KERYX BIOPHARMACEUTICALS INC
Form 10-Q
November 04, 2005

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 September 30, 2005

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 an accelerated filer (as defined in Rule 12b-2 of the Act). Yes x No £

There were 37,697,351 shares of the registrant’s common stock, $0.001 par value, outstanding as of November 1, 2005.

KERYX BIOPHARMACEUTICALS, INC.
FORM 10-Q
FOR THE QUARTER ENDED SEPTEMBER 30, 2005

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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 factors which may be identified from time to time in our other filings with the Securities and Exchange Commission, or the SEC, or in the documents where such forward-looking statements appear. All written or oral forward-looking statements attributable to us are expressly qualified in their entirety by these cautionary statements. Such forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the development, manufacturing, and approval of KRX-101, KRX-0401, and our additional product candidates or any other products we may acquire or in-license;
- expectations for incurring additional capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our business strategy;
- expected losses; and
- expectations for future capital requirements.

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

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

PART I. FINANCIAL INFORMATION

ITEM 1. FINANCIAL STATEMENTS

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Balance Sheets as of September 30, 2005, and December 31, 2004

(in thousands, except share and per share amounts)

	September 30, 2005 (Unaudited)	December 31, 2004 (Audited)
Assets		
Current assets		
Cash and cash equivalents	$ 87,220	$ 29,699
Short-term investment securities	8,855	20,035
Accrued interest receivable	180	144
Other receivables and prepaid expenses	1,725	622
Total current assets	97,980	50,500
Long-term investment securities	13,870	--
Property, plant and equipment, net	753	145
Other assets (primarily intangible assets), net	129	217
Total assets	$ 112,732	$ 50,862
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 5,027	$ 3,079
Accrued compensation and related liabilities	31	743
Deferred revenue	148	140
Total current liabilities	5,206	3,962
Contingent equity rights	4,004	4,004
Other liabilities	327	92
Total liabilities	9,537	8,058
Stockholders' equity		
Common stock, $0.001 par value per share (60,000,000 and 60,000,000 shares authorized, 37,729,922 and 31,373,280 shares issued, 37,673,822 and 31,317,180 shares outstanding at September 30, 2005, and December 31, 2004, respectively)	38	31
Additional paid-in capital	210,686	132,643
Treasury stock, at cost, 56,100 shares at September 30, 2005 and December 31, 2004, respectively	(89)	(89)
Unearned compensation	(2,155)	(2,228)
Deficit accumulated during the development stage	(105,285)	(87,553)
Total stockholders' equity	103,195	42,804
Total liabilities and stockholders' equity	$ 112,732	$ 50,862

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Interim Unaudited Consolidated Statements of Operations for the
Three and Nine Months Ended September 30, 2005 and 2004

(in thousands, except share and per share amounts)

	Three months ended September 30,		Nine months ended September 30,		Amounts accumulated during the development stage
	2005	2004	2005	2004	
Revenue:					
Service revenue	$ 82	$ 397	$ 365	$ 642	$ 1,174
Management fees from related party	--	--	--	--	300
Total revenue	82	397	365	642	1,474
Operating expenses:					
Cost of services	197	416	539	619	1,374
Research and development:					
Non-cash compensation	226	70	539	295	7,679
Non-cash acquired in-process research and development	--	--	--	18,800	18,800
Other research and development	6,501	2,594	15,723	6,313	55,435
Total research and development expenses	6,727	2,664	16,262	25,408	81,914
General and administrative:					
Non-cash compensation	258	161	611	967	5,277
Other general and administrative	671	596	2,015	2,434	23,685
Total general and administrative expenses	929	757	2,626	3,401	28,962
Total operating expenses	7,853	3,837	19,427	29,428	112,250
Operating loss	(7,771)	(3,440)	(19,062)	(28,786)	(110,776)
Interest and other income, net	823	187	1,330	452	5,982
Net loss before income taxes	(6,948)	(3,253)	(17,732)	(28,334)	(104,794)
Income taxes	--	--	--	1	491
Net loss	$ (6,948)	$ (3,253)	$ (17,732)	$ (28,335)	$ (105,285)

Basic and diluted loss per common share	$ (0.19)	$ (0.11)	$ (0.53)	$ (0.95)	$ (6.02)
Weighted average shares used in computing basic and diluted net loss per common share	36,721,122	30,743,132	33,261,801	29,683,258	17,489,330

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Interim Unaudited Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2005 and 2004

(in thousands)

	Nine months ended September 30,		Amounts accumulated during the development stage
	2005	**2004**	**stage**
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (17,732)	$ (28,335)	$ (105,285)
Adjustments to reconcile cash flows used in operating activities:			
Acquired in-process research and development	--	18,800	18,800
Stock compensation expense	1,150	1,262	12,956
Issuance of common stock to technology licensor	--	--	359
Interest on convertible notes settled through issuance of preferred shares	--	--	253
Depreciation and amortization	136	116	2,557
Loss on disposal of property, plant and equipment	2	--	172
Impairment charges	--	--	2,482
Exchange rate differences	--	(3)	94
Changes in assets and liabilities, net of effects of acquisitions:			
(Increase) in other receivables and prepaid expenses	(1,103)	(233)	(1,354)
(Increase) decrease in accrued interest receivable	(36)	67	(180)
Increase in accounts payable and accrued expenses	1,948	147	3,714
(Decrease) in accrued compensation and related liabilities	(712)	(647)	(541)
Increase (decrease) in other liabilities	235	(46)	172
Increase (decrease) in deferred revenue	8	(244)	(308)
Net cash used in operating activities	(16,104)	(9,116)	(66,109)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(682)	(18)	(5,109)
Proceeds from disposals of property, plant and equipment	1	--	425
(Increase) in note and accrued interest receivable from related party	--	(4)	(356)
(Increase) in other assets	(4)	(4)	(1,200)
Proceeds from maturity of (investment in) held-to-maturity short-term securities	11,205	(1,048)	(3,805)
(Investment in) available-for-sale short-term securities	(25)	(5,000)	(6,050)
Proceeds from sale of available-for-sale short-term securities	--	--	1,000

(Investment in) held-to-maturity long-term securities	(13,870)	--	(13,870)
Net cash used in investing activities	(3,375)	(6,074)	(28,965)

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Interim Unaudited Consolidated Statements of Cash Flows for the Nine Months Ended September 30, 2005 and 2004
(continued)

(in thousands)

