, 2006
Diagnostics	--	--
Services	--	--
Products	$ 3,208	$ 3,208
Total	$ 3,208	$ 3,208

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

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

The following discussion and analysis contains forward-looking statements about our plans and expectations of what may happen in the future. Forward-looking statements are based on a number of assumptions and estimates that are inherently subject to significant risks and uncertainties, and our results could differ materially from the results anticipated by our forward-looking statements as a result of many known or unknown factors, including, but not limited to, those factors discussed in "Risk Factors." See also the "Special Cautionary Notice Regarding Forward-Looking Statements" set forth at the beginning of this report.

You should read the following discussion and analysis in conjunction with the unaudited, consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited, consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2006.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including 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 and Drug Administration, or FDA. Additionally, we are developing Zerenex™, an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase II clinical development for the treatment of hyperphosphatemia (elevated phosphorous levels) in patients with end stage renal disease, or ESRD. We are also developing clinical-stage oncology compounds, including KRX-0401 (perifosine), 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-0601	Multiple forms of cancer	Phase II
KRX-0404	Multiple forms of cancer	Pre-clinical
Neurology		
KRX-0701	Diabetic neuropathy	Phase II
KRX-0501	Neurological disorders	Phase I

Recent Developments

Sulonex

In June 2007, we announced the randomization of the last patient in our pivotal Phase III clinical trial of Sulonex for the treatment of diabetic nephropathy. This Phase III clinical program, with a total of 1,056 randomized patients worldwide, is being conducted under the Subpart-H guidelines for accelerated approval pursuant to an SPA with the FDA. Based on the completion of randomization, we expect to have the last patient complete the six months of active treatment before the end of the year.

At the American Diabetes Association Annual Meeting in June 2007, the Collaborative Study Group, or the CSG, presented in a poster presentation final Phase II data from the U.S.-based pilot Phase II multi-center clinical study conducted by the CSG. A total of 149 patients were randomized into one of three groups (47 patients to placebo, 50 patients to 200 mg/day of sulodexide, and 52 patients to 400 mg/day of sulodexide) and administered study medication (All-Patient Treated Group). Out of the 149 patients in the All-Patient Treated Group (APT), 130 patients were included in the Intent-to-Treat (ITT) analysis at the end of the treatment period (six months). Nineteen patients were excluded from the ITT analysis due to the presence of a urinary tract infection and/or a missing baseline urinary albumin creatinine ratio (uACR) data.

The results for the primary composite endpoint of therapeutic success (defined as normalization with a 25% reduction in the uACR or a 50% reduction in the uACR) for the ITT group at six months (end of treatment phase) is shown in the table below:

Table 1—Percent of Patients Achieving Therapeutic Success 6 Months (End of Treatment)

	Placebo	200 mg/day sulodexide	400 mg/day sulodexide
Number of Patients	39	42	49
Number of Patients with Therapeutic Success	6	14	9
Proportion or Percentage	15%	33%	18%
95% Confidence Interval	6% - 31%	20% - 50%	9% - 32%

The trend for the increased rate of therapeutic success with the 200 mg/day dose of sulodexide versus placebo was also presented by the CSG in the poster.

Table 2—Trend for Increased Rate of Therapeutic Success[1]

Treatment Comparison	Outcome	% of Events Placebo	% of Events 200 mg/day	Odds Ratio	p Values
200 mg/day vs. Placebo	Normalization	7.7%	16.7%	2.40	0.315
200 mg/day vs. Placebo	50% Reduction	12.8%	28.6%	2.72	0.105
200 mg/day vs. Placebo	Therapeutic Success	15.4%	33.3%	2.75	0.075

(1) 95% confidence interval for therapeutic success at six month for the Odds ratio was 0.84 to 9.83.

Table 3—Percent of Patients Achieving Therapeutic Success at Six-Month Sustained Two-Months (Post-Treatment)

	Placebo	200 mg/day sulodexide	400 mg/day sulodexide
Proportion or Percentage	7.9%	22.0%	13.0%
95% Confidence Interval	1.7% - 21.4%	10.6% - 37.6%	4.9% - 26.3%

The change in the geometric mean albumin to creatinine ratio over time was presented in the poster and is shown in the table below.

