2007 ANNUAL REPORT

TO STOCKHOLDERS

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Fiscal Year Ended December 31, 2007.
OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**
For the Transition Period from _____ to _____.

Commission File Number 000-30929

KERYX BIOPHARMACEUTICALS, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**13-4087132**
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification No.)
750 Lexington Avenue New York, New York	**10022**
(Address of Principal Executive Offices)	(Zip Code)

(212) 531-5965
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Common Stock, Par Value $0.001 Per Share	**NASDAQ Global Market**
(Title of Class)	(Name of Each Exchange on Which Registered)

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filed, an accelerated filer, or a non-accelerated filer. See definition of "accelerated filer and large accelerated filer" in Rule 12b-2 of the Exchange Act). (Check one):

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐

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

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was $424,156,031 as of June 30, 2007, based on the closing sale price of such stock as reported on the Nasdaq Global Market.

There were 43,746,153 shares of the registrant's common stock outstanding as of February 21, 2008.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2008 Annual Meeting of Stockholders are incorporated by reference in Part III of this Annual Report on Form 10-K.

KERYX BIOPHARMACEUTICALS, INC.

ANNUAL REPORT ON FORM 10-K
For the Fiscal Year Ended December 31, 2007

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This Annual Report on Form 10-K contains trademarks and trade names of Keryx Biopharmaceuticals, Inc., including our name and logo.

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

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

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

Item 1. Business.

Overview

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Our lead compound under development is Sulonex™ (sulodexide), which we previously referred to as KRX-101, a first-in-class, oral heparinoid compound for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes. Sulonex is in a pivotal Phase 3 and Phase 4 clinical program under a Special Protocol Assessment, or SPA, with the Food & Drug Administration, or FDA. Additionally, we are developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 2 clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. We are also developing clinical-stage oncology compounds, including KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth. KRX-0401 also modulates a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase 2 clinical development for multiple tumor types and we expect to move into a Phase 3 clinical program in 2008. 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 product sales from our drug candidates.

The table below summarizes the status of our product pipeline. Each of these drugs is discussed more fully under the heading "Products under Development."

Product candidate	Target indication	Development status
Endocrine/Renal		
Sulonex™ (sulodexide)	Diabetic nephropathy	Phase 3 & Phase 4
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	Phase 2
Oncology		
KRX-0401 (perifosine)	Renal cancer and other multiple forms of cancer	Phase 2
KRX-0402 (O^6-benzylguanine) or (O^6-BG)	Brain cancer	Phase 2
KRX-0601 (7-hydroxystaurosporine)	Multiple forms of cancer	Phase 2
KRX-0404 (ErPC)	Multiple forms of cancer	Pre-clinical
Neurology		
KRX-0701 (dexlipotam)	Diabetic neuropathy	Phase 2
KRX-0501	Neurological disorders	Phase 1

Our Strategy

Our mission is to create long-term shareholder value by acquiring, developing and commercializing medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Our strategy to achieve this mission is to:

- seek to acquire medically important, novel drug candidates in late pre-clinical or early clinical development;
- utilize our clinical development capabilities to manage and drive our drug candidates through the clinical development process to approval; and

- commercialize our drug candidates, either alone or in partnership, which we believe is important to provide maximum shareholder value.

Under our strategy, we currently plan over the next twelve months to:

- complete the analysis of our pivotal Phase 3 trial and continue our Phase 4 program for Sulonex;
- prepare a New Drug Application for Sulonex (sulodexide) for filing with the FDA;
- if we meet the primary objective of our pivotal Phase 3 trial for Sulonex, develop the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA;
- launch a Phase 3 study for KRX-0401 (perifosine) in patients with advanced renal cell carcinoma;
- continue to build our clinical development and regulatory capabilities and conduct additional pre-clinical, toxicology and clinical trials for our portfolio products, including Zerenex, KRX-0401, KRX-0402, KRX-0501, KRX-0601 and KRX-0701; and
- seek to in-license or acquire additional compounds.

Corporate Information

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 its operations in January 1997. Our executive offices are located at 750 Lexington Avenue, New York, New York 10022. Our telephone number is 212-531-5965, and our e-mail address is infokeryx.com.

We maintain a website with the address www.keryx.com. We make available free of charge through our Internet website our annual reports on Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K, and any amendments to these reports, as soon as reasonably practicable after we electronically file such material with, or furnish such material to, the SEC. We are not including the information on our website as a part of, nor incorporating it by reference into, this report.

Products Under Development

Endocrine/Renal

Sulonex™ *(sulodexide)*

Overview

Our lead compound under development is Sulonex (sulodexide), which we previously referred to as KRX-101. We own the exclusive rights to develop, market and sell Sulonex for the treatment of diabetic nephropathy in North America, Japan and certain other markets outside of Europe. Diabetic nephropathy is a long-term complication of diabetes in which the kidneys are progressively damaged. Sulonex is a glycosaminoglycan compound with structural similarities to the broad family of marketed heparins and low molecular weight heparins. This drug has been marketed in a number of European, Asian and South American countries for many years by our licensor for certain cardiovascular conditions and has an established safety profile at the doses used for such indications. Additionally, it has been observed in several clinical trials conducted in Europe and the U.S., including two randomized, double-blind, placebo-controlled Phase 2 studies, that Sulonex can reduce urinary protein excretion in patients with diabetic nephropathy. Sulonex is in a pivotal Phase 3 and Phase 4 clinical program under an SPA with the FDA. These trials are being conducted by the Collaborative Study Group, or the CSG, the world's largest standing renal clinical trials group. The Phase 3 trial was completed in the first quarter of 2008.

We plan to develop Sulonex in the United States, and possibly other countries where we have exclusive license rights, for the treatment of diabetic nephropathy and potentially for other indications.

Market Opportunity

According to the American Diabetes Association, or the ADA, there are 20.8 million people in the United States (approximately 7% of the population) who have diabetes. Of this population, approximately 14.6 million have been diagnosed with diabetes, of whom approximately 90-95% have been diagnosed with Type II

diabetes. Type II diabetes results from the combination of insulin deficiency and the body's relative insensitivity to the insulin present, as opposed to Type I diabetes, in which severe insulin deficiency results from destruction of the insulin-producing beta cells of the pancreas. Moreover, the ADA estimates that approximately 40% of all diabetics in the United States, or approximately eight million people, have diabetic nephropathy. Capoten® (captopril), an Angiotension Converting Enzyme inhibitor (ACE), and Avapro® (irbesartan) and Cozaar® (losartan), Angiotension Receptor Blockers (ARBs), are the only prescription pharmaceutical therapies currently approved to treat diabetic nephropathy in the United States. Despite treatment with these medications, progression of diabetic nephropathy continues in a significant percentage of patients reflecting an unmet medical need.

Diabetes is the most common cause of ESRD in the United States and in many other developed nations, and represents approximately 45% of all new cases of ESRD in the United States. Despite advances in clinical care, including improvements in glycemic or blood sugar control and blood pressure control, the number of Type I and Type II diabetes-related cases of ESRD continues to rise. In particular, the incidence of Type II diabetes-related ESRD is rapidly increasing. Approximately 20% of diabetics on dialysis in the United States survive for five years, making the mortality of end-stage renal failure in this group higher than most forms of cancer. Unfortunately, renal transplantation is an option for less than 15% of diabetics with ESRD, as compared to 35-40% of non-diabetics, principally due to age and concomitant vascular disease. Despite recent advances, diabetic nephropathy remains a potentially catastrophic illness for which partial but insufficient treatment is currently available.

Scientific Background

Both Type I and Type II diabetes are characterized by insufficient insulin effect upon insulin-requiring tissues. As insulin is required for normal metabolism of glucose, fat and protein, diabetes is accompanied by abnormal blood levels of these substances. In the short term, hyperglycemia, or elevated blood glucose, causes the classic symptoms of diabetes: excessive thirst, frequent urination and weight loss. In the long term, hyperglycemia, as well as other effects resulting from insufficient insulin effect, can progressively damage critical anatomic structures resulting in chronic diabetic complications. We are developing Sulonex for the treatment of diabetic nephropathy, a long-term complication of diabetes in which the kidneys are progressively damaged. This progressive damage could result in diminished kidney function and progress to ESRD, which ultimately leads to death unless treated by dialysis and/or renal transplant.

The kidney consists of two anatomically and functionally distinct components placed in serial configuration. The first component is the glomerulus, which performs the critical filtering function of the kidney. Blood is passed through delicate microscopic glomerular capillary loops, which, acting as sieves, allow waste chemicals and excess water to pass through into the glomerular filtrate while retaining desirable components, such as blood cells and albumin, within the blood. One of the key components of the glomerular capillary filtering membrane is highly anionic, or negatively charged, glycosaminoglycan molecules that are similar to the chemical components of Sulonex. The glomerular filtrate, the precursor of what will eventually be excreted as urine, flows into the next serial component, which is the tubular interstitial structure. In the tubules, further water is extracted from the filtrate and minerals and other body chemicals are absorbed from or secreted into the filtrate.

In patients who have diabetic nephropathy, it is the delicate glomerular loops that first sustain damage as a result of the diabetic state. These harmful effects include:

- The delicate filtering membranes of the glomerular loops thicken and their crucial anionic glycosaminoglycan molecules are either depleted or altered and lose some or all of their negative charge. Since the negative charge of the glycosaminoglycan components is believed to provide selectivity to the filtration process by the glomerular membranes, this loss of negative charge results in the release of protein, usually albumin, from the blood into the filtrate and urine. The release of abnormal amounts of protein or albumin into the urine is called proteinuria or albuminuria, respectively.