	Nine months ended September 30,		Amounts accumulated during the development stage
	2005	**2004**	**stage**
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from short-term loans	$ --	$ --	$ 500
Proceeds from long-term loans	--	--	3,251
Payment of assumed notes payable and accrued interest in connection with the ACCESS Oncology acquisition	--	(6,322)	(6,322)
Issuance of convertible note, net	--	--	2,150
Issuance of preferred shares, net	--	--	8,453
Receipts on account of shares previously issued	--	--	7
Proceeds from initial public offering, net	--	--	46,298
Proceeds from secondary public offering, net	75,843	--	75,843
Proceeds from private placements, net	--	31,707	45,795
Proceeds from exercise of options and warrants	1,157	3,726	6,408
Purchase of treasury stock	--	--	(89)
Net cash provided by financing activities	77,000	29,111	182,294
Cash acquired in acquisition	--	94	94
Effect of exchange rate on cash	--	3	(94)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	57,521	14,018	87,220
Cash and cash equivalents at beginning of year	29,699	21,672	--
CASH AND CASH EQUIVALENTS AT END OF PERIOD	$ 87,220	$ 35,690	$ 87,220
NON - CASH TRANSACTIONS			
Issuance of common stock in connection with acquisition	$ --	$ 6,325	$ 6,325
Issuance of contingent equity rights in connection with acquisition	--	$ 4,003	4,004
Assumption of liabilities in connection with acquisition	--	$ 8,724	8,723
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	$	--	$ 1,026	$ 1,166
Cash paid for income taxes	$	--	$ 1	$ 432

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Notes to Interim Consolidated Financial Statements as of September 30, 2005 (unaudited)

NOTE 1 - GENERAL

BASIS OF PRESENTATION

Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") is a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. The Company was incorporated in Delaware in October 1998 (under the name Paramount Pharmaceuticals, Inc., which was later changed to Lakaro Biopharmaceuticals, Inc. in November 1999, and finally to Keryx Biopharmaceuticals, Inc. in January 2000). The Company commenced activities in November 1999, and since then has operated in one segment of operations, namely 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. and Neryx Biopharmaceuticals, Inc., both U.S. corporations incorporated in the State of Delaware, and Keryx (Israel) Ltd., Keryx Biomedical Technologies Ltd., and K.B.I. Biopharmaceuticals Ltd., each organized in Israel. In 2003, the Company's three subsidiaries in Israel ceased operations and are currently in the process of being closed down. Substantially all of the Company's biopharmaceutical development and administrative activities during the three and nine months ended September 30, 2005, and 2004, respectively, 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. See Note 4 - ACCESS Oncology Acquisition for additional information. The assets and liabilities of ACCESS Oncology that the Company acquired and assumed pursuant to the acquisition have been included in the Company's consolidated financial statements as of February 5, 2004.

The accompanying unaudited interim consolidated financial statements were prepared in accordance with U.S. generally accepted accounting principles ("GAAP") for interim financial information and with the instructions to Form 10-Q and Article 10 of Regulation S-X. Accordingly, they do not include all of the information and footnotes required by GAAP for complete financial statements. All adjustments that are, in the opinion of management, of a normal recurring nature and are necessary for a fair presentation of the interim consolidated financial statements have been included. Nevertheless, these financial statements should be read in conjunction with the Company's audited consolidated financial statements contained in its Annual Report on Form 10-K for the year ended December 31, 2004. The results of operations for the three and nine months ended September 30, 2005, 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 applies the intrinsic value-based method of accounting prescribed by the Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB 25”), and related interpretations, including Financial Accounting Standards Board (“FASB”) Interpretation 44, “Accounting for Certain Transactions involving Stock Compensation, an Interpretation of APB Opinion No. 25,” to account for its fixed-plan stock options for employees and directors. Under this method, compensation expense is recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price. Statement of Financial Accounting Standards (“SFAS”) No. 123, “Accounting for Stock-Based Compensation” (“SFAS No. 123”) is applied to stock options and warrants granted to persons other than employees and directors.

The following is a pro forma unaudited presentation of reported net loss and net loss per share, calculated to show adjusted values had the compensation expenses for stock options granted under the Company’s stock option plans been determined based on fair value at the grant dates consistent with the method of SFAS No. 123:

(in thousands, except per share amounts)	Three months ended September 30, 2005	Three months ended September 30, 2004	Nine months ended September 30, 2005	Nine months ended September 30, 2004	Amounts accumulated during the development stage
Net loss, as reported	$ (6,948)	$ (3,253)	$ (17,732)	$ (28,335)	$ (105,285)
Add: Stock-based compensation expense to employees and directors determined under the intrinsic value-based method, as included in reported net loss	111	111	334	556	10,068
Deduct: Stock-based compensation expense to employees and directors determined under fair value based method	(931)	(267)	(2,853)	(3,223)	(19,272)
Pro forma net loss	$ (7,768)	$ (3,409)	$ (20,251)	$ (31,002)	$ (114,489)
Basic and diluted loss per common share:					
As reported	$ (0.19)	$ (0.11)	$ (0.53)	$ (0.95)	$ (6.02)
Pro forma	$ (0.21)	$ (0.11)	$ (0.61)	$ (1.04)	$ (6.55)

The value of these options has been estimated using the Black-Scholes model. The weighted average fair market value of options granted during the three and nine months ended September 30, 2005, as of the date of the grant, was $9.68 and $7.84, respectively. The assumptions used in the calculation of the fair value of options granted during the three and nine months ended September 30, 2005, were a weighted average expected term of 5.0 years and 4.92 years, respectively, a weighted average expected volatility rate of 82.47% and 84.88%, respectively, and a weighted average risk-free interest rate of 3.91% and 3.72%, respectively.

NET LOSS PER SHARE

Basic net loss per share is computed by dividing the losses allocable to common stockholders by the weighted average number of shares of common stock outstanding for the period. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options and warrants exercisable as of September 30, 2005, and 2004, which are not included in the computation of net loss per share amounts, were 4,587,096 and 4,657,147, respectively.

NOTE 2 - RECENTLY ISSUED ACCOUNTING STANDARDS

In December 2004, the FASB issued SFAS No. 123R, “Share-Based Payment” (“SFAS 123R”). SFAS 123R will replace SFAS 123, which was issued in 1995. SFAS 123R requires that the fair value of the grant of employee stock options be reported as an expense. Historically, the Company has disclosed the pro forma expense effect of stock options granted under the Company’s stock option plans in Note 1 - General: Stock-Based Compensation of its financial statements. Under SFAS 123R, the Company would have been required to implement the new standard as of the beginning of the first interim or annual period that began after June 15, 2005. Calendar year-end companies, therefore, would have been permitted to follow the pre-existing accounting literature for the first and second quarters of 2005, but would be required to follow SFAS 123R for their third quarter reports.

On April 15, 2005, the Securities and Exchange Commission (the “SEC”) approved a new rule permitting companies to implement SFAS 123R at the beginning of their first annual period, rather than the first interim period, beginning after June 15, 2005. This means, for example, that the financial statements for a calendar year-end company do not need to comply with SFAS 123R until the interim financial statements for the first quarter of 2006 are filed with the SEC.