Table 4—Change in Geometric Mean Albumin to Creatinine Ratio over Time

Treatment Group	Baseline	2-Month	4-Month	6-Month (End	Post-Treatment

				of Treatment)	
Placebo (n= 39)	73	70	78	85	87
200 mg/day (n= 42)	74	58	65	57	66
400 mg/day (n= 49)	67	70	67	73	74

During this study, the following coagulation parameters were assessed prior to dosing (baseline) and at the end of treatment (6-month): fibrinogen, APTT, INR ratio, and prothrombin time (PT). There were no significant changes in the coagulation parameters for placebo, 200 mg/day of sulodexide and 400 mg/day of sulodexide when comparing mean endpoint values to mean baseline values for the parameters assessed.

The number of patients with at least one adverse event of any type, a serious adverse event or possibly related adverse event was reported in the poster and is shown in the table below.

Table 5—Adverse Event Data

	Any Adverse Event			Serious Adverse Event			Possibly Related Adverse Event		
Treatment	N	% of Patients	N of Events	N	% of Patients	N of Events	N	% of Patients	N of Events
Placebo (n= 47)	38	81%	102	4	9%	4	5	11%	9
200 mg/d (n= 50)	46	92%	174	16	36%	20	7	14%	11
400 mg/d (n= 52	42	81%	114	4	10%	4	11	21%	14

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The CSG summarized in the poster that this Phase II trial was not powered to obtain definitive results for efficacy. However, observed trends were consistent with the hypothesis that administration of sulodexide is associated with a decreased urine albumin excretion in the patient population studied and the decrease in albumin excretion rate, defined as the achievement of normoalbuminuria or 50% decrease in albuminuria, appeared to be maintained for two months after cessation of therapy. A manuscript on the final results from this study has been prepared by the CSG and will be submitted to a peer-reviewed journal for publication.

We are engaged in an arbitration proceeding with the licensor of the active ingredient in Sulonex, Alfa Wasserman S.p.A. The dispute concerns certain terms of the License Agreement related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. The matter is expected to proceed to an arbitration hearing in the United Kingdom in early fourth quarter 2007. The outcome of the arbitration should not affect the validity of the license, but whether we are required to share data with Alfa Wasserman for that company's use outside of our licensed territories and our ongoing management of the licensed patent portfolio. Alfa Wasserman also seeks unspecified damages. If the arbitrator determines that we owe Alfa Wasserman the data, and that failure to deliver such data constitutes a material breach of the License Agreement, then we will have 28 days to cure such breach following the final arbitration decision by delivering any data required to be provided. Failure to cure would entitle Alfa Wasserman to terminate the License Agreement.

Zerenex

In August 2007, we provided the FDA with our 28-day toxicology package for rats and dogs. Assuming the FDA accepts our 28-day toxicology package, we plan to commence a Phase II high-dose exposure clinical trial in the fourth quarter of 2007. Once we have the Phase II high-dose exposure clinical trial underway, we will have a better understanding of when we believe we can commence our Phase III pivotal program.

KRX-0701

During the first half of 2007, we in-licensed KRX-0701 (Dexlipotam) (tromethamine-salt of R(+)- -lipoic acid), a compound being investigated for the treatment of diabetic neuropathy and possibly other neuropathic conditions. Currently, there is an Investigational New Drug Application for Dexlipotam in the United States and we are planning to initiate a Phase II dose-ranging study in 2008. KRX-0701 is considered to be an antioxidant and can normalize the cell redox imbalance that occurs in diabetes. We hold an exclusive worldwide license to KRX-0701, which we licensed from Degussa AG, a wholly owned subsidiary of the RAG Group based in Germany. In accordance with the terms of the agreement, we made an up-front payment and will make milestone payments as well as pay royalties on product sales.

KRX-0501

In May 2007, we initiated a first-in-man Phase I study for KRX-0501, a nerve growth factor enhancer, in healthy volunteers to assess the pharmacokinetic profile. KRX-0501 was licensed from Krenitsky Pharmaceuticals, Inc. in 2005 and we hold a worldwide license to develop and sell the product for all indications. KRX-0501 is believed to have potential for use in the treatment of neurological conditions such as diabetic neuropathic pain, Huntington and Alzheimer's disease, as well as chemotherapy-induced neuropathy.