- In addition, hyperglycemia induced overproduction of TGF beta, a regulatory protein, by the kidney induces the accumulation of Type IV collagen resulting in scar formation in the area surrounding the glomerular capillaries. Over time, the extrinsic pressure of this scar tissue causes collapse of individual glomeruli, loss of functionality and release of albumin into the filtrate and urine.

In normally functioning kidneys, it is believed that interstitial structures are exposed to limited amounts of albumin. It is believed that the exposure of the interstitial structures to excessive albumin ultimately leads to a potent inflammatory and scarring response (mediated in part by TGF beta) in the tubules, as well as in the surrounding interstitial tissues. This scarring results in progressive diminution in kidney function. As might be expected, increasing urinary albumin excretion closely parallels this drop in kidney function. In ESRD, kidney function declines to the point where dialysis or transplantation becomes necessary to sustain life.

Clinical Data

European Clinical Data

In Europe, there have been more than 20 studies published assessing the safety and efficacy of Sulonex in humans. Sulonex has been administered to more than 3,000 patients in clinical trials conducted in Europe for the treatment of certain diabetic and non-diabetic conditions and, to our knowledge, has not demonstrated any significant side effects at the doses tested for those uses.

European researchers, with the support of Alfa Wassermann S.p.A., or Alpha Wasserman, the licensor of Sulonex, conducted a randomized, double-blind, placebo-controlled, Phase 2 study of the use of Sulonex to treat diabetic nephropathy in 223 patients in Europe between 1996 and 1999. In this study, also known as the DiNAS study, Type I and Type II diabetics with diabetic nephropathy were treated daily for four months with 50, 100 and 200 milligram gelcaps of Sulonex. These patients showed substantial dose-dependent reduction in proteinuria or pathological urinary albumin excretion rates. In this study, the higher the dose administered daily, the greater the demonstrated decrease in albumin excretion versus placebo. The DiNAS study was published in the June 2002 issue of the Journal of the American Society of Nephrology.

U.S.-based Clinical Data

Our U.S.-based pilot Phase 2 multi-center clinical study was conducted by the CSG. This randomized, double-blind, placebo-controlled study compared two doses (200 mg and 400 mg daily) of Sulonex versus placebo for the treatment of diabetic nephropathy in 149 patients between 2003 and 2005. In June 2007, at the American Diabetes Association Annual Meeting, the CSG presented, in a poster presentation, the final Phase 2 data from the U.S.-based pilot Phase 2 multi-center clinical study. Most recently, the results of the study were published in *Nephrology Dialysis Transplantation* in December, 2007. The design and results of the study are discussed below.

Design of the Phase 2 Study

The Phase 2 study was designed as a pilot for the fully-powered pivotal SUN-MICRO Phase 3 study. In this Phase 2 study, two doses of Sulonex (200 mg and 400 mg) were compared to placebo in diabetic patients with persistent microalbuminuria on therapy with the maximum approved or tolerated dose of an ACE, or an ARB. Patients were treated with Sulonex or placebo for six months and followed for an additional two months post-treatment. Patients were randomized 1:1:1, placebo, 200 mg and 400 mg of Sulonex, respectively.

In this Phase 2 study, the primary endpoint for the study was the percentage of patients achieving "Therapeutic Success" at six months. This is also the endpoint in the protocol for the Phase 3 clinical trial, and which was agreed to with the FDA under an SPA. A patient is considered a Therapeutic Success if they achieve one of the following outcomes following the six months in the study:

(1) 50% reduction in albumin to creatinine ratio or ACR (ACR is a standard measurement used to assess the level of kidney disease in these patients. ACR measures the level of albumin protein in urine, also referred to as albuminuria), or

(2) Normalization of ACR with at least a 25% reduction in ACR (in this study the normal laboratory range for albuminuria was defined as less than 20 mg of albumin to 1g of creatinine).

Phase 2 Study Results

A total of 149 patients were randomized into one of three groups (47 patients to placebo, 50 patients to 200 mg/day of sulodexide, and 52 patients to 400 mg/day of sulodexide) and administered study medication (All-Patient Treated Group). Out of the 149 patients in the All-Patient Treated Group (APT), 130 patients were included in the Intent-to-Treat (ITT) analysis at the end of the treatment period (six months). Nineteen patients were excluded from the ITT analysis due to the presence of a urinary tract infection and/or a missing baseline urinary albumin creatinine ratio (uACR) data.

The results for the primary composite endpoint of "Therapeutic Success" (defined as normalization with a 25% reduction in the urinary albumin creatinine ratio or a 50% reduction in the urinary albumin creatinine ratio) for the ITT group at six months (end of treatment phase) is shown in the table below:

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

	Placebo	200 mg/day Sulodexide	400 mg/day Sulodexide
Number of Patients	39	42	49
Number of Patients with Therapeutic Success at 6 Months	6	14	9
Proportion or Percentage	15.4%	33.3%	18.4%
95% Confidence Interval	6% – 31%	20% – 50%	9% – 32%

The Phase 2 trial was not powered to obtain definitive results for efficacy. However, observed trends were consistent with the hypothesis that administration of sulodexide (at 200 mg/day) is associated with a decreased urine albumin excretion in the patient population studied (table 2 below) and an increase in the number of patients achieving Therapeutic Success, defined as the achievement of normoalbuminuria or 50% decrease in albuminuria, and that effect appeared to be maintained for two months after cessation of therapy (table 4 below).

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

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

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

Table 3-Mean Albumin to Creatinine Ratio over Time

Treatment Group	Baseline	2-Month	4-Month	6-Month (End of Treatment)	Post-Treatment
Placebo (n=39)	73	70	78	85	87
200 mg/day (n=42)	74	58	65	57	66
400 mg/day (n=49)	67	70	67	73	74

Table 4-Percent of Patients Achieving Therapeutic Success at Eight Months (Two Months Post-Treatment)

	Placebo n=38	200 mg/day Sulodexide n=41	400 mg/day Sulodexide n=46
Proportion or Percentage	7.9%	22.0%	13.0%
95% Confidence Interval	1.7% – 21.4%	10.6% – 37.6%	4.9% – 26.3%

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

Table 5-Adverse Event Data

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

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

Development Status

In June 2000, we filed an investigational new drug application, or IND, with the FDA for permission to conduct a clinical trial for the treatment of patients with diabetic nephropathy. In 2001, Sulonex was granted Fast-Track designation for the treatment of diabetic nephropathy, and, in 2002, we announced that the FDA had agreed, in principle, to permit us to avail ourselves of the accelerated approval process under subpart H of the FDA's regulations governing applications for the approval to market a new drug. Generally, subpart H, which allows for the use of surrogate endpoints in Phase 3 trials to support the approval of an NDA with confirmatory studies completed post-approval, could greatly reduce the development time to market.

In the third quarter of 2003, we announced that the CSG would conduct the U.S.-based Phase 2/3 clinical program for Sulonex 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 ACE inhibitor and an ARB that are currently approved for the treatment of diabetic nephropathy.

In the fourth quarter of 2003, we initiated the Phase 2 portion of our Phase 2/3 clinical program for Sulonex, and in the third quarter of 2004, we completed the target enrollment for the Phase 2 portion of the clinical program. The results of the Phase 2 are presented above under the caption "Phase 2 Study Results."

In January 2005, we announced that the CSG recommended that we proceed to the Phase 3 portion of our Phase 2/3 clinical program of Sulonex. 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 2 clinical trial of Sulonex discussed above, and an efficacy assessment of the same data set conducted by the CSG.

In March 2005, we announced that we had finalized an SPA agreement with the FDA for the Phase 3 and Phase 4 clinical trials of Sulonex.

In June 2005, we announced the initiation of our pivotal Phase 3 and Phase 4 clinical program for Sulonex. We are conducting both of these trials under our SPA with the FDA. This clinical plan consists of: a single Phase 3 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 4 confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. The Phase 3 portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of Sulonex versus a placebo in patients with persistent microalbuminuria. The Phase 4 portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of Sulonex versus a placebo in patients with persistent macroalbuminuria. The CSG is conducting the pivotal Phase 3 and Phase 4 clinical program of Sulonex for the treatment of diabetic nephropathy.

In November 2005, we announced final results from our Phase 2 study of Sulonex for diabetic nephropathy at the American Society of Nephrology's (ASN) Renal Week. Interim results from this study had been previously announced at the National Kidney Foundation's Spring Clinical Meeting in May 2005. The Phase 2 study is discussed above under "U.S.-based Clinical Data." In June 2007, final results from this study were the subject of a poster presentation at the American Diabetes Association meeting.

In November 2006, we announced that the DSMC responsible for monitoring Sulonex in the Phase 3 microalbuminuria and Phase 4 macroalbuminuria studies met. Following a review of the blinded and unblinded data from both studies, the DSMC concluded that it saw no cogent reason to recommend alteration or termination of either trial. The DSMC raised no safety concerns regarding Sulonex or the trials.

In February 2007, we announced that we had completed the enrollment portion of the Phase 3 clinical trial.

In March 2007, we announced that the DSMC responsible for monitoring Sulonex in the Phase 3 microalbuminuria and Phase 4 macroalbuminuria studies met again. Following a review of the blinded and unblinded data from both studies, the DSMC once again concluded that there is no cogent reason to recommend alteration or termination of either trial. The DSMC raised no safety concerns regarding Sulonex or the trials.