On October 18, 2005, the FASB issued FASB Staff Position (FSP) 123(R)-2, “Practical Accommodation to the Application of Grant Date as Defined in FASB Statement No. 123(R)” (“FSP-123(R)-2”). FSP-123(R)-2 provides guidance about the mutual understanding by the employee and employer of the key terms and conditions of a share-based payment award that is one of the criteria for determining when an award has been granted under SFAS 123R. Under FSP-123(R)-2, assuming all other criteria are met, a mutual understanding of the key terms and conditions of an award is presumed to exist at the date the award is approved in accordance with the relevant corporate governance requirements if (a) the recipient does not have the ability to negotiate the key terms and conditions of the award with the employer and (b) the key terms of the award are expected to be communicated to all of the recipients within a relatively short period of time from the date of approval. The guidance in FSP 123R-2 should be applied on initial adoption of SFAS-123R.

The Company plans to adopt SFAS 123R and FSP-123(R)-2 in the first quarter of 2006. The estimated impact of adopting SFAS 123R and FSP-123(R)-2 will have a material impact on the Company’s consolidated financial statements.

NOTE 3 - STOCKHOLDERS' EQUITY

During the nine months ended September 30, 2005, the compensation committee of the Company’s board of directors granted options to purchase 952,500 shares of the Company’s common stock to the Company’s employees, directors and consultants. As a result of these grants, the Company recorded non-cash compensation expense for grants to consultants of approximately $52,000 and $137,000 during the three and nine months ended September 30, 2005, respectively. The exercise price of the options granted during the nine months ended September 30, 2005, was between $11.22 and $16.67 per share and equaled the market value on the date of grant. Options and warrants for the purchase of 117,930 shares of the Company’s common stock were forfeited during the nine months ended September 30, 2005. In addition, options and warrants for the purchase of 576,642 shares of the Company’s common stock were exercised during the nine months ended September 30, 2005.

On July 20, 2005, the Company completed a public offering of 5,780,000 shares of its common stock (including the exercise of a 750,000 over-allotment option granted to the underwriters) to investors at $14.05 per share. Total proceeds to the Company from this public offering were approximately $75.8 million, net of offering expenses of approximately $5.4 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-119376) filed with the SEC on September 29, 2004, and declared effective by the SEC on October 13, 2004. As part of the transaction, on July 11, 2005, the Company filed a registration statement on Form S-3 (File No. 333-126494) with the SEC registering an additional 780,000 shares, which became effective upon filing.

NOTE 4 - ACCESS ONCOLOGY ACQUISITION

On February 5, 2004, the Company acquired ACCESS Oncology, a related party, for a purchase price of approximately $19,502,000. The purchase price included the Company's assumption of certain liabilities of ACCESS Oncology equal to approximately $8,723,000, the issuance of shares of the Company's common stock valued at approximately $6,325,000, contingent equity rights valued at approximately $4,004,000 and transaction costs of approximately $450,000.

At the effective time of the merger, each share of ACCESS Oncology common stock, including shares issuable upon the exercise of options exercised before March 1, 2004, and upon the exercise of outstanding warrants, was converted into the right to share in the contingent equity rights pro rata with the other holders of ACCESS Oncology common stock. Pursuant to the merger agreement, 623,145 shares of the Company's common stock valued at approximately $6,325,000 have been issued to the preferred stockholders of ACCESS Oncology. An additional 4,433 shares of the Company's common stock are issuable to those preferred stockholders of ACCESS Oncology who have yet to provide the necessary documentation to receive shares of the Company's common stock.

The contingent equity rights will be paid upon the achievement of the following milestones:

- 500,000 shares of the Company's common stock upon enrollment of the first patient in a Keryx-sponsored Phase III (or other pivotal) clinical trial for any of the acquired ACCESS Oncology drug candidates;

- 750,000 shares of the Company's common stock upon the first new drug application acceptance by the Food and Drug Administration, or FDA, for any of the acquired ACCESS Oncology drug candidates;

- 1,750,000 shares of the Company's common stock upon the first FDA approval of any of the acquired ACCESS Oncology drug candidates; and

- 372,422 shares of the Company's common stock following the first 12-month period that sales of all of the acquired ACCESS Oncology drug candidates combined exceeds $100 million.

In no event will the Company issue more than 4,000,000 shares of its common stock pursuant to the merger agreement. These 4,000,000 shares include 627,578 shares issued or issuable to date and any contingent shares as described above. Accordingly, the amount of the Company's common stock deliverable to the former ACCESS Oncology stockholders as milestone consideration will be no more than 3,372,422 shares. The Company's stockholders approved the issuance of shares of its common stock payable as contingent milestone consideration at the 2004 annual meeting of stockholders, which took place on June 10, 2004.

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

As required by FASB Interpretation No. 4, "Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method" ("FIN 4"), the Company recorded a charge in the three months ended March 31, 2004, of $18,800,000 for the portion of the purchase price allocated to acquired in-process research and development.

The following unaudited pro forma financial information presents the combined results of operations of the Company and ACCESS Oncology as if the acquisition had occurred as of the beginning of the periods presented. The unaudited pro forma financial information is not necessarily indicative of what the Company's consolidated results of operations actually would have been had it completed the acquisition at the dates indicated. In addition, the unaudited pro forma financial information does not purport to project the future results of operations of the combined company.

(in thousands, except per share amounts)		**Nine months ended September 30, 2004**
Revenue	$	744
Net loss	$	(9,478)

Basic and diluted loss per common share	$	(0.32)

The unaudited pro forma financial information above reflects the elimination of balances and transactions between the Company and ACCESS Oncology, which upon completion of the merger would be considered intercompany balances and transactions. The entries include the elimination of certain interest income and expense and the elimination of the reimbursement of salaries and related facility costs of two employees of ACCESS Oncology, both of which net to zero. In addition, the unaudited pro forma financial information above excludes the non-recurring, non-cash charge of $18,800,000 related to acquired in-process research and development in the nine months ended September 30, 2004.

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

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

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

You should read the following discussion and analysis in conjunction with the unaudited, consolidated financial statements, and the related footnotes thereto, appearing elsewhere in this report, and in conjunction with management's discussion and analysis and the audited, consolidated financial statements included in our annual report on Form 10-K for the year ended December 31, 2004.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Our lead compound under development is KRX-101 (sulodexide), a first-in-class, oral heparinoid compound for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes. KRX-101 is in a pivotal Phase III and Phase IV clinical program under a Special Protocol Assessment, or SPA, with the Food & Drug Administration, or FDA. Additionally, we are developing clinical-stage oncology compounds, including KRX-0401, a novel, first-in-class, oral modulator of Akt, a pathway associated with tumor survival and growth, and other important signal transduction pathways. 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.