Financial Management Change

On June 18, 2007, we announced that Ronald C. Renaud, Jr., Senior Vice President and Chief Financial Officer, resigned his position with us effective June 27, 2007. Mark Stier, our Chief Accounting Officer, has assumed responsibilities for all financial functions at Keryx.

General Corporate

We are a development stage company and have no drug product sales to date. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, and from public offerings of our common stock. We have devoted substantially all of our efforts to the identification, in-licensing and development of drug candidates. We have incurred negative cash flow from operations each year since our inception. We anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our product development efforts, our clinical trials and in-licensing and acquisition activities.

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

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 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, 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 drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred.

Our general and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including investor relations, general legal activities and facilities-related expenses.

Our results of operations include non-cash compensation expense as a result of the grants of stock options, restricted stock and warrants. Compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statements of operations. We expect to continue to incur significant non-cash compensation as a result of Statement of Financial Accounting Standards (“SFAS”) No. 123R, “Share-Based Payment” (“SFAS No. 123R”), which we adopted on January 1, 2006. For awards of options and warrants to consultants and other third-parties, compensation expense is determined at the “measurement date,” in accordance with the fair value method prescribed by the provisions of Emerging Issues Task Force Issue No. 96-18, “Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services” (“EITF 96-18”). The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. These awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. In addition, because some of the options, restricted stock and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

Our ongoing clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we 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.

RESULTS OF OPERATIONS

Three months ended June 30, 2007 and June 30, 2006

Diagnostic Revenue. Diagnostic revenue increased by $13,000 to $36,000 for the three months ended June 30, 2007, as compared to diagnostic revenue of $23,000 for the three months ended June 30, 2006. We do not expect our diagnostic revenue to have a material impact on our financial results during the remainder of 2007.

Service Revenue. Service revenue decreased by $210,000 to $14,000 for the three months ended June 30, 2007, as compared to service revenue of $224,000 for the three months ended June 30, 2006. The decrease in service revenue was primarily due to the timing and extent 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 2007.

Cost of Diagnostics Sold. Cost of diagnostics sold decreased by $3,000 to $16,000 for the three months ended June 30, 2007, as compared to an expense of $19,000 for the three months ended June 30, 2006. We do not expect our cost of diagnostics sold to have a material impact on our financial results during the remainder of 2007.

Cost of Services. Cost of services decreased by $68,000 to $30,000 for the three months ended June 30, 2007, as compared to an expense of $98,000 for the three months ended June 30, 2006. The decrease in cost of services was primarily due to the timing and extent of services performed in accordance with our service contracts. We do not expect our cost of services to have a material impact on our financial results during the remainder of 2007.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option and restricted stock grants was $1,178,000 for the three months ended June 30, 2007, as compared to an expense of $2,104,000 for the three months ended June 30, 2006. The three months ended June 30, 2006 included $565,000 of additional non-cash compensation expense related to the adjustment of an award, which expense should have been recognized in the three months ended March 31, 2006. Additionally, in the three months ended June 30, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense (selling, general and administrative). This change accounted for approximately $537,000 of the difference.

Other Research and Development Expenses. Other research and development expenses increased by $3,333,000 to $15,685,000 for the three months ended June 30, 2007, as compared to $12,352,000 for the three months ended June 30, 2006. The increase in other research and development expenses was due primarily to a $2,160,000 increase in expenses related to our Sulonex pivotal Phase III and Phase IV clinical programs, and due to a $1,214,000 increase in expenses related to our other clinical compounds.

We expect our other research and development costs to increase modestly during the remainder of 2007 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, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to stock option and restricted stock grants was $1,407,000 for the three months ended June 30, 2007, as compared to an expense of $3,541,000 for the three months ended June 30, 2006. This difference was primarily attributable to, during the three months ended June 30, 2006, approximately $1,697,000 of expense for modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second quarter of 2006. Additionally, in the three months ended June 30, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense

(selling, general and administrative), accounting for approximately $537,000 of increased expense, which offsets the decrease in expense discussed above. In addition, during the six months ended June 30, 2007, we recorded a reduction of expense of approximately $479,000 associated with stock option forfeitures following the resignation of our chief financial officer.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $534,000 to $2,394,000 for the three months ended June 30, 2007, as compared to an expense of $1,860,000 for the three months ended June 30, 2006. The increase in other selling, general and administrative expenses was due primarily to an increase in legal fees of approximately $246,000 associated with the maintenance of our products, as well as increased expenses associated with the scale-up of our operations and infrastructure to prepare to commercialize our drug candidates. We expect our other selling, general and administrative costs to increase over the remainder of 2007.