In June 2007, we announced the randomization of the last patient in our pivotal Phase 3 clinical trial of Sulonex for the treatment of diabetic nephropathy, concluding randomization with a total of 1,056 randomized patients worldwide.

In December 2007, we announced that the DSMC responsible for monitoring Sulonex in the Phase 3 microalbuminuria and Phase 4 macroalbuminuria studies met to evaluate the data from the ongoing Phase 3 trial. Following a complete review of all available safety and efficacy data, the DSMC found no cogent reason to recommend alteration or termination of the Phase 3 trial. The DSMC raised no safety concerns regarding Sulonex or the trial.

In the first quarter of 2008, the Phase 3 trial was completed. Assuming a positive outcome from our Phase 3 trial, we are targeting an NDA filing for Sulonex (sulodexide) by the end of 2008.

The ultimate clinical timeline, and consequent cost, for further development of Sulonex will depend, in part, on the successful completion and outcomes of our Phase 3/4 trials, and ultimate approval, if any, by the FDA.

Zerenex™ *(ferric citrate)*

Overview

Zerenex (ferric citrate) is an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 2 clinical development for the treatment of hyperphosphatemia (elevated serum phosphorous levels) in patients with ESRD.

Market Opportunity

In the U.S., according to data from the U.S. Renal Data System, there are approximately 485,000 patients with end-stage renal disease, or ESRD, and the number of ESRD patients is projected to rise 60% to approximately 785,000 by 2020. The vast majority of ESRD patients, over 350,000, require dialysis. Phosphate retention and the resulting hyperphosphatemia in patients with ESRD on dialysis are usually associated with secondary hyperparathyroidism, renal osteodystrophy, soft tissue mineralization and the progression of renal failure. ESRD patients usually require treatment with phosphate-binding agents to lower and maintain serum phosphorus at acceptable levels.

Aluminum-type phosphate binders were widely used in the past. However, the systemic absorption of aluminum from these agents and the potential toxicity associated with their use no longer make this type of binder a viable treatment option.

Calcium-type phosphate binders are commonly used to bind dietary phosphate; however, they promote positive net calcium balance and an increased risk of metastatic calcification in many patients, especially in those patients taking vitamin D analogs and those with adynamic bone disease.

Non-calcium-based, non-absorbed phosphate binders, including sevelamer hydrochloride and sevelamer carbonate are among the most prescribed phosphate binders in the U.S. Compared to the calcium-type binders, fewer coronary and aortic calcifications have been documented, however, there is a risk of metabolic acidosis with sevelamer hydrochloride, the potential for gastrointestinal problems, and sevelamer can affect concomitant vitamin K and vitamin D treatment.

Lanthanum-type phosphate binders are another alternative. Lanthanum is a rare earth element and is minimally absorbed in the gastrointestinal tract. Lower level tissue deposition, particularly in bone and liver, has been observed in animals. However, the long-term effects due to the accumulation of lanthanum in these tissues have not been clearly determined.

The need for alternative phosphate-binding agents has long been recognized, especially given the increasing prevalence of ESRD as well as shortcomings with current therapies. Zerenex has the potential to be an effective and safe treatment in lowering and/or maintaining serum phosphorus levels 5.5 mg/dL in patients with ESRD and hyperphosphatemia.

Clinical Data

In June 2006, we announced final results from the Phase 2 multi-center study entitled: "A randomized, double-blind, placebo-controlled, dose ranging study of the effects of Zerenex on serum phosphate in patients with end stage renal disease (ESRD)." This Phase 2 study was conducted under an IND sponsored by our licensors in both the United States and Taiwan.

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

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

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

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

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

* mean (standard deviation)

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

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

* mean (standard deviation)

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

In addition, Zerenex has been studied in two previous Phase 2 clinical trials using single fixed dose regimens. In both studies, Zerenex was able to significantly reduce serum phosphorous (p .005), and the degree of reduction appeared to be generally comparable to calcium-based products which were used as positive control arms in those studies. The study was not designed to compare Zerenex to calcium-based products, therefore, no formal assessment can be made of the comparative efficacy. See Tables 3 and 4 below.

Table 3-Effects on Serum Phosphorus at 4 Weeks (n=28)

Open Label, Randomized, Parallel Groups, 2 sites

	Serum Phosphorous		
	Baseline (mg/dL)	End-Point (Four Weeks) (mg/dL)	Change from Baseline
Ferric Citrate (Zerenex™) (4.5 g/day)	7.2+/-2.5	5.9+/-2.0	P<0.005
Calcium Acetate (PhosLo®) (4 g/day)(1)	7.2+/-2.0	5.6+/-1.7	P<0.005

(1) Serum calcium increased significantly from baseline to end of treatment (8.7 +/- 0.5 mg/dL to 9.2 +/- 0.7 mg/dL) only in the calcium acetate group.

Table 4-Effects on Serum Phosphorus at 4 Weeks (n=54)z

Open Label, Randomized, Crossover, 2 sites

	Serum Phosphorous		
	Baseline (mg/dL)	End-Point (Four Weeks) (mg/dL)	Change from Baseline
Ferric Citrate (Zerenex™) (3 g/day)	6.7+/-1.9	5.7+/-1.6	P<0.001
Calcium Carbonate (3 g/day)(1)	7.2+/-1.9	5.2+/-1.5	P<0.001

(1) Serum calcium increased only in patients treated with calcium carbonate.

Development Status

In July 2006, we met with the FDA to discuss the further development of Zerenex, including Phase 3 study design and requirements prior to moving into Phase 3. To support higher doses and longer duration of treatment in Phase 3, we agreed with the FDA to conduct additional studies. As agreed with the FDA, chronic toxicity studies in animals are being conducted, as well as a shorter-term high-dose tolerance and safety study in patients.

In August 2007, we provided the FDA with our 28-day toxicology package for rats and dogs. The FDA accepted our 28-day toxicology package and we plan to commence a Phase 2 high-dose exposure clinical trial in the first quarter of 2008. In addition to the 28-day toxicology study, we are conducting a 90-day toxicology study in rats and a 16-week toxicology study in dogs. This will assist the Company in designing the chronic toxicity studies. Initiation of the shorter-term, high-dose tolerance and safety clinical trial is expected in the first quarter of 2008.

Oncology

KRX-0401 (perifosine)

Overview

We are also developing KRX-0401 (perifosine), which is a novel, potentially first-in-class, oral anti-cancer agent that modulates Akt, and a number of other key signal transduction pathways, including the JNK and MAPK pathways, all of which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. The effects of perifosine on Akt are of particular interest because of the importance of this pathway in the development of most cancers, the evidence that it is often activated in tumors that are resistant to other forms of anticancer therapy, and the difficulty encountered thus far in the discovery of drugs that will inhibit this pathway without causing excessive toxicity. High levels of activated Akt (pAkt) are seen frequently in many types of cancer and have been correlated with poor prognosis in patients with soft-tissue sarcoma, gastric, hepatocellular, endometrial, prostate, renal cell, head and neck

cancers and hematological malignancies, as well as glioblastoma. The majority of tumors expressing high levels of pAkt were high-grade, advanced stage or had other features associated with poor prognosis. High pAkt is often seen in tumors that are resistant to conventional cancer treatments, including radiotherapy, chemotherapy, endocrine therapy, and especially therapy with some of the newer biologicals. Published data suggest that the Akt pathway is frequently activated in renal cell cancer and that this tumor type may be particularly responsive to Akt inhibition.

To date, over 1,700 patients have been treated with KRX-0401 in trials conducted both in the United States and Europe. Its safety profile is distinctly different from that of most cytotoxic agents. It does not appear to cause myelosuppression (depression of the immune system that may lead to life threatening infections), thrombocytopenia (a decrease in platelets that may result in bleeding), skin rash, flu-like symptoms or alopecia (hair loss); all of these toxicities occur frequently with many of the currently available treatments for cancer. The main side effects of perifosine are nausea, vomiting, diarrhea and fatigue, but these are either mild or non-existent in lower doses that have induced tumor regression. Responses have been seen with both daily and weekly regimens. At the doses studied, the daily regimens were better tolerated.

In Phase 1/2 trials, KRX-0401 has induced tumor regressions and/or caused disease stabilization in a variety of tumor types. KRX-0401 has shown single agent partial responses in renal cell and hepatocellular carcinoma, soft tissue sarcoma, GIST tumors, mesothelioma, and carcinoma of the appendix. There is also evidence of activity in hematological malignancies, especially multiple myeloma. Disease stabilization, defined as time on treatment without progression for at least 6 months has been seen in 20 tumor types, including metastatic renal cell cancer, hepatocellular carcinoma, melanoma, carcinoid, prostate, head and neck, breast, and small cell lung cancer. Responding patients, including stable disease, have been treated for various durations up to more than three years.

Pre-Clinical and Clinical Data

In vitro, KRX-0401 inhibits the growth of a variety of human tumor cell lines and has substantial activity in vivo against a number of murine tumor models and human xenografts. Investigators at the US National Cancer Institute, or NCI, were among the first to study the effects of KRX-0401 on Akt using a prostate cell line, PC-3 that is known to have constitutively activated Akt. Their results demonstrated that KRX-0401 blocked phosphorylation of Akt but did not decrease the total amount of Akt present in the cell. In model systems the drug appears to be synergistic with radiotherapy and additive or synergistic with cytotoxics such as cisplatin, doxorubicin, and cyclophosphamide. In these experiments, the combination regimens were superior to chemotherapy alone and were well tolerated. Recent data suggest that KRX-0401 may be additive or synergistic with newer targeted agents such as tyrosine kinase inhibitors sorafenib (Nexavar®) and sunitinib (Sutent®).