KRX-101

Our lead compound under development is KRX-101, to which we own the exclusive rights to use KRX-101 for the treatment of diabetic nephropathy in North America, Japan and certain other markets outside of Europe. KRX-101 has undergone testing in this indication in multiple clinical trials conducted in Europe, including a randomized 223 patient, double-blind, placebo-controlled Phase II study, known as the DiNAS study. In this study, Type I and Type II diabetic nephropathy patients were treated daily for four months with 50, 100 and 200 milligram gelcaps of KRX-101. These patients showed substantial dose-dependent reduction in proteinuria or pathological urinary albumin excretion rates. The DiNAS study was published in the June 2002 issue of the *Journal of the American Society of Nephrology.* In 2001, the FDA granted KRX-101 "Fast-Track" designation for the treatment of diabetic nephropathy.

In the third quarter of 2003, we announced that the Collaborative Study Group, or the CSG, the world's largest standing renal clinical trial group comprised of academic and tertiary nephrology care centers, would conduct the U.S.-based Phase II/III clinical program for KRX-101 for the treatment of diabetic nephropathy. The CSG has conducted multiple large-scale clinical trials resulting in over 40 publications in peer-reviewed journals. In addition, the CSG conducted the pivotal studies for two of the three drugs, including an angiotension converting enzyme, or ACE, inhibitor and an angiotension receptor blocker, or ARB, that are currently approved for the treatment of diabetic nephropathy.

In the fourth quarter of 2003, we initiated the Phase II portion of our Phase II/III clinical program for KRX-101, and in the third quarter of 2004, we completed the target enrollment for the Phase II portion of the clinical program.

In January 2005, we announced that the CSG recommended that we proceed to the Phase III portion of our Phase II/III clinical program of KRX-101. This recommendation was based on the completion, by an independent Data Safety Monitoring Committee, or DSMC, on January 4, 2005, of a safety evaluation of the first interim analysis from the 149-patient, randomized, double-blind, placebo-controlled Phase II clinical trial of KRX-101, and an efficacy assessment of the same data set conducted by the CSG.

In March 2005, we announced that we had finalized a SPA agreement with the FDA for the Phase III and Phase IV clinical trials of KRX-101.

In May 2005, we announced positive interim results from the Phase II clinical study for KRX-101, presented at the National Kidney Foundation's Spring Clinical Meeting. The Phase II study compared two oral doses of KRX-101, 200 and 400 milligrams, versus a placebo in patients with diabetic microalbuminuria who were receiving an ACE inhibitor or ARBs. In this study, patients were treated with KRX-101 or a placebo for six months and were monitored for an additional two months post-treatment. The primary endpoint for the study was “therapeutic success” of the two dose levels combined versus a placebo at six months. Therapeutic success was a binary composite endpoint defined as: conversion from microalbuminuria to normoalbuminuria (with at least a 25% reduction in microalbuminuria) as measured by the albumin/creatinine ratio, or ACR; or at least a 50% reduction in the ACR level relative to baseline. In October 2005, we announced that the final data from our Phase II study of KRX-101 for diabetic nephropathy will be presented at the American Society of Nephrology’s (ASN) Renal Week on November 11, 2005.

In June 2005, we announced the initiation of our pivotal Phase III and Phase IV clinical program for KRX-101. We are conducting both of these trials under our SPA with the FDA. This clinical plan consists of: a single Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; supportive data from previously conducted clinical studies; and substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. The Phase III portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of KRX-101 versus a placebo in patients with persistent microalbuminuria. The Phase IV portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of KRX-101 versus a placebo in patients with persistent macroalbuminuria. The CSG has completed the Phase II trial and is conducting the pivotal Phase III and Phase IV clinical program of KRX-101 for the treatment of diabetic nephropathy.

KRX-0401

KRX-0401 is a novel, first-in-class, oral modulator of Akt and other important signal transduction pathways. This compound has demonstrated preliminary single agent anti-tumor activity and is currently in a Phase II clinical program where it is being studied both as a single agent and in combination with other anti-cancer treatments for multiple forms of cancer.

Five Phase I studies of KRX-0401 have been completed, including two in the U.S., by the National Cancer Institute, or NCI, a department of the National Institutes of Health, or NIH, as part of a Cooperative Research and Development Agreement, or CRADA. These trials demonstrated that KRX-0401 can be safely given to humans with an acceptable toxicity profile and no observed myelosuppression, or bone marrow suppression. We believe that the Phase I data provides clinical evidence of the anti-cancer effects of KRX-0401.

The NCI has completed a number of Phase II clinical trials studying KRX-0401 as a single agent, including studies in prostate, breast, head and neck and pancreatic cancers, as well as melanoma and sarcomas. In total, nine NCI clinical trials have been conducted across the six tumor types mentioned. The NCI and its collaborators have presented data from four of their Phase II studies, including from Phase II studies involving prostate, sarcoma, head and neck and breast cancers. Findings from these studies led the investigators to conclude that the drug was safe and well-tolerated at the Phase II dose utilized. In the sarcoma study, the investigators reported a partial response (greater than 50% decrease in tumor mass) as well as several disease stabilizations. With the responses seen in the Phase I trials, there are now three sarcoma patients with durable partial responses. This has led us to consider exploring additional studies in sarcoma.

During the second quarter of 2004, we announced the initiation of a Phase II program utilizing KRX-0401 as a single agent and in combination with a number of standard anti-cancer therapies in multiple tumor types. To date, we have initiated a number of trials under this program, including single agent studies in lung cancer and sarcoma, and combination studies with a number of standard anti-cancer treatments, such as gemcitabine, paclitaxel, docetaxel, Herceptin® and endocrine therapy. We have also initiated an “all-comers” Phase II clinical trial evaluating KRX-0401 as a single-agent, administered either weekly or daily in a variety of tumor types.

In May 2005, we announced that Phase II data presented at the annual meeting of the American Society of Clinical Oncology in Orlando, Florida demonstrated the tolerability and potential efficacy of KRX-0401 in the treatment of patients with biochemically recurrent hormone-sensitive prostate cancer, or HSPC, patients. The investigators concluded that KRX-0401 in HSPC patients is feasible, well-tolerated and has been shown to reduce prostate-specific antigen levels in some patients. Because of its inhibitory effects on the Akt and related pathways, we believe that further studies of KRX-0401 in combination with androgen ablation and chemotherapy are warranted.

Additional Product Candidates

Our cancer portfolio also includes KRX-0402, an inhibitor of DNA repair, which is also being studied by the NCI under a CRADA arrangement in multiple clinical trials.

During 2004 and in the first quarter of 2005, we in-licensed two pre-clinical compounds in accordance with our acquisition and in-licensing strategy, which have been designated as KRX-0404 and KRX-0501, respectively. These compounds are in the areas of oncology and neurology, respectively.