Interest and Other Income, Net. Interest and other income, net, decreased by $699,000 to $1,200,000 for the three months ended June 30, 2007, as compared to income of $1,899,000 for the three months ended June 30, 2006. The decrease resulted from a lower level of invested funds as compared to the comparable period last year.

Six months ended June 30, 2007 and June 30, 2006

Diagnostic Revenue. Diagnostic revenue increased by $43,000 to $66,000 for the six months ended June 30, 2007, as compared to diagnostic revenue of $23,000 for the six months ended June 30, 2006. The increase in diagnostic revenue was primarily due to the inclusion of six months of Accumin's results in the period ended June 30, 2007. The prior period included results from April 6, 2006, the acquisition date. We do not expect our diagnostic revenue to have a material impact on our financial results during the remainder of 2007.

Service Revenue. Service revenue decreased by $310,000 to $26,000 for the six months ended June 30, 2007, as compared to service revenue of $336,000 for the six months ended June 30, 2006. The decrease in service revenue was primarily due to the timing and extent 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 2007.

Cost of Diagnostics Sold. Cost of diagnostics sold increased by $19,000 to $38,000 for the six months ended June 30, 2007, as compared to an expense of $19,000 for the six months ended June 30, 2006. The increase in cost of diagnostics sold was primarily due to the inclusion of six months of Accumin's results in the period ended June 30, 2007. The prior period included results from April 6, 2006, the acquisition date. We do not expect our cost of diagnostics sold to have a material impact on our financial results during the remainder of 2007.

Cost of Services. Cost of services decreased by $207,000 to $62,000 for the six months ended June 30, 2007, as compared to an expense of $269,000 for the six months ended June 30, 2006. The decrease in cost of services was primarily due to the timing and extent of services performed in accordance with our service contracts. We do not expect our cost of services to have a material impact on our financial results during the remainder of 2007.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option and restricted stock grants was $2,173,000 for the six months ended June 30, 2007, as compared to an expense of $4,828,000 for the six months ended June 30, 2006. This difference was primarily attributable to, during the six months ended June 30, 2006, approximately $1,128,000 of expense for the accelerated vesting of options due to the achievement of a financial milestone, and additionally, in the six months ended June 30, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense (selling, general and administrative). This change accounted for approximately $1,149,000 of the difference.

Other Research and Development Expenses. Other research and development expenses increased by $8,446,000 to $33,131,000 for the six months ended June 30, 2007, as compared to $24,685,000 for the six months ended June 30, 2006. The increase in other research and development expenses was due primarily to a $4,983,000 increase in expenses related to our Sulonex pivotal Phase III and Phase IV clinical programs (the comparative period last year

included one-half, or $1,000,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone). In addition, the increase was due to a $3,487,000 increase in expenses related to our other clinical compounds (including $1,127,000 of expenses relating to the in-licensing and purchase of related inventory for KRX-0701).

We expect our other research and development costs to increase modestly during the remainder of 2007 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, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to stock option and restricted stock grants was $3,413,000 for the six months ended June 30, 2007, as compared to an expense of $6,358,000 for the six months ended June 30, 2006. This difference was primarily attributable to, during the six months ended June 30, 2006, approximately $1,636,000 of expense for the accelerated vesting of options, due to the achievement of a financial milestone, and approximately $1,697,000 of expense for modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second quarter of 2006. Additionally, in the six months ended June 30, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense (selling, general and administrative), accounting for approximately $1,149,000 of increased expense, which offsets the decrease in expenses discussed above. In addition, during the six months ended June 30, 2007, we recorded a reduction of expense of approximately $479,000 associated with stock option forfeitures following the resignation of our chief financial officer.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $684,000 to $5,189,000 for the six months ended June 30, 2007, as compared to an expense of $4,505,000 for the six months ended June 30, 2006. Other selling, general and administrative expenses for the six months ended June 30, 2007 includes an impairment charge of approximately $600,000 related to certain intangibles associated with Accumin's diagnostic product. Additionally, there was an increase in legal fees of approximately $534,000 associated with the maintenance of our products. The comparative period last year included one-half, or $1,000,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone. In addition, during the six months ended June 30, 2007, we incurred additional expenses associated with the scale-up of our operations and infrastructure to prepare to commercialize our drug candidates. We expect our other selling, general and administrative costs to increase over the remainder of 2007.