Pre-clinical studies presented at the American Society of Hematology Annual Meeting in December 2005 demonstrated KRX-0401's potential utility in the treatment of multiple myeloma and possibly other forms of hematological malignancy. These studies demonstrated KRX-0401 to be active against human multiple myeloma cell lines and freshly isolated myeloma cells from multiple myeloma patients' bone marrow, including those cells which were resistant to dexamethasone and doxorubicin. KRX-0401 was shown to modulate a number of key cellular functions involved in the replication and death of multiple myeloma cells, and, as in other cell lines, it was shown to be a potent Akt inhibitor. KRX-0401 was active *in vitro* and *in vivo* when used alone. Investigators at the Dana-Farber Cancer Institute demonstrated that it is synergistic when combined with bortezomib (Velcade®), dexamethasone and a number of other drugs used to treat multiple myeloma. In these experiments, treatment with bortezomib alone inhibited phosphorylation of ERK while increasing Akt activation. KRX-0401 inhibited phosphorylation of Akt while increasing ERK activation. The two drugs together inhibited phosphorylation of both Akt and ERK, and these effects correlated with the increased efficacy of the combination.

Seven Phase 1 single agent studies of KRX-0401 have been completed, three in Europe by Zentaris and four in the United States by the NCI, a department of the National Institutes of Health, or NIH, as part of a Cooperative Research and Development Agreement, or CRADA, and by us. 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. The dose limiting toxicity in the Phase 1 studies was gastrointestinal:

nausea, vomiting and diarrhea. In addition, some patients experienced fatigue, especially with prolonged administration. In these Phase 1 studies, there was single agent activity as evidenced by two durable partial responses (one of which lasted more than six months and the other more than 18 months) out of 10 patients with previously treated, evaluable soft tissue sarcomas, a tumor type relatively unresponsive to chemotherapy. In addition, 22 patients were considered by the investigators to have had disease stabilization for two or more months, including patients with sarcomas (2), prostate cancer (3), non-small cell lung cancer (2), breast cancer (2), colon cancer (2), melanoma (2), renal cancer (3), ovarian cancer (1), salivary gland cancer (1), mesothelioma (2) and hepatoma (2). The meaning of disease stabilization in an individual patient in a Phase 1 study is difficult to assess because the time to progression is variable and may give a false impression of stabilization in individual patients. We believe that the Phase 1 data provides clinical evidence of the anti-cancer effects of KRX-0401.

Five Phase 1/2 studies of KRX-0401 in combination with other drugs have been conducted by Keryx; another eight are ongoing. Other drugs that have been included in these combinations are gemcitabine, paclitaxel, docetaxel, prednisone, doxorubicin, capecitabine, pemetrexed, irinotecan, Doxil® (doxorubicin HCl liposome injection), trastuzumab, various endocrine therapies, imatinib, bortezomib, sorafenib, and sunitinib. In general KRX-0401 has not added to the toxicities expected when these other drugs are used alone, and in general it has not been necessary to reduce the dose of either perifosine or the other drug in the combination. KRX-0401 has also been studied in combination with radiotherapy without evidence of increased toxicity.

The NCI has completed a number of Phase 2 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 these six tumor types. Findings from these studies led most of these investigators to conclude that the drug was safe and well-tolerated at the Phase 2 dose utilized. The studies used dosing schedules in which a large "bolus" dose was given on day one or once every 28 days followed by daily doses either continuously ("continuous" regimen) or on days 2 to 21 of a four-week cycle ("intermittent" regimen). Bolus doses ranged from 300 mg to 900 mg followed by daily doses of 100 – 150 mg. These studies confirm the safety profile of the bolus plus daily regimens, which had very limited grade 3 and no grade 4 gastrointestinal toxicity, the dose limiting toxicity in most of the Phase 1 trials. However, studies using the "continuous" regimen appeared to be better tolerated than studies that used the "intermittent" regimen.

In the NCI Phase 2 sarcoma study that utilized the "continuous" regimen, the investigators reported a partial response (greater than 50% decrease in tumor mass) as well as several disease stabilizations. No response was seen in the other NCI sarcoma trial in which the less well tolerated "intermittent" dose schedule was used. In the NCI Phase 2 breast cancer study, investigators scored three of 15 evaluable patients as having stable disease. One of these patients had measurable tumor regression that failed to reach the level of a partial response by the time the patient elected to withdraw from the study because of gastrointestinal toxicity. The breast cancer trial utilized the more toxic "intermittent" regimen. In one of the prostate cancer studies the "continuous" regimen was given to patients with recurrent hormone-sensitive prostate cancer whose only manifestation of disease was an elevation of PSA. PSA levels fell in 5 of 22 evaluable patients enrolled in this trial, but no PSA level fell by more than 50%. Twenty patients were considered by the investigators to have had disease stabilization. The median time to progression was 6.6 months, but one patient continued on treatment without further progression for 3.3 years. In other prostate cancer study the "intermittent" regimen was evaluated in patients with hormone-refractory disease that was more widespread. In this study there were no radiographic responses or PSA declines of 50% or greater, but four patients had stable PSA values for 12 weeks or longer. Eleven of 14 patients, or 78%, in whom circulating tumor cells were measured pre- and post-treatment, showed a decreased number of circulating tumor cells after treatment. In the melanoma trial published by the National Cancer Institute of Canada, one patient with a primary mucosal melanoma of the vagina and inguinal adenopathy had a 50% reduction in the size of the palpable nodes after four cycles but developed new disease after the fifth cycle. None of the patients with head and neck or pancreatic cancers enrolled in these NCI trials responded.

A review from all completed and ongoing Phase 1 and Phase 2 studies demonstrated that KRX-0401 induced 21 partial responses in various malignancies including renal cell and hepatocellular carcinoma, soft tissue sarcoma, GIST tumors, mesothelioma, carcinoma of the appendix, and multiple myeloma. Disease

stabilization, defined as time on treatment without progression for at least 6 months was seen in 20 tumor types, including metastatic renal cell cancer, hepatocellular carcinoma, soft tissue sarcoma, melanoma, carcinoid, prostate, head and neck, breast, and small cell lung cancer.

In June 2006, we announced data of KRX-0401 in patients with advanced renal cell carcinoma (RCC). These patients were a cohort of a Phase 2, multi-center trial of KRX-0401 conducted by Keryx that included multiple tumor types. Patients were randomized to either a daily (50 mg or 100 mg) or weekly (900 mg or 1200 mg) dose of KRX-0401. Although the study is ongoing, 416 patients had been enrolled at the time of the last analysis, and 24 of these had advanced RCC. All patients in this study were to have had prior standard therapy. Most patients had received two chemotherapy regimens for metastatic disease. In November 2007, updated data on the renal cancer patients enrolled in this trial were announced. The results are summarized in the table below. One of the four responding patients had previously failed to respond to both sorafenib and sunitinib.

Perifosine Efficacy in Renal Cell Cancer

	Number of Patients		
	All Doses	Lower Doses 50 or 100 mg Daily	Higher Doses 900 or 1200 mg Weekly
Total enrolled, all tumor types	416	205	211
Renal Cell Cancers	24	12	12
Evaluable for response*	13	7	6
Partial response (RECIST)	4	2	2
Durations of response (months)	4, 7, 9, 12	7, 12	4, 9
Stable ≥ 6 months	4	3	1
Duration stable disease (months)	10, 13, 14, 18+	10, 13, 14	18+
Response rate†	31%	29%	33%
Clinical benefit rate††	62%	71%	50%

* Patients with measurable disease on study for at least 2 months and at least one tumor measurement after initiation of perifosine

\+ Patient had not yet progressed at the time of the analysis

† *RECIST criteria*

†† *PR or Stable for ≥6 months*

In a Phase 1 study of KRX-0401 combined with sorafenib, 18 patients with advanced cancers were enrolled in one of four cohorts. Ten of these patients had advanced renal cell carcinoma with some patients having received a prior tyrosine kinase inhibitor (sunitinib). No grade 4 toxicities were reported and 1 grade 3 hand/foot syndrome has been seen. The combination has been generally well tolerated.

In June 2007, an analysis of the response to perifosine of sarcoma patients enrolled in one of three Phase 1 or four Phase 2 trials that enrolled patients with soft sarcomas were presented at the American Society of Clinical Oncology meetings in Chicago. There were a total of 145 patients, 76 treated with one of 3 regimens defined retrospectively as being "lower doses" and 69 treated with "higher doses." Only 82 patients were fully evaluable. The most common reason that patients were inevaluable is that they were removed from study for toxicity without evidence of tumor progression. This happened more often among patients treated with the higher doses. In addition, patients were considered inevaluable if they had rapid progression shortly after drugs was started (2 months) and before perifosine would have had much chance to work. The definition of clinical benefit rate (CBR) used in this analysis is identical to that used previously in an analysis of the effectiveness of mTOR inhibitors for patients with soft tissue sarcomas. The overall CBR in evaluable patients, 52%, was not significantly different in the two patient cohorts defined by the dose administered. The response rate in an intent-to-treat analysis was higher in patients treated with the lower doses because of the higher proportion of patients on the higher dose regimens who could not tolerate drug.