General Corporate

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

In the first quarter of 2004, we completed the acquisition of ACCESS Oncology, Inc., or ACCESS Oncology, a privately-held, cancer-focused biotechnology company. The acquired drug portfolio included three clinical stage oncology compounds, designated as KRX-0401, KRX-0402 and KRX-0403. As a part of the acquisition of ACCESS Oncology, we acquired the Online Collaborative Oncology Group, Inc., or OCOG, a subsidiary of ACCESS Oncology, which provides clinical trial management and site recruitment services to us, as well as other biotechnology and pharmaceutical companies.

We are a development stage company and have no product sales to date. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, and from public offerings of our common stock. We have devoted substantially all of our efforts to the discovery, in-licensing and

development of drug candidates. We have incurred negative cash flow from operations each year since our inception. We anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our planned product development efforts, our clinical trials and potential in-licensing and acquisition opportunities.

Our revenues consist 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 cost of services consist of all costs specifically associated with client programs such as salaries, benefits paid to personnel, payments to third-party vendors and systems and other support facilities associated with delivering services to our clients. Cost of services are recognized as services are performed.

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our product candidates, as well as expenses related to in-licensing and acquisition of new product candidates. We expense our research and development costs as they are incurred.

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

Our results of operations include non-cash compensation expense as a result of the grants of stock options and warrants. Compensation expense for fixed award options and warrants granted to employees and directors represents the intrinsic value (the difference between the stock price of the common stock and the exercise price of the options or warrants) of the options and warrants at the date of grant. For variable awards, we consider the difference between the stock price at reporting date and the exercise price, in the case where a measurement date has not been reached. The compensation cost is recorded over the respective vesting periods of the individual stock options and warrants. The expense is included in the respective categories of expense in the statement of operations. We expect to incur significant non-cash compensation expense in the future; however, because some of the options and warrants issued to employees, consultants and other third-parties either do not vest immediately or vest upon the achievement of certain milestones, the total expense is uncertain.

Our ongoing clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our product candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we may 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 September 30, 2005 and September 30, 2004

Revenue. Service revenue decreased by $315,000 to $82,000 for the three months ended September 30, 2005, as compared to revenue of $397,000 for the three months ended September 30, 2004. The decrease in service revenue was primarily due to a reduction in service contracts in the current period. We do not expect our service revenues to have a material impact on our financial results during the remainder of 2005.

Cost of Services Expense. Cost of services expense decreased by $219,000 to $197,000 for the three months ended September 30, 2005, as compared to expense of $416,000 for the three months ended September 30, 2004. The decrease in cost of services was primarily due to a reduction in service contracts in the current period. We do not

expect our cost of service expense to have a material impact on our financial results during the remainder of 2005.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants and warrant issuances was $226,000 for the three months ended September 30, 2005, as compared to an expense of $70,000 for the three months ended September 30, 2004. The expenses in the three months ended September 30, 2005, and September 30, 2004 were due to the adjustment to fair market value of previously-issued options to consultants.

Non-Cash Acquired In-Process Research and Development Expense. We did not record a charge for the three months ended September 30, 2005 and 2004, respectively.

Other Research and Development Expenses. Other research and development expenses increased by $3,907,000 to $6,501,000 for the three months ended September 30, 2005, as compared to expenses of $2,594,000 for the three months ended September 30, 2004. The increase in other research and development expenses was due primarily to a $3,990,000 increase in expenses related to our KRX-101 clinical program, including costs associated with the initiation of our pivotal Phase III and Phase IV clinical trials.

We expect our other research and development costs to increase during the remainder of 2005 as a result of the pivotal Phase III and Phase IV clinical program for KRX-101 and the expansion of the clinical program for KRX-0401, including the planned commencement of additional single agent and combination trials, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense related to stock option grants and warrant issuances was $258,000 for the three months ended September 30, 2005, as compared to an expense of $161,000 for the three months ended September 30, 2004. For the three months ended September 30, 2005 and September 30, 2004, adjustment to fair market value of previously-issued options to consultants accounted for expenses of $147,000 and $50,000, respectively. Additionally, the continued vesting of options granted to certain directors below market value on the date of issuance (but equal to market price at grant date) accounted for expenses of $111,000 in each period.

Other General and Administrative Expenses. Other general and administrative expenses increased by $75,000 to $671,000 for the three months ended September 30, 2005, as compared to expenses of $596,000 for the three months ended September 30, 2004. The increase in general and administrative expenses was due primarily to increased facility expenses related to the operating lease entered into in 2005.

We expect our other general and administrative costs to increase modestly over the remainder of 2005 primarily as a result of our clinical development programs, as well as increased costs associated with being a public company.

Interest and Other Income, Net. Interest and other income, net, increased by $636,000 to $823,000 for the three months ended September 30, 2005, as compared to income of $187,000 for the three months ended September 30, 2004. The increase resulted from a higher level of invested funds due to the completion of a public offering that closed in July 2005, as well as due to the general increase in short-term market interest rates when compared to the comparable period last year.

Income Taxes. We did not record any income tax expense for the three months September 30, 2005 and 2004, respectively.

Nine months ended September 30, 2005 and September 30, 2004

Revenue. Service revenue decreased by $277,000 to $365,000 for the nine months ended September 30, 2005, as compared to revenue of $642,000 for the nine months ended September 30, 2004. The decrease in service revenue was primarily due to a reduction in service contracts in the current period. We do not expect our service revenues to have a material impact on our financial results during the remainder of 2005.

Cost of Services Expense. Cost of services expense decreased by $80,000 to $539,000 for the nine months ended September 30, 2005, as compared to expense of $619,000 for the nine months ended September 30, 2004. The decrease in cost of services expense was primarily due to a reduction in service contracts in the current period. We do not expect our cost of service expense to have a material impact on our financial results during the remainder of 2005.

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Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants and warrant issuances was $539,000 for the nine months ended September 30, 2005, as compared to an expense of $295,000 for the nine months ended September 30, 2004. For the nine months ended September 30, 2005, and September 30, 2004, adjustment to fair market value of previously-issued options to consultants accounted for expenses of $424,000 and $238,000, respectively. Additionally, the issuance of options to consultants accounted for using the fair value method accounted for expenses of $115,000 and $57,000, respectively.

Non-Cash Acquired In-Process Research and Development Expense. We did not record a charge for the nine months ended September 30, 2005. As required by Financial Accounting Standards Board Interpretation No. 4, “Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method," or FIN 4, the Company recorded a charge of $18,800,000 in the nine months ended September 30, 2004, for the estimate of the portion of the purchase price of ACCESS Oncology allocated to acquired in-process research and development. A project-by-project valuation was performed with the assistance of independent valuation specialists to determine the fair value of research and development projects of ACCESS Oncology, which were in-process, but not yet completed.