Interest and Other Income, Net. Interest and other income, net, decreased by $240,000 to $2,641,000 for the six months ended June 30, 2007, as compared to income of $2,881,000 for the six months ended June 30, 2006. The decrease resulted from a lower level of invested funds as compared to the comparable period last year.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations from inception primarily through public offerings of our common stock, various private placement transactions, and option and warrant exercises.

As of June 30, 2007, we had $88.3 million in cash, cash equivalents, interest receivable, and short-term and long-term securities, a decrease of $37.3 million from December 31, 2006. Cash used in operating activities for the six months ended June 30, 2007 was $34.4 million, as compared to $27.9 million for the six months ended June 30, 2006. 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, 2007, net cash provided by in investing activities of $10.1 million was primarily the result of the maturity and sale of marketable securities in our investment portfolio, net of purchases, of approximately $12.9 million, partially offset by purchases of property, plant and equipment of approximately $2.8 million. For the six months ended June 30, 2007, net cash used in financing activities of $65,000 was primarily the result of the surrendering to us of 23,848 shares of common stock, by our President and former Chief Financial Officer, in order to satisfy tax withholding obligations upon the vesting of restricted stock, at a cost of approximately $268,000, offset by $203,000 of proceeds from the exercise of options.

We have entered into a relationship with a U.S.-based contract manufacturer for Sulonex to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture and produce initial commercialization quantities of Sulonex (for approximately one to three years from launch). As of June 30, 2007, we have spent approximately $10.8 million in capital expenditures building our manufacturing suite for Sulonex. We anticipate that in the second half of 2007, after equipment validation has been completed, the facility will be ready for its intended use.

We believe that our $88.3 million in cash, cash equivalents, interest receivable and investment securities as of June 30, 2007 will be sufficient to enable us to meet our planned operating needs and capital expenditures through the date of the release of our Phase III Sulonex data, expected in the first half of 2008. Depending on the outcome of our Phase III study, our cash requirements will vary dramatically. In the event of a negative outcome, we believe our current capital resources will enable us to meet our revised operating needs and capital expenditures for at least 12 to 24 months from January 2008.

Our cash and cash equivalents and investment securities as of June 30, 2007 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, 2007, 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 liquidity. We expect that our liquidity needs throughout 2007 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 approximately $67 million of our common stock available for sale on this shelf registration statement. We may offer these securities from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in the best interest of Keryx and our stockholders. We believe that the availability to conduct such offerings enhances our ability to raise additional capital to finance our operations.

OFF-BALANCE SHEET ARRANGEMENTS

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

OBLIGATIONS AND COMMITMENTS

Our material contractual obligations were summarized and included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2006. There have been no material changes outside the ordinary course of business in the contractual obligations since December 31, 2006.

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:

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Stock Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. In applying SFAS No. 123R, 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 addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

In accordance with EITF 96-18 “Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,” total compensation expense for options 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, 2007, there was approximately $3.2 million of net goodwill on our consolidated balance sheet. Prior to the impairment charge taken in the first quarter of 2007, we amortized our identifiable intangible assets associated with Accumin over their estimated economic lives, which was 12 years, the life of the patents, using the straight-line method.

Impairment. In accordance with Statement of Financial Accounting Standards No. 144, “Accounting for the Impairment or Disposal of Long-Lived Assets,” the Company recognizes an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management’s policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, the Company makes certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized. The Company continues to derive revenue from the sale of the Accumin diagnostic tool. During the first quarter of 2007, management reviewed both its original and projected revenue estimates associated with the diagnostic tool. As a result of this analysis, the Company concluded that the asset was impaired and recorded an impairment charge of approximately $600,000 to write-down identifiable intangible long-lived assets associated with Accumin. The charge was recorded in other selling, general and administrative expenses within the Diagnostics segment.