In December 2006 and again in December 2007, we reported results from a Phase 2 study of KRX-0401 alone and in combination with dexamethasone in patients with advanced relapsed and refractory multiple myeloma. Sixty-seven highly pre-treated multiple myeloma patients (median age 62 yrs) were treated with KRX-0401 at 150 mg qd to assess the single agent activity in this patient population. Patients had a median of 4 lines of prior therapy (range 1 – 11) and 94% of patients were previously treated with at least one course of dexamethasone. If a patient progressed on KRX-0401 alone, dexamethasone (20 mg twice weekly) was added to their KRX-0401 regimen. Toxicity was manageable with no deep vein thrombosis or peripheral neuropathy reported. The most common grade 3/4 adverse events were nausea (8%); vomiting (5%); diarrhea (2%); fatigue (2%), neutropenia (17%), anemia (6%) and increased creatinine (8% in the context of PD and light chain nephropathy). Ten patients discontinued therapy due to an adverse event. Twenty-one patients had KRX-0401 reduced from 150 to 100 mg qd with no difference in response noted.

In this heavily pre-treated and relapsed/refractory patient population, KRX-0401 as monotherapy was considered by the investigators to be active with 33 of 50 evaluable patients (66%) achieving stable disease. (See table below) Dexamethasone was added in 39 of 55 pts with progressive disease. In 29 patients evaluable for response to the combination the overall response rate (CR+PR+MR) was 35% and 52% had disease stabilization. Enrollment objectives were met and the study is now closed.

Perifosine Efficacy in Multiple Myeloma

	Number (%)	Duration of Response (Weeks)
Perifosine Alone		
Evaluable or response	50	
Response		
MR	1 (2%)	24
Stable Disease*	33 (66%)	6 – 45+ (median 10)
Perifosine + Dexamethasone		
Evaluable for response	29	
Response		
PR	4 (14%)	36, 39, 63+, 64+
MR	6 (21%)	15, 18, 19, 28+, 30, 70
Stable Disease*	15 (52%)	6 – 31 (median 14)

* *Stable disease: 25% change in m-protein*

In December 2007 we announced the first results of a trial combining KRX-0401 with bortezomib in patients with advanced multiple myeloma previously treated with bortezomib. This trial was designed as a Phase 1/2 study. The Phase 1 portion enrolled 18 patients (median age 64 yrs) with advanced multiple myeloma (83% relapsed and refractory) who were enrolled in one of four cohorts. Patients had a median of 5 lines of prior therapy and 100% of patients were previously treated with at least one course of therapy on bortezomib. KRX-0401 was escalated from 50 to 100 mg qd while bortezomib was escalated from 1.0 to 1.3 mg/mm^2. No dose-limiting toxicity and no grade 3 peripheral neuropathy were reported. Toxicities were generally easily managed and tolerated. Dexamethasone 20 mg (day of and day after each bortezomib dose) was added in patients with progressive disease on KRX-0401 plus bortezomib alone. Sixteen patients on either bortezomib plus KRX-0401 alone or with dexamethasone were evaluable for response, assessed by modified EBMT/Blade criteria. An overall response rate of 56% (CR + PR + MR) was reported with an additional 31% of patients achieving stable disease. The Phase 2 portion of the study is currently open with KRX-0401 50 mg daily + bortezomib 1.3 mg/m^2, on days 1, 4, 8, 11 of a 21 day cycle. The investigators concluded that the combination of KRX-0401 and bortezomib (+/- dexamethasone) was well tolerated and is active in heavily pre-treated and relapsed/refractory multiple myeloma, including bortezomib-resistant patients.

Development Status

During the second quarter of 2004, we announced the initiation of a Phase 2 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 and breast cancer and sarcoma, and combination studies with a number of standard anti-cancer treatments, such as gemcitabine, paclitaxel, docetaxel, pemetrexed, capecitabine, doxorubicin, Doxil® (doxorubicin HCl liposome injection), irinotecan, Herceptin® (trastuzumab) , and endocrine therapy. We have also initiated an "all-comers" Phase 2 clinical trial evaluating KRX-0401 as a single-agent, administered either weekly or daily in a variety of tumor types. Preliminary results have been reported from many of these studies and are described above.

In December 2006, we announced the initiation of a corporate-sponsored Phase 2 clinical program to evaluate KRX-0401 as a treatment for rare sarcomas. This Phase 2 study is being conducted by the Sarcoma Alliance for Research through Collaboration (SARC) multi-center network, which includes nationally recognized sarcoma centers and investigators throughout the United States. This clinical trial is entitled "A Phase II Trial of Perifosine in Patients with Chemo-Insensitive Sarcomas." In this Phase 2 study, the single agent activity of KRX-0401 is being evaluated in patients with chondrosarcoma, alveolar soft part sarcomas and extra-skeletal myxoid chondrosarcomas. Patients are treated with KRX-0401 until disease progression. This study follows previous Phase 1 and Phase 2 trials of perifosine in patients with chemo-insensitive sarcoma that showed responding patients experienced very little toxicity and the duration of responses observed on both weekly and daily dosing schedules varied from six months to more than 18 months. Furthermore, some of the partial responses occurred in patients with sarcoma subtypes that have been traditionally unresponsive to conventional therapy.

In December 2006, we announced the initiation of a multi-center Phase 1 clinical program to explore the convenient all-oral combination of KRX-0401, Revlimid® and dexamethasone for the treatment of relapsed or refractory multiple myeloma. This trial will be completed in 2008. The results of these Phase 1/2 trials will determine the feasibility of initiating randomized trials in patients with multiple myeloma.

During 2007 the Phase 1 portion of a Phase 1/2 trial evaluating the combination of perifosine with Velcade® (bortezomib) was completed. The results are summarized above. Patients are now being enrolled in the Phase 2 component of this study.

During 2007 four trials were initiated to evaluate perifosine alone or in combination for patients with advanced renal cell cancer. Two of these were Phase 2 studies of perifosine alone, either in patients resistant to the tyrosine kinase inhibitors (sorafenib or sunitinib) or in patients resistant to mTOR inhibitors. Two of these trials were Phase 1/2 studies of perifosine in combination with sorafenib or sunitinib. All four of these trials are still accruing patients and will continue throughout 2008. In addition, a randomized trial evaluating perifosine in patients with advanced renal cancer is planned for 2008.

KRX-0402

KRX-0402 (O^6-benzylguanine or O^6-BG) is a small molecule that was specifically designed to block the DNA repair protein, MGMT. MGMT confers resistance to certain alkylating agents, such as temozolomide and BCNU, that are commonly used to treat brain cancer, melanoma and non-Hodgkin's lymphoma. Recent research has shown that KRX-0402 can also potentiate the activity of other alkylating agents, such as cyclophosphamide, ifosphamide, cisplatinum and carboplatinum. These drugs are some of the most widely used chemotherapy drugs and are commonly used to treat breast cancer, non-small cell lung cancer and ovarian cancer. To date, nearly 800 patients have received KRX-0402 in multiple clinical studies. Dose limiting toxicity for KRX-0402 in combination with chemotherapy is bone marrow suppression. KRX-0402 alone has no identified dose limiting toxicity. We are currently assessing the future development prospects of KRX-0402.

KRX-0601 (7-hydroxystaurosporine)

KRX-0601 is a novel multi-kinase inhibitor for the treatment of cancer which, in pre-clinical models, has demonstrated a synergistic effect with agents inhibiting the PI3K pathway, including KRX-0401. KRX-0601 is currently in several Phase 2 clinical trials both as a single agent and in combination with other anticancer agents which are being conducted under the direction and sponsorship of the NCI. KRX-0601 is an anticancer drug that belongs to the family of drugs called staurosporine analogs which have demonstrated an ability to inhibit multiple kinases involved in cell-cycle progression and apoptosis, including Chk-1 and PDK1. In pre-clinical studies, KRX-0601 has demonstrated synergistic effect with DNA-damaging agents including

chemotherapy and radiation therapy. In-vitro, KRX-0601 has been shown to be synergistic with agents affecting the PI3-K pathway including KRX-0401 and mTOR inhibitors. In clinical trials, as reported by investigators at the National Cancer Institute, durable single-agent responses have been seen in patients with anaplastic large-cell lymphoma. We are currently assessing the future development prospects of KRX-0601.

KRX-0404

KRX-0404, currently in pre-clinical development, is an alkylphosphocholine, but, in contrast to KRX-0401, it is suitable for intravenous administration. We are currently assessing the future development prospects of KRX-0404.

Neurology

KRX-0501

KRX-0501 is an orally available small molecule in clinical development with the potential to treat neurological disorders via its unique ability to enhance nerve growth factor, a naturally occurring protein which is essential in the development and survival of certain sympathetic and sensory neurons in both the central and peripheral nervous systems. In May 2007, we initiated a first-in-man Phase 1 study for KRX-0501, a nerve growth factor enhancer, in healthy volunteers to assess the pharmacokinetic profile.

KRX-0501 was licensed from Krenitsky Pharmaceuticals, Inc. in 2005 and we hold a worldwide license to develop and sell the product for all indications. KRX-0501 is believed to have potential for use in the treatment of neurological conditions such as diabetic neuropathic pain, Huntington and Alzheimer's disease, as well as chemotherapy-induced neuropathy.