Other Research and Development Expenses. Other research and development expenses increased by $9,410,000 to $15,723,000 for the nine months ended September 30, 2005, as compared to expenses of $6,313,000 for the nine months ended September 30, 2004. The increase in other research and development expenses was due primarily to a $6,765,000 increase in expenses related to our KRX-101 clinical program, including costs associated with the initiation of our pivotal Phase III and Phase IV clinical trials, and a $2,671,000 increase in expenses related to our clinical stage, oncology drug portfolio, primarily the KRX-0401 clinical program (the $2,671,000 increase includes $159,000 for the purchase of additional license rights and interests covering patent rights for KRX-0402). The comparative period last year included one-half, or $500,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone.

We expect our other research and development costs to increase during the remainder of 2005 as a result of the pivotal Phase III and Phase IV clinical program for KRX-101 and the expansion of the clinical program for KRX-0401, including the planned commencement of additional single agent and combination trials, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (General and Administrative). Non-cash compensation expense related to stock option grants and warrant issuances was $611,000 for the nine months ended September 30, 2005, as compared to an expense of $967,000 for the nine months ended September 30, 2004. For the nine months ended September 30, 2005 and September 30, 2004, adjustment to fair market value of previously-issued options to consultants accounted for expenses of $256,000 and $240,000, respectively. Additionally, the issuance of options to consultants accounted for using the fair value method accounted for expenses of $22,000 and $172,000, respectively, and the continued vesting of options granted to certain directors below market value on the date of issuance (but equal to market price at grant date) accounted for expenses of $333,000 and $555,000, respectively.

Other General and Administrative Expenses. Other general and administrative expenses decreased by $419,000 to $2,015,000 for the nine months ended September 30, 2005, as compared to expenses of $2,434,000 for the nine months ended September 30, 2004. The decrease in general and administrative expenses in the current period was due primarily to the absence of payroll expenses incurred in the comparable period last year relating to one-half, or $500,000, of a one-time bonus to our Chief Executive Officer for the achievement of a corporate milestone pursuant to his employment agreement. The compensation of our Chief Executive Officer is allocated equally between other research and development expenses and other general and administrative expenses to reflect the allocation of his responsibilities and activities for Keryx.

We expect our other general and administrative costs to increase modestly over the remainder of 2005 primarily as a result of our clinical development programs, as well as increased costs associated with being a public company.

Interest and Other Income, Net. Interest and other income, net, increased by $878,000 to $1,330,000 for the nine months ended September 30, 2005, as compared to income of $452,000 for the nine months ended September 30, 2004. The increase resulted from a higher level of invested funds due to the completion of a public offering that closed in July 2005, as well as due to the general increase in short-term market interest rates when compared to the comparable period last year.

Income Taxes. We did not record any income tax expense for the nine months ended September 30, 2005. For the nine months ended September 30, 2004, income tax expense was $1,000. Our income tax expense for the nine months ended September 30, 2004 resulted from state taxes imposed on our capital.

LIQUIDITY AND CAPITAL RESOURCES

We have financed our operations from inception primarily through our public offerings, various private placement transactions, and option and warrant exercises. As of September 30, 2005, we received net proceeds of $46.3 million from our initial public offering, net proceeds of $75.8 million from our recent public offering, net proceeds of approximately $60.4 million from private placements of our common and preferred stock and convertible notes, including the conversion of $3.2 million of loans into contributed capital, and proceeds of $6.4 million from the exercise of options and warrants.

As of September 30, 2005, we had $110.1 million in cash, cash equivalents, interest receivable, and short-term and long-term securities, an increase of $60.2 million from December 31, 2004. Cash used in operating activities for the nine months ended September 30, 2005, was $16.1 million, as compared to $9.1 million for the nine months ended September 30, 2004. 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 KRX-101, and expansion of the KRX-0401 clinical program. For the nine months ended September 30, 2005, net cash used in investing activities of $3.4 million was primarily the result of an investment in securities. For the nine months ended September 30, 2005, net cash provided by financing activities of $77.0 million was primarily the result of a public offering completed in July 2005, as well as net proceeds from the exercise of options and warrants.

In July 2005, we completed a public offering of 5,780,000 shares of our common stock (including the exercise of a 750,000 over-allotment option granted to the underwriters) to investors at $14.05 per share. We received approximately $75.8 million in proceeds, net of offering expenses of approximately $5.4 million.

We believe that our $110.1 million in cash, cash equivalents, interest receivable and investment securities as of September 30, 2005 will be sufficient to enable us to meet our planned operating needs and capital expenditures for at least the next 24 months. Additionally, we also believe that our cash position provides us with added flexibility in our in-licensing and product acquisition program to potentially strengthen our portfolio with additional clinical-stage drug candidates.

Our cash and cash equivalents and investment securities as of September 30, 2005 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 September 30, 2005, we are unaware of any known trends or any known demands, commitments, events, or uncertainties that will, or that are reasonably likely to, result in a material increase or decrease in our required liquidity. We expect that our liquidity needs throughout 2005 will continue to be funded from existing cash, cash equivalents, and short-term marketable securities.

OFF-BALANCE SHEET ARRANGEMENTS

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

OBLIGATIONS AND COMMITMENTS

As of September 30, 2005, we have known contractual obligations, commitments and contingencies of $90,012,000. Of this amount, $86,982,000 relates to research and development agreements (primarily relating to our pivotal Phase III and Phase IV clinical program for KRX-101), of which $27,425,000 is due within the next year, with the remaining balance due as per the schedule below. The additional $3,030,000 relates to our operating lease obligations, of which $631,000 is due within the next year, with the remaining balance due as per the schedule below.

		Payment due by period			
Contractual obligations	**Total**	**Less than 1 year**	**1-3 years**	**3-5 years**	**More than 5 years**
Research and development agreements	$ 86,982,000	$ 27,425,000	$ 41,676,000	$ 17,881,000	$ --
Operating leases	3,030,000	631,000	1,193,000	1,193,000	13,000
Total	$ 90,012,000	$ 28,056,000	$ 42,869,000	$ 19,074,000	$ 13,000

Additionally, we have undertaken to make contingent milestone payments to certain of our licensors of up to approximately $67.0 million over the life of the licenses, of which approximately $47.3 million will be due upon or following regulatory approval of the licensed drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, we remain obligated to pay one licensor $50,000 annually until the license expires. We have also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights if its drug candidates meet certain development milestones. In addition, pursuant to his employment agreement, our Chief Executive Officer is entitled to receive a one-time $2.0 million performance-based cash bonus upon our achievement of certain levels of market capitalization or working capital. The commitments described in this paragraph are not reflected in the table above.