Statement of Financial Accounting Standards No. 142, “Goodwill and Other Intangible Assets,” or 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 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.

Accounting For Our Manufacturing Suite. We have entered into a relationship with a U.S.-based contract manufacturer for Sulonex to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture and produce initial commercialization quantities of Sulonex (for approximately one to three years from launch). As of June 30, 2007, we have spent approximately $10.8 million in capital expenditures building the suite. We anticipate that in the second half of 2007, after equipment validation has been completed, the facility will be ready for its intended use and we will begin to depreciate this asset at that time. Significant estimates and judgments were made, and will continue to be made, relating to the appropriate in-service date of these assets and the related asset retirement obligation.

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, 2007, 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, 2007, 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

Evaluation of Disclosure Controls and Procedures

As of June 30, 2007, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Accounting Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Accounting Officer concluded that, as of June 30, 2007, our disclosure controls and procedures were effective.

Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended June 30, 2007, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

We, and our subsidiaries, are not a party to, and our property is not the subject of, any material pending legal proceedings, other than as noted below.

In July 2003, Keryx (Israel) Ltd., one of our Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of our Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, our Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,023,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. In July 2005, Keryx (Israel)

Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. and Michael S. Weiss to vacate service of process outside of Israel was held in June 2006. On October 15, 2006, the Court held that the service of the claim against Mr. Weiss is vacated. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. However, the service against us was sustained. We appealed this holding. The appeal was denied on June 18, 2007, and we filed a petition for certiorari to the Supreme Court of Israel. The motion is pending. 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., ("AusAm") a debtor in a pending Chapter 11 proceeding, in a court-approved transaction. Subsequent to the closing, disputes arose between AusAm and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, AusAm 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.)). The matter has been settled pursuant to a settlement agreement approved by the Bankruptcy Court on April 10, 2007. Under the settlement, Keryx paid AusAm $110,075 on April 12, 2007 in full settlement of all claims made by AusAm in the action.

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, 2007, we had an accumulated deficit of approximately $229.5 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, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases as we are studying. 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 United States.

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. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Since we are seeking accelerated approval under an SPA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint is achieved, an SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, changes in scientific or medical evidence or sentiment or internal inconsistency in the data prior to making their final decision. The FDA may also seek the guidance of an advisory panel prior to making their final decision. 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. 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.

Pre-clinical testing and clinical development are long, expensive and uncertain processes. If our drug candidates do not receive the necessary regulatory approvals, we will be unable to commercialize our drug candidates.

We have not received, and may never receive, regulatory approval for the commercial sale of any of our drug candidates. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. It may take us many years to complete the testing of our drug candidates and failure can occur at any stage of this process. Negative or inconclusive results or medical events during a clinical trial could cause us to delay or terminate our development efforts.

Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies. 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 Sulonex Phase III study will track the data from the pilot Collaborative Study Group Phase II study or the DiNAS Phase II study, or that the results from the Sulonex Phase IV study will yield sufficient efficacy data. Results from these earlier Sulonex studies 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. Interpretation of the prior safety and efficacy data of Sulonex, or our other drug candidates, may also be flawed and there can be no assurance that safety and/or efficacy concerns from the prior data were overlooked or misinterpreted, which in subsequent, larger studies appear and prevents approval of Sulonex or our other drugs candidates.

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. While we have engaged a clinical research organization with experience in conducting regulatory trials, errors in the conduct, monitoring and/or auditing could invalidate the results from a regulatory perspective.

Because all of our proprietary technologies are licensed to us by third parties, termination of these license agreements would prevent us from developing our drug candidates.

We do not own any of our drug candidates. We have licensed the rights, patent or otherwise, to our drugs candidates from third parties. These license agreements require us to meet development 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. From time to time, in the ordinary course of business, we may have disagreements with our licensors or collaborators regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our drug candidates or could require or result in litigation or arbitration, which would be time-consuming and expensive.