KRX-0701

KRX-0701 (dexlipotam) or (tromethamine-salt of R (+)-α-lipoic a cid) is a compound being investigated for the treatment of diabetic neuropathy and possibly other neuropathic conditions. Currently, there is an Investigational New Drug Application for KRX-0701 in the United States and we are planning to initiate a Phase 2 dose-ranging study in 2008 for diabetic neuropathy. KRX-0701 is considered to be an antioxidant and can normalize the cell redox imbalance that occurs in diabetes.

During the first half of 2007, we acquired an exclusive worldwide license to KRX-0701 from Degussa AG, a wholly owned subsidiary of the RAG Group based in Germany. In accordance with the terms of the agreement, we made an up-front payment and will make milestone payments as well as pay royalties on product sales.

The Company plans to enter into a Phase 2 study in the second half of 2008.

Costs and Time to Complete Product Development

The information below provides estimates regarding the costs associated with the completion of the current development phase and our current estimated range of the time that will be necessary to complete that development phase for our drug candidates. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 1A under the heading "Risks Associated with Our Product Development Efforts."

Product Candidate	Target Indication	Development Status	Completion of Phase	Estimated Cost to Complete Phase
Endocrine/Renal				
Sulonex™ (sulodexide)	Diabetic nephropathy	Phase 3	1st Qtr. 2008	Approximately $3 million
		Phase 4	Not estimable	Not estimable
Zerenex™ (ferric citrate)	Hyperphosphatemia inpatients with end-stage renal disease	Phase 2	Late 2008 / Early 2009	Approximately $6 million
Oncology				
KRX-0401 (perifosine)	Renal cancer and other multiple forms of cancer	Phase 2	Not estimable	Not estimable
KRX-0402 (O^6-benzylguanine) or (O^6-BG)	Brain cancer	Phase 2	Not estimable	Not estimable
KRX-0601 (7-hydroxystaurosporine)	Multiple forms of cancer	Phase 2	Not estimable	Not estimable
KRX-0404 (ErPC)	Multiple forms of cancer	Pre-clinical	Not estimable	Not estimable
Neurology				
KRX-0701 (dexlipotam)	Diabetic neuropathy	Phase 2	Not estimable	Not estimable
KRX-0501	Neurological disorders	Phase 1	2009	Approximately $2 million

Completion dates and costs in the above table are estimates due to the uncertainties associated with clinical trials and the related requirements of development. In cases where the requirements for clinical trials and development programs have not been fully defined, or are dependent on the success of other trials, we cannot estimate trial completion or cost with any certainty. The actual spending on each trial during the year is also dependent on funding. We therefore direct your attention to Item 7 under the heading Liquidity and Capital Resources.

Intellectual Property and Patents

General

Patents and other proprietary rights are very important to the development of our business. We will be able to protect our proprietary technologies from unauthorized use by third parties only to the extent that our proprietary rights are covered by valid and enforceable patents, supported by regulatory data exclusivity or are effectively maintained as trade secrets. It is our intention to seek and maintain patent and trade secret protection for our drug candidates and our proprietary technologies. As part of our business strategy, our policy is to actively file patent applications in the United States and, when appropriate, internationally to cover methods of use, new chemical compounds, pharmaceutical compositions and dosing of the compounds and compositions and improvements in each of these. We also rely on trade secret information, technical know-how, innovation and agreements with third parties to continuously expand and protect our competitive position. We have a number of patents and patent applications related to our compounds and other technology, but we cannot guarantee the scope of protection of the issued patents, or that such patents will survive a validity or enforceability challenge, or that any of the pending patent applications will issue as patents.

Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the United States that claim technology also claimed

by us, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent.

If a patent is issued to a third party containing one or more preclusive or conflicting claims, and those claims are ultimately determined to be valid and enforceable, we may be required to obtain a license under such patent or to develop or obtain alternative technology. In the event of a litigation involving a third party claim, an adverse outcome in the litigation could subject us to significant liabilities to such third party, require us to seek a license for the disputed rights from such third party, and/or require us to cease use of the technology. Further, our breach of an existing license or failure to obtain a license to technology required to commercialize our products may seriously harm our business. We also may need to commence litigation to enforce any patents issued to us or to determine the scope and validity of third-party proprietary rights. Litigation would involve substantial costs.

Sulonex (sulodexide)

Pursuant to our license for sulodexide, we initially had the rights to ten patent families, including nine families of issued United States patents and foreign counterparts, and one family of a pending United States patent application and foreign counterparts. However, we determined that several of the licensed patents were not material to our business strategy and relinquished all rights to those patents. The four remaining patent families currently under license cover the use of sulodexide or glycosaminoglycans for the treatment of diabetic nephropathy, retinopathy or neuropathy. In addition, we subsequently filed five additional United States patent applications and certain foreign counterparts relating to this product, which applications are currently pending. The remaining licensed patents, and the additional patent applications, are being maintained throughout the territories in which they were filed.

U.S. Patent No. 5,496,807 covers the use of sulodexide to treat a patient with diabetic nephropathy exhibiting microalbuminuria or macroalbuminuria. This patent expires in 2014. Based on the provisions of the Patent Term Extension Act, we currently believe that we would qualify for patent term extension of at least three years, thereby extending our patent exclusivity, for the issued United States patent to at least 2017. We believe that we will have sufficient time to commercially utilize the inventions directed to the treatment of diabetic nephropathy.

U.S. Patent No. 7,259,152 covers the use of oral formulations of sulodexide for the treatment of diabetic nephropathy in patients with both insulin dependent and non-insulin dependent diabetes mellitus. This patent expires in 2020.

Other Clinical-Stage Compounds, including KRX-0401(perifosine)

Pursuant to our acquisition of ACCESS Oncology, Inc. in February 2004, we have the exclusive commercial rights to a series of patents and patent applications in the United States, Canada and Mexico related to perifosine. These patents and patent applications cover composition of matter and methods of treatment. In addition, as a result of the acquisition, we have obtained a United States patent and foreign counterparts directed to a pharmaceutical composition comprising KRX-0402 (O^6-benzylguanine) expiring in 2010 (with extension expected through 2015).

Pursuant to our license agreement for KRX-0601, we have the exclusive commercial rights to a series of patent applications worldwide excluding Japan. These patents and patent applications cover composition of matter and process of making for UCN-01 and liposomal formulations of UCN-01. The composition of matter patent expired in June 2007. The method of use patents expire from 2013 to 2017.

Pursuant to our license for Zerenex (ferric citrate) with Panion & BF Biotech, Inc., or Panion, we have the exclusive commercial rights to a series of patent applications worldwide, excluding certain Asian-Pacific countries. These patents and patent applications cover a method of treatment of hyperphosphatemia in patients with ESRD, as well as a method for the manufacture of ferric citrate. Panion holds one use patent expiring

2017 (with extensions expected through 2020) and two manufacturing process patents (expiring 2023). We are continuing to research additional uses for this compound and anticipate filing additional patent applications in the future.

Other Intellectual Property Rights

We depend upon trademarks, trade secrets, know-how and continuing technological advances to develop and maintain our competitive position. To maintain the confidentiality of trade secrets and proprietary information, we require our employees, scientific advisors, consultants and collaborators, upon commencement of a relationship with us, to execute confidentiality agreements and, in the case of parties other than our research and development collaborators, to agree to assign their inventions to us. These agreements are designed to protect our proprietary information and to grant us ownership of technologies that are developed in connection with their relationship with us. These agreements may not, however, provide protection for our trade secrets in the event of unauthorized disclosure of such information.

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act to provide market exclusivity for certain of our drug candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the United States, or, diseases that affect more than 200,000 individuals in the United States but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. We believe that certain of the indications for our drug candidates will be eligible for orphan drug designation; however, we cannot assure that our drugs will obtain such orphan drug designation or that we will be the first to receive FDA approval for such drugs so as to be eligible for market exclusivity protection. With respect to KRX-0402 and KRX-0601, we may rely predominantly on the market exclusivity provided under the orphan drug regulations as the patents on these drugs may expire prior to commercialization.

Licensing Agreements and Collaborations

We have formed strategic alliances with a number of companies for the manufacture and commercialization of our products. Our current key strategic alliances are discussed below.

Alfa Wassermann S.p.A.

Under a license agreement with Alfa Wassermann, we have the exclusive rights to sulodexide (Sulonex) for the treatment of diabetic nephropathy, neuropathy and retinopathy in the United States, Canada, Japan, Australia, New Zealand, South Africa and Israel. The license entitles Alfa Wassermann to annual license fees, royalties and certain milestone payments. Under the license, we must use our reasonable best efforts to commercially exploit and market sulodexide. In certain circumstances Alfa Wassermann is entitled to use proprietary information developed by us and, if it chooses to do so, will be required to pay a percentage of the expenses incurred by us to develop such proprietary information. If the license is not terminated sooner, it will terminate upon the later of the date of expiration of the last claim under the licensed patent rights or ten years from our first commercial sale of a licensed product. See "Item 3. Legal Proceedings" for additional information.

Collaborative Study Group

In June 2005, we announced that the CSG will be conducting our pivotal Phase 3 and Phase 4 clinical program of sulodexide for the treatment of diabetic nephropathy. The CSG receives a monthly fee and reimbursement of expenses from us as compensation for its work in connection with this clinical program. The CSG also has the right to publish data arising from the clinical program. The agreement remains in force through June 2009, unless extended by the parties. Either party may terminate the agreement at any time upon 30 days written notice to the other party.

Opocrin, S.p.A.