During 2004, we entered into a temporary lease arrangement with our President for the utilization of part of his residence for office space associated with our employees in San Francisco, California. We have expensed a total of $62,000 (which includes $12,000 for the first quarter of 2005 and $50,000 for 2004) pursuant to the terms of this arrangement, which amount has been included in accounts payable and accrued expenses in the accompanying balance sheet as of September 30, 2005. In April 2005, we moved our San Francisco operations to new office space and terminated our temporary lease arrangement with our President.

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 disclosures of contingent assets and liabilities at the date of our financial statements and the reported amounts of revenues and expenses during the applicable period. Actual results may differ from these estimates under different assumptions or conditions.

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

Stock Compensation. We have granted options to employees, directors and consultants, as well as warrants to other third parties. In applying Statement of Financial Accounting Standards No. 123, “Accounting for Stock-Based Compensation,” or SFAS 123, we use the Black-Scholes pricing model to calculate the fair market value of our options and warrants. 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 or warrant, the closing market price of our stock and the exercise price. We have assumed for the purposes of the Black-Scholes calculation that an option will be exercised one year and two years after it fully vests for consultants and employees, respectively. We base our estimates of our stock price volatility on the volatility during the period prior to the grant of the option or warrant; 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.

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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.

We account for stock-based employee and director compensation arrangements in accordance with the provisions of APB Opinion No. 25, “Accounting for Stock Issued to Employees,” and the Financial Accounting Standards Board, or FASB, Interpretation No. 44, “Accounting for Certain Transactions Involving Stock Compensation,” as permitted by SFAS 123. We also comply with the disclosure provisions of SFAS 123 and Statement of Financial Accounting Standards No. 148, “Accounting for Stock-Based Compensation-Transition and Disclosure.”

Accounting Related to the Valuation of Acquired In-Process Research and Development. As required by FASB Interpretation No. 4, “Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method," or FIN 4, we recorded a charge for the three months ended March 31, 2004, of $18,800,000 for the estimate of the portion of the ACCESS Oncology purchase price allocated to acquired in-process research and development.

A project-by-project valuation using the guidance in Statement of Financial Accounting Standards No. 141, “Business Combinations” and the AICPA Practice Aid “Assets Acquired in a Business Combination to Be Used In Research and Development Activities: A Focus on Software, Electronic Devices and Pharmaceutical Industries” was performed with the assistance of independent valuation specialists to determine the fair value of research and development projects of ACCESS Oncology which were in-process, but not yet completed.

The fair value was determined using the income approach on a project-by-project basis. This method starts with a forecast of the expected future net cash flows. These cash flows are then adjusted to present value by applying an appropriate discount rate that reflects the project’s stage of completion and other risk factors. These other risk factors can include the nature of the product, the scientific data associated with the technology, the current patent situation and market competition.

The following assumptions were made in order to forecast future net cash flows:

- revenue that is likely to result from specific in-process research and development projects, including estimated patient populations, estimated selling prices, estimated market penetration and estimated market share and year-over-year growth rates over the product life cycles;
- cost of sales related to the potential products using industry data or other sources of market data;
- sales and marketing expense using industry data or other market data;
- general and administrative expenses; and
- research and development expenses.

The valuations are based on information that was available as of the acquisition date and the expectations and assumptions 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.

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 requires management to estimate our actual current tax exposure and assess 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. Our income tax expense during the nine months ended September 30, 2004 resulted from state taxes imposed on our capital.

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 September 30, 2005, we had an accumulated deficit of approximately $105.3 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 or technologies.

We have not yet commercialized any products or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, 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 and technologies.

If we are unable to successfully complete our clinical trial programs, or if such clinical trials take longer to complete than we project, our ability to execute our current business strategy will be adversely affected.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases as we are studying. In addition, one of our current trials for KRX-101 is designed to continue until a pre-specified 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 basis.

Additionally, we have finalized with the FDA our SPA, regarding a subpart H clinical development plan for the clinical development of KRX-101 for diabetic nephropathy. This clinical plan consists of: a single Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; supportive data from previously conducted clinical studies; and substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria, before filing a New Drug Application, or NDA, with the FDA. The subpart H process is complex and requires careful execution and 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 KRX-101. If the FDA approves KRX-101 for marketing on the basis of our SPA, our Phase IV clinical trial may yield insufficient efficacy data or give rise to safety concerns, which could result in withdrawal of such approval or could cause us to withdraw the product from the market. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

If our drug candidates do not receive the necessary regulatory approvals, we will be unable to commercialize our drug candidates.

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

Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Specifically, we received the recommendation to proceed, as planned, into our pivotal Phase III and Phase IV program for KRX-101 from the CSG based on a safety and efficacy assessment of a first interim analysis of data from our ongoing Phase II study for KRX-101, and we recently announced further interim results from this trial. In October 2005, we announced that the final data from our Phase II study of KRX-101 for diabetic nephropathy will be presented at the American Society of Nephrology's (ASN) Renal Week on November 11, 2005. There can be no assurance that the full data from the Phase II study will track the data from these interim analyses of the Phase II study. Moreover, the recommendation to move into our pivotal program, as well as the announced interim data, may not be indicative of results from future clinical trials and the risk remains that the pivotal program for KRX-101 may generate efficacy data that will be insufficient for the approval of the drug, or may raise safety concerns that may prevent approval of the drug.

Clinical trials also have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. If we experience delays in the testing or approval process or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the United States and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process.

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

We do not own any of our drug candidates. We have licensed the patent rights to these drugs candidates from others. These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates.

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

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

Contract manufacturers often encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and foreign regulations, production costs and development of advanced manufacturing techniques and process controls. Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidates. In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple manufacturers may be difficult because the number of potential manufacturers is limited and, particularly in the case of KRX-101, 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 KRX-101 which we believe will be adequate to satisfy our current clinical and initial commercial supply needs; however, as we scale-up for commercial manufacturing, we will need to ensure that the manufacturing process matches the established process on a larger scale. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, as we scale-up, reproducibility will be required for the successful commercialization of KRX-101. There can be no assurance that we will be successful in this endeavor. Additionally, as we scale-up, we will likely incur capital expenditures to enable larger scale production.

If we are not able to obtain the raw materials required for the manufacture of our lead product candidate, KRX-101, our ability to develop and market this product candidate will be substantially harmed.

Source materials for KRX-101, our lead product candidate, are derived from porcine mucosa. Long-term supplies for KRX-101 could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products, over which we will have no control. Additionally, diseases affecting the world supply of pigs could have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell KRX-101. Such negative impact could materially affect the commercial success of KRX-101.

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.

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 KRX-101 is approved by the FDA, we anticipate conducting our own sales and marketing effort to support the drug, and we may adopt this strategy with respect to future drug products. We currently have no experience in sales, marketing or distribution. To directly market and distribute any products, we must build a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build such a sales and marketing organization on our own or with the assistance of a contract sales organization. For some market opportunities, we may need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our products. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

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

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

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

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

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

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

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

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

the effectiveness of our sales, marketing and distribution efforts.