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

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture 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. In addition, we have entered into an agreement with the same manufacturer to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture launch and initial commercialization (approximately one to three years from launch) quantities of Sulonex. As we move forward, we plan to build additional manufacturing capacity to meet the future demands for Sulonex. As with all heparin-like compounds, the end product is sensitive to the manufacturing process utilized. Accordingly, as we scale-up we will need to accurately reproduce the established process on the larger scale to ensure successful commercialization of Sulonex. There can be no assurance that we will be successful in this endeavor. Additionally, as we scale-up, we have incurred, and will continue to incur, capital expenditures to enable larger scale production. Through June 30, 2007, we have spent approximately $10.8 million in

capital expenditures building the current manufacturing suite. If we fail to obtain regulatory approval for Sulonex, we may incur significant losses disposing of the assets associated with our manufacturing suite.

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.

Key raw 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. We estimate, in part, based on the number of pigs killed worldwide and estimates of projected supplies of porcine mucosa, that there is enough potential supply of this raw material to commercialize Sulonex. If our estimates of the potential supply of this key raw material are not accurate or we cannot secure adequate amounts of the potential supply of such material, then the market potential of Sulonex will not be realized. 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. Additionally, if these third parties fail to perform their obligations under our agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor and ensure the quality of such work, we may face delays in achieving the regulatory milestones required for commercialization of one or more drug candidates.

Our reliance on third parties, such as clinical research organizations, or CROs, may result in delays in completing, or a failure to complete, clinical trials if they fail to perform under our agreements with them.

In the course of product development, we engage CROs to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. If the CROs fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory manner, we may face delays in completing our clinical trials, as well as commercialization of one or more drug candidates. Furthermore, any loss or delay in obtaining contracts with such entities may also delay the completion of our clinical trials and the market approval of drug candidates.

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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.

Notwithstanding our current plans to commercialize Sulonex and our other drug candidates, from time to time we may consider offers or hold discussions with companies for partnerships or the acquisition of our company or any of our products. Any accepted offer may preclude us from the execution of our current business plan.

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

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our drug products will depend on a number of factors, including:

perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidates;

the rates of adoption of our products by medical practitioners and the target populations for our products;

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

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

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

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

the effectiveness of our sales, marketing and distribution efforts.

Because we expect sales of our products, if approved, to generate substantially all of our revenues in the long-term, the failure of our drugs to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

If our competitors develop and market products that are less expensive, more effective or safer than our drug products, our commercial opportunities may be reduced or eliminated.

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our drug products obsolete or noncompetitive. To compete successfully in this industry we must identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. 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 7, 2007, we had 43 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. Although we have an employment agreement with Mr. Weiss, this agreement does not prevent him from terminating his employment with us.

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

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

Acquisitions involve a number of operational risks, including:

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

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

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

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

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

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

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

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

government and health administration authorities;

private health insurers;

managed care programs; and

other third-party payors.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for our products. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, their market acceptance may be reduced. In particular, we are currently projecting that the price of Sulonex will be at a significant premium to the currently marketed products that are approved for the treatment of diabetic nephropathy. The inability to obtain adequate reimbursement for Sulonex would limit our ability to generate revenue and prevent us from realizing the market potential of Sulonex.

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as proposals relating to the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price) and government control of prescription drug pricing. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

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

The use of our drug candidates in clinical trials, the future sale of any approved drug candidates and new technologies, and the sale of Accumin, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials and the sale of Accumin. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for a product;

injury to our reputation;

our inability to continue to develop a drug candidate;

withdrawal of clinical trial volunteers; and

loss of revenues.

Consequently, a product liability claim or product recall may result in losses that could be material.

In connection with providing our clinical trial management and site recruitment services, we may be exposed to liability that could have a material adverse effect on our financial condition and results of operations.

The Online Collaborative Oncology Group, Inc., or OCOG, a subsidiary we acquired through our acquisition of ACCESS Oncology, provides clinical trial management and site recruitment services to us as well as other biotechnology and pharmaceutical companies. In conducting the activities of OCOG, any failure on our part to comply with applicable governmental regulations or contractual obligations could expose us to liability to our clients and could have a material adverse effect on us. We also could be held liable for errors or omissions in connection with the services we perform. In addition, the wrongful or erroneous delivery of health care information or services may expose us to liability. If we were required to pay damages or bear the costs of defending any such claims, the losses could be material.