Pursuant to a license with Opocrin, S.p.A., a private drug manufacturer, we have a non-exclusive worldwide license to the manufacturing process of sulodexide for a period of twelve years from the date of the first commercial sale of the product.

AEterna Zentaris Inc.

In September 2002, we signed a commercial license agreement with Zentaris AG, a wholly owned subsidiary of AEterna Zentaris Inc., relating to the development of perifosine covering composition of matter and methods of treatment. This agreement grants us the exclusive rights to perifosine (KRX-0401) in the United States, Canada and Mexico. Zentaris is entitled to certain royalty payments, as well as additional compensation upon successful achievement of certain milestones. The license terminates upon the later of the expiration of all underlying patent rights or ten years from the first commercial sale of KRX-0401 in any of the covered territories. We also have the right to extend the agreement for an additional five years beyond the expiration of all underlying patents.

The National Institutes of Health

In October 2000, we entered into a worldwide, exclusive commercial sub-license agreement with Procept, Inc., a wholly owned subsidiary of Paligent, Inc., relating to the development and marketing of KRX-0402 (O^6-benzylguanine). In March 2005, we entered into an agreement with Procept and the NIH, which amended the license agreement between Procept and the NIH whereby we obtained all of Procept's rights and interests, and assumed all of Procept's obligations, under the agreement. The NIH is entitled to certain milestone payments, as well as royalty payments on net sales of KRX-0402. The license terminates upon the expiration of all underlying patent rights.

Panion & BF Biotech, Inc.

In November 2005, we entered into a license agreement with Panion. Under the license agreement, we have acquired the exclusive worldwide rights, excluding certain Asian-Pacific countries, for the development and marketing of ferric citrate (Zerenex). Panion is entitled to certain milestone payments, as well as royalty payments on net sales of Zerenex. The license terminates upon the expiration of all underlying patent rights. See "Item 3. Legal Proceedings" for additional information.

Kyowa Hakko Kogyo Co., Ltd.

In September 2006, we entered into an exclusive license agreement with Kyowa Hakko Kogyo Co., Ltd. of Tokyo, Japan, or Kyowa, for the worldwide development and commercialization rights, excluding Japan, to KRX-0601. Kyowa is entitled to milestone payments as well as royalties on product sales, if any. The license terminates upon the expiration of all underlying patent rights.

AusAm Biotechnologies, Inc.

In April 2006, Accumin Diagnostics, Inc., or ADI, our wholly-owned subsidiary, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc., or AusAm. ADI may be required to pay up to a maximum of $16.1 million in royalties on revenue from a next generation product following FDA marketing approval.

Degussa AG

During the first half of 2007, we acquired an exclusive worldwide license to KRX-0701 from Degussa AG, a wholly owned subsidiary of the RAG Group based in Germany. In accordance with the terms of the agreement, we made an up-front payment and will make milestone payments as well as pay royalties on product sales.

Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd.

In September 2007, we entered into a sublicense agreement with Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii"), JT's pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive rights for the development and commercialization of Zerenex (ferric citrate) in Japan. The licensing arrangement calls for JT and Torii to pay us up to $100 million in up-front license fees and payments upon the achievement of pre-specified milestones, including up to $20 million in up-front payments and near-term milestones, of which Keryx received $12 million in October 2007. In addition, upon commercialization, JT and Torii will make royalty payments to Keryx on net sales of ferric citrate in Japan. JT and Torii will be responsible for the future development and commercialization costs in Japan.

Competition

Competition in the pharmaceutical and biotechnology industries is intense. 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. 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, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of preclinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier.

Supply and Manufacturing

We have limited experience in manufacturing products for clinical or commercial purposes. We have entered into a relationship with Scientific Protein Laboratories, LLC, or SPL, a U.S.-based contract manufacturer, to manufacture Sulonex which we believe will be adequate to satisfy our current clinical trial and early commercial market needs. Manufacture will be conducted in a manufacturing suite built within their current facility by Keryx, which they will operate on our behalf. We believe this suite will be suitable to manufacture launch and initial commercialization (1 to 3 years) quantities of Sulonex. This new manufacturing suite has been completed and facility validation is in progress, with expected completion in 2008. As with all heparin-like compounds, the end product is sensitive to the manufacturing process utilized and we will need to accurately reproduce the established process on the larger scale to ensure successful commercialization of Sulonex. There can be no assurance that we will be successful in this endeavor. We have incurred, and will continue to incur, capital expenditures to enable this larger scale production. To date, we have spent $11.2 million in capital expenditures to build the current manufacturing suite.

As we move forward, we plan to build additional manufacturing capacity to meet the future demands for Sulonex and create back-up manufacturing capabilities.

The creation of a reproducible process is also critical in successfully sourcing Sulonex from multiple suppliers to create back-up manufacturing capabilities and/or to meet market demand. We believe that multi-sourcing is possible provided we can demonstrate that the manufacturing process is the same at all suppliers and the product produced by them is equivalent.

Key raw materials for Sulonex, our lead product candidate, are derived from porcine mucosa. Long-term supplies for Sulonex could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products, over which we will have no control. We estimate, in part, based on the number of pigs killed worldwide and estimates of projected supplies of porcine mucosa, that there is enough potential supply of this raw material to commercialize Sulonex. If our estimates of the potential supply of this key raw material are not accurate or we cannot secure adequate amounts of the potential supply of such material, then the market potential of Sulonex will not be realized. Additionally, diseases affecting the world supply of pigs, or safety issues associated with heparin products, generally, or specifically associated with heparin manufactured by our suppliers, including SPL, could have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell Sulonex. Supply of heparin from China is important to all participants in the heparin business and, therefore, we are following closely the evaluations of applicable controls and regulations in China. We believe the long term results of this added scrutiny will be beneficial both to the heparin industry in general, and to patients in particular, resulting in an even higher level of quality assurance. Accordingly, we will continue to monitor this situation closely to determine its impact, if any, on Keryx and Sulonex. All of these factors could materially affect the commercial success of Sulonex.

We have established contract manufacturing relationships for the supply of Zerenex to ensure that we will have sufficient material for clinical trials. In addition, we are establishing the basis for commercial production capabilities. As with any supply program, obtaining raw materials of the correct quality cannot be guaranteed and we cannot ensure that we will be successful in this endeavor.

We have also established contract manufacturing relationships for the supply of KRX-0401 and KRX-0402.

At the time of commercial sale, to the extent possible and commercially practicable, we would seek to engage a back-up supplier for each of our product candidates. Until such time, we expect that we will rely on a single contract manufacturer to produce each of our product candidates under current Good Manufacturing Practice, or cGMP, regulations. Our third-party manufacturers have a limited number of facilities in which our product candidates can be produced and will have limited experience in manufacturing our product candidates in quantities sufficient for conducting clinical trials or for commercialization. Our third-party manufacturers will have other clients and may have other priorities that could affect their ability to perform the work satisfactorily and/or on a timely basis. Both of these occurrences would be beyond our control.

We expect to similarly rely on contract manufacturing relationships for any products that we may in-license or acquire in the future. However, there can be no assurance that we will be able to successfully contract with such manufacturers on terms acceptable to us, or at all.

Contract manufacturers are subject to ongoing periodic and unannounced inspections by the FDA, the Drug Enforcement Agency and corresponding state agencies to ensure strict compliance with cGMP and other state and federal regulations. Our contractors in Europe face similar challenges from the numerous European Union and member state regulatory agencies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations.

If we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these new manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA regulations and standards and may require significant lead times and delay. Furthermore, switching manufacturers may be difficult because the number of potential manufacturers is limited. It may be difficult or impossible for us to find a replacement manufacturer quickly or on terms acceptable to us, or at all.

Government and Industry Regulation

Numerous governmental authorities, principally the FDA and corresponding state and foreign regulatory agencies, impose substantial regulations upon the clinical development, manufacture and marketing of our drug candidates, as well as our ongoing research and development activities. None of our drug candidates have been approved for sale in any market in which we have marketing rights. Before marketing in the United States, any drug that we develop must undergo rigorous pre-clinical testing and clinical trials and an extensive regulatory approval process implemented by the FDA under the Federal Food, Drug, and Cosmetic Act of 1938, as amended . The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval. The approval process takes many years, requires the expenditure of substantial resources and may involve ongoing requirements for post-marketing studies or surveillance. Before commencing clinical trials in humans, we must submit an IND to the FDA containing, among other things, pre-clinical data, chemistry, manufacturing and control information, and an investigative plan. Our submission of an IND may not result in FDA authorization to commence a clinical trial.

The FDA may permit expedited development, evaluation, and marketing of new therapies intended to treat persons with serious or life-threatening conditions for which there is an unmet medical need under its

fast track drug development programs. A sponsor can apply for fast track designation at the time of submission of an IND, or at any time prior to receiving marketing approval of the NDA. To receive fast track designation, an applicant must demonstrate:

- that the drug is intended to treat a serious or life-threatening condition;
- that the drug is intended to treat a serious aspect of the condition; and
- that the drug has the potential to address unmet medical needs, and this potential is being evaluated in the planned drug development program.

The FDA must respond to a request for fast track designation within 60 calendar days of receipt of the request. Over the course of drug development, a product in a fast track development program must continue to meet the criteria for fast track designation. Sponsors of products in fast track drug development programs must be in regular contact with the reviewing division of the FDA to ensure that the evidence necessary to support marketing approval will be developed and presented in a format conducive to an efficient review. Sponsors of products in fast track drug development programs ordinarily are eligible for priority review and also may be permitted to submit portions of an NDA to the FDA for review before the complete application is submitted. In 2001, Sulonex received fast track designation.