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

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

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

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

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

As of October 31, 2005, we had 30 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. In addition, while we have an employment agreement with Mr. Weiss, this agreement would not prevent him from terminating his employment with us.

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

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

Acquisitions involve a number of operational risks, including:

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

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

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

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

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

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

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

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

government and health administration authorities;

private health insurers;

managed care programs; and

other third-party payors.

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

Health care reform measures could adversely affect our business.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as those relating to reimportation of drugs into the U.S. from other countries where they are 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, and the future sale of any approved products, 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. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

decreased demand for a product;

injury to our reputation;

our inability to continue to develop a drug candidate;

withdrawal of clinical trial volunteers; and

loss of revenues.

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

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

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

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

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company with 30 employees. We also have significantly fewer employees than many other companies that have a product candidate in late-stage clinical development, and we rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Related to Our Financial Condition

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

We believe that our $110.1 million in cash, cash equivalents, interest receivable and investment securities as of September 30, 2005 will be sufficient to enable us to meet our planned operating needs and capital expenditures for at least the next 24 months. Our forecast of the period of time through which our cash, cash equivalents, interest receivable and investment securities will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

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

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

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

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

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

If we are unable to obtain additional funds on terms favorable to us, or at all, our business would be harmed.

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash and cash equivalents, interest receivable and investment securities will be sufficient to fund our operating expenses and capital requirements for at least the next 24 months; however, the actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate, depending upon:

the progress of our development activities;

the progress of our research activities;

the number and scope of our development programs;

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

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

our ability to achieve our milestones under our licensing arrangements;

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

the costs and timing of regulatory approvals.

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

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

In July 2003, our Israeli subsidiary vacated its Jerusalem facility, after giving advance notice to the landlord. On May 1, 2005, the landlord of the Jerusalem facility filed suit in Israel claiming that we were liable as a result of the alleged breach of the lease agreement by our subsidiary. The amount demanded by the landlord totals 4,345,313 NIS or approximately $945,000 at the September 30, 2005 exchange rate, 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. To date, we have not yet recorded a charge to reflect any potential liability associated with this lawsuit as it is too early to accurately estimate the amount of the charge, if any.

In September 2001, one of our Israeli subsidiaries received the status of an "Approved Enterprise," a status which grants certain tax benefits in Israel in accordance with the "Law for the Encouragement of Capital Investments, 1959." Through December 31, 2003, our Israeli subsidiary, which ceased operations in 2003, has received tax benefits in the form of exemptions of approximately $744,000 as a result of our subsidiary's status as an "Approved Enterprise." As part of the restructuring implemented during 2003, we closed down our Jerusalem laboratory facility. In October 2003, the subsidiary received a letter from the Israeli Ministry of Industry and Trade that its Approved Enterprise status was cancelled as of July 2003 and that past benefits would not need to be repaid. The Israeli tax authorities have yet to confirm this position; however, we believe that, based on the letter received from the Ministry of Industry and Trade, it is unlikely that past benefits will need to be repaid, and therefore, we have not recorded any charge with respect to this potential liability. There can be no assurances that the Israeli tax authorities will confirm this position. As a result, we may be liable to repay some or all of the tax benefits received to date, which could adversely affect our cash flow and results of operations.

Risks Related to Our Intellectual Property

If we are unable to adequately protect our intellectual property, third parties may be able to use our intellectual property, which could adversely affect our ability to compete in the market.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug products and technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

We rely on trade secrets to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to some of our drug products and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.

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

Third parties may assert that we are using their proprietary intellectual property without authorization. In addition, third parties may have or obtain patents in the future and claim that our drug products or technologies infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected our drug products or technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected our drug products or technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

Risks Related to Our Common Stock

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

As of September 30, 2005, our executive officers, directors and principal stockholders (including their affiliates) beneficially owned, in the aggregate, approximately 21.6% of our outstanding common stock, including, for this purpose, currently exercisable options and warrants held by our executive officers, directors and principal stockholders. As a result, these persons, acting together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our common stock.

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

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, your equity in us may be significantly diluted. We may be required to issue up to 3,372,422 shares of our common stock to former shareholders of ACCESS Oncology upon achievement of certain milestones. In addition, we may enter into arrangements permitting us to issue shares of common stock in lieu of certain cash payments such as milestones.

As of September 30, 2005, our executive officers, directors, and principal stockholders beneficially own, in the aggregate, approximately 21.6% of our common stock, including currently exercisable warrants and options held by them. If some or all of them should decide to sell a substantial number of their holdings, it could have a material adverse effect on the market for our common stock.

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

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

developments concerning our drug candidates;

announcements of technological innovations by us or our competitors;

introductions or announcements of new products by us or our competitors;

announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;

changes in financial estimates by securities analysts;

actual or anticipated variations in quarterly operating results;

expiration or termination of licenses, research contracts or other collaboration agreements;

conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

changes in the market valuations of similar companies; and

additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business.

Certain anti-takeover provisions in our charter documents and Delaware law could make a third-party acquisition of us difficult. This could limit the price investors might be willing to pay in the future for our common stock.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock with rights senior to those of the common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate

actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

ITEM 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 September 30, 2005, 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 September 30, 2005, was less than 13 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

Our disclosure controls and procedures are designed to ensure that information required to be disclosed in our periodic filings with the SEC is (1) recorded, processed, summarized and reported properly, within the time periods specified in the SEC's rules and forms and (2) accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, on a timely basis so that proper disclosure can be made. Our Chief Executive Officer and Principal Financial Officer conducted an evaluation of our disclosure controls and procedures as of September 30, 2005, and concluded that our disclosure controls and procedures were effective.

There were no changes in our internal controls over financial reporting during the three months ended September 30, 2005, that have materially affected, or are reasonably likely to materially affect our internal controls over financial reporting.

Our management, including our Chief Executive Officer and Principal Financial Officer, does not expect that our disclosure controls and procedures or our internal controls over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

PART II. OTHER INFORMATION

ITEM 1. LEGAL PROCEEDINGS

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 NIS or approximately $945,000 at the September 30, 2005, exchange rate, 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. 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.

ITEM 6. EXHIBITS

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

3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.1 to the Registrant's Annual Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004, and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant’s Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.
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 November 4, 2005.
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, November 4, 2005.
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, November 4, 2005.
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 November 4, 2005.

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: November 4, 2005

By: /s/ Ron Bentsur

Ron Bentsur
Vice President, Finance and Investor Relations
(Principal Financial and Accounting Officer)

EXHIBIT INDEX

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

31.1	Certification of Chief Executive Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated November 4, 2005.
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