Our corporate compliance efforts cannot guarantee that we are in compliance with all potentially applicable regulations.

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company with 43 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 believe that our corporate compliance program is sufficient to ensure compliance with applicable regulations, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Related to Our Financial Condition

Our current cash, cash equivalents and investment securities may not be adequate to support our operations for the length of time that we have estimated.

We believe that our $88.3 million in cash, cash equivalents, interest receivable and investment securities as of June 30, 2007 will be sufficient to enable us to meet our planned operating needs and capital expenditures through the date of the release of our Phase III Sulonex data, expected in the first half of 2008. Depending on the outcome of our Phase III study, our cash requirements will vary dramatically. In the event of a negative outcome, we believe our current capital resources will enable us to meet our revised operating needs and capital expenditures for at least 12 to 24 months from January 2008. Our forecast of the period of time through which our cash, cash equivalents, interest receivable and investment securities will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

the timing of completion and results from clinical trials for our drug candidates, especially Sulonex;

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 through the date of the release of our Phase III Sulonex data, expected in the first half of 2008. Depending on the outcome of our Phase III study, our cash requirements will vary dramatically. In the event of a negative outcome, we believe our current capital resources will enable us to meet our

revised operating needs and capital expenditures for at least 12 to 24 months from January 2008. 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 timing of completion and results from clinical trials for our drug candidates, especially Sulonex;

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, Keryx (Israel) Ltd., one of our Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of our Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, our Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,023,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. to vacate service of process outside of Israel was held in June 2006. On October 15, 2006, the Circuit Court of Jerusalem held that the service of process on Keryx was sustained. We appealed this holding. The appeal was denied on June 18, 2007, and we filed a petition for certiorari to the Supreme Court of Israel. The motion is pending. 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. In 2007, the Israeli tax authorities commenced an examination of the Israeli tax returns of one of the Company’s subsidiaries in Israel for the tax years 2003 through 2006. 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.

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 our drug products or technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use our drug products or technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Risks Related to Our Common Stock

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

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

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders may be significantly diluted. 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.

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 20, 2007, we held our annual meeting of stockholders. The following matters were voted on by the stockholders: the election of directors, the ratification of our independent registered public accounting firm, the approval of an amendment to our certificate of incorporation to increase the number of authorized shares of our common stock, and the approval of our 2007 Long-Term Incentive Plan. At the meeting, Kevin J. Cameron, Wyche Fowler, Jr., I. Craig Henderson, Malcolm Hoenlein, Jack Kaye, Eric Rose, and Michael S. Weiss were re-elected to our board of directors.

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

Nominee	Total Votes For	Total Votes Withheld
Kevin J. Cameron	35,006,731	1,698,997
Wyche Fowler, Jr.	32,015,455	4,750,273
I. Craig Henderson, M.D.	26,178,380	10,587,348
Malcolm Hoenlein	31,861,536	4,904,192
Jack Kaye, CPA	35,006,831	1,698,897
Eric Rose, M.D.	35,068,956	1,696,772
Michael S. Weiss	26,310,648	10,455,080

The vote with respect to the ratification of the appointment of KPMG LLP as our independent registered public accounting firm set forth below:

Total Votes For	Total Votes Against	Abstention and Broker Non-Votes
36,494,013	266,175	5,540

The vote with respect to the approval of an amendment to our certificate of incorporation to increase the number of authorized shares of our common stock to 95 million shares is set forth below.

Total Votes For	Total Votes Against	Abstention and Broker Non-Votes
33,832,449	2,925,829	7,447

The vote with respect to the approval of our 2007 Long-Term Incentive Plan is set forth below:

Total Votes For	Total Votes Against	Abstention and Broker Non-Votes
15,509,140	12,730,425	8,526,163

ITEM 6. EXHIBITS

The exhibits listed on the Exhibit Index are included with this report.

3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-Q for the quarter ended September 30, 2004, filed on August 12, 2004, and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007.
31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.

SIGNATURES

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

KERYX BIOPHARMACEUTICALS, INC.

Date: August 9, 2007	By:	/s/ Mark Stier Chief Accounting Officer Principal Financial Officer

EXHIBIT INDEX

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

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31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated August 9, 2007.