Sponsors of drugs designated as fast track also may seek approval under the FDA's accelerated approval regulations under subpart H. Pursuant to subpart H, the FDA may grant marketing approval for a new drug product on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely, based on epidemiologic, therapeutic, pathophysiologic, or other evidence, to predict clinical benefit or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. Approval will be subject to the requirement that the applicant study the drug further to verify and describe its clinical benefit where there is uncertainty as to the relation of the surrogate endpoint to clinical benefit or uncertainty as to the relation of the observed clinical benefit to ultimate outcome. Post-marketing studies are usually underway at the time an applicant files the NDA. When required to be conducted, such post-marketing studies must also be adequate and well-controlled. The applicant must carry out any such post-marketing studies with due diligence.

In November of 2002, we announced that the FDA agreed in principal that the NDA for Sulonex may be filed under subpart H. Final approval will be based on a determination by the FDA of the safety and efficacy of Sulonex based on a surrogate endpoint.

In March 2005, we announced that we had finalized a SPA with the FDA for the Phase 3 and Phase 4 clinical trials of Sulonex. The clinical plan to support an NDA approval for Sulonex under subpart H, as agreed upon with the FDA under an SPA, consists of: (i) a single Phase 3 trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; (ii) supportive data from previously conducted clinical studies; and (iii) substantial recruitment into our Phase 4 confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria.

The subpart H process is complex and requires careful execution. No assurance can be given that we will be able to meet the requirements set forth in the SPA. Even if we meet those requirements, the FDA is not obligated to grant approval of our NDA for Sulonex. If the FDA approves Sulonex for marketing on the basis of our Phase 3 trial, our Phase 4 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.

Clinical testing must meet requirements for institutional review board oversight, informed consent and good clinical practices, and must be conducted pursuant to an IND, unless exempted.

For purposes of NDA approval, clinical trials are typically conducted in the following sequential phases:

- *Phase 1*: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.
- *Phase 2*: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.
- *Phase 3*: Studies establish safety and efficacy in an expanded patient population.
- *Phase 4*: The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

The length of time necessary to complete clinical trials varies significantly and may be difficult to predict. Clinical results are frequently susceptible to varying interpretations that may delay, limit or prevent regulatory approvals. Additional factors that can cause delay or termination of our clinical trials, or that may increase the costs of these trials, include:

- slow patient enrollment due to the nature of the clinical trial plan, the proximity of patients to clinical sites, the eligibility criteria for participation in the study or other factors;
- inadequately trained or insufficient personnel at the study site to assist in overseeing and monitoring clinical trials or delays in approvals from a study site's review board;
- longer treatment time required to demonstrate efficacy or determine the appropriate product dose;
- insufficient supply of the drug candidates;
- adverse medical events or side effects in treated patients; and
- ineffectiveness of the drug candidates.

In addition, the FDA may place a clinical trial on hold or terminate it if it concludes that subjects are being exposed to an unacceptable health risk. Any drug is likely to produce some toxicity or undesirable side effects in animals and in humans when administered at sufficiently high doses and/or for a sufficiently long period of time. Unacceptable toxicity or side effects may occur at any dose level at any time in the course of studies in animals designed to identify unacceptable effects of a drug candidate, known as toxicological studies, or clinical trials of drug candidates. The appearance of any unacceptable toxicity or side effect could cause us or regulatory authorities to interrupt, limit, delay or abort the development of any of our drug candidates and could ultimately prevent approval by the FDA or foreign regulatory authorities for any or all targeted indications.

Before receiving FDA approval to market a product, we must demonstrate that the product is safe and effective for its intended use by submitting to the FDA an NDA containing the pre-clinical and clinical data that have been accumulated, together with chemistry and manufacturing and controls specifications and information, and proposed labeling, among other things. The FDA may refuse to accept an NDA for filing if certain content criteria are not met and, even after accepting an NDA, the FDA may often require additional information, including clinical data, before approval of marketing a product.

As part of the approval process, the FDA must inspect and approve each manufacturing facility. Among the conditions of approval is the requirement that a manufacturer's quality control and manufacturing procedures conform to cGMP. Manufacturers must expend time, money and effort to ensure compliance with cGMP, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA will not allow us to market products that have been affected by the failure.

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain

changes to an approved NDA, including, with certain exceptions, any changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and advertising of our products will be limited to those specified in an FDA approval, and the advertising of our products will be subject to comprehensive regulation by the FDA. Drugs approved under Subpart H carry additional restrictions on marketing activities, including the requirement that all promotional materials to be used in support of the product are pre-submitted to FDA. Claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetic Act. Violations of the Federal Food, Drug, and Cosmetic Act or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

Should we wish to market our products outside the United States, we must receive marketing authorization from the appropriate foreign regulatory authorities. The requirements governing the conduct of clinical trials, marketing authorization, pricing and reimbursement vary widely from country to country. At present, companies are typically required to apply for foreign marketing authorizations at a national level. However, within the European Union, registration procedures are available to companies wishing to market a product in more than one European Union member state. Typically, if the regulatory authority is satisfied that a company has presented adequate evidence of safety, quality and efficacy, then the regulatory authority will grant a marketing authorization. This foreign regulatory approval process, however, involves risks similar or identical to the risks associated with FDA approval discussed above, and therefore we cannot guarantee that we will be able to obtain the appropriate marketing authorization for any product in any particular country.

Failure to comply with applicable federal, state and foreign laws and regulations would likely have a material adverse effect on our business. In addition, federal, state and foreign laws and regulations regarding the manufacture and sale of new drugs are subject to future changes. We cannot predict the likelihood, nature, effect or extent of adverse governmental regulation that might arise from future legislative or administrative action, either in the United States or abroad.

Research and Development

Company-sponsored research and development expenses (excluding non-cash compensation and acquired in-process research and development expenses) totaled $24,182,000 in 2005, $56,139,000 in 2006, and $74,889,000 in 2007. "Other research and development expenses" consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our product candidates and technologies, as well as expenses related to in-licensing of new product candidates. See "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations-Overview."

Employees

As of February 22, 2008, we had 50 full-and part-time employees. None of our employees are represented by a collective bargaining agreement, and we have never experienced a work stoppage. We consider our relations with our employees to be good.

Item 1A. Risk Factors

You should carefully consider the following risks and uncertainties. If any of the following occurs, our business, financial condition or operating results could be materially harmed. These factors could cause the trading price of our common stock to decline, and you could lose all or part of your investment.

Risks Related to Our Business

We have a limited operating history and have incurred substantial operating losses since our inception. We expect to continue to incur losses in the future and may never become profitable.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2007, we had an accumulated deficit of approximately $278.3 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.

We have not yet commercialized any of our drug candidates and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates.

Risks Associated with Our Product Development Efforts

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

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases as we are studying. In addition, one of our current trials for Sulonex is designed to continue until a pre-determined number of events have occurred to the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates and may also incur increased costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective or timely basis. In addition, conducting multi-national studies adds another level of complexity and risk as we are subject to events affecting countries outside the United States.

Additionally, we have finalized an SPA agreement with the FDA for the Phase 3 and Phase 4 clinical trials of Sulonex. The clinical plan to support a new drug application, or NDA, approval for Sulonex under subpart H, as agreed upon with the FDA under an SPA, consists of: (i) a single Phase 3 trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; (ii) supportive data from previously conducted clinical studies; and (iii) substantial recruitment into our Phase 4 confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. The subpart H process is complex and requires careful execution. No assurance can be given that we will be able to meet the requirements set forth in the SPA. Even if we meet those requirements, the FDA is not obligated to grant approval of our NDA for Sulonex. Many companies who have been granted an SPA and/or the right to utilize an accelerated approval approach have failed to obtain approval. Since we are seeking accelerated approval under an SPA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint is achieved, an SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, changes in scientific or medical evidence or sentiment or internal inconsistency in the data prior to making

their final decision. The FDA may also seek the guidance of an advisory panel prior to making their final decision. In addition, the FDA will have access to, and will review, the safety database for our Phase 4 clinical trial prior to granting approval. Any concerns arising from that review could delay or prevent the approval of Sulonex. If the FDA approves Sulonex for marketing on the basis of our Phase 3 trial, our Phase 4 clinical trial may yield insufficient efficacy data or give rise to safety concerns, which could result in withdrawal of such approval or could cause us to withdraw the product from the market. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

Additionally, we have never filed an NDA or similar application for approval in the United States or in any country, which may result in a delay in, or the rejection of, our filing of an NDA or similar application. During the drug development process, regulatory agencies will typically ask questions of drug sponsors. While we endeavor to answer all such questions in a timely fashion, or in the NDA filing, some questions may not be answered by the time we file our NDA. Unless the FDA waives the requirement to answer any such unanswered questions, our NDA may be delayed or rejected. For example, with respect to Sulonex, during the development process, the FDA has raised certain non-clinical questions. To answer some of these questions requires a bioassay for which the analytical tools do not currently exist. The FDA has requested that we diligently pursue such an assay. We believe that we have diligently pursued, and will continue to diligently pursue, such an assay. If the FDA determines that we have not been diligent, or otherwise determines that our NDA fails to answer required questions, then our NDA could be delayed or rejected. In addition, NDA approval can be delayed or denied due to unanswered questions relating to chemistry, manufacturing and controls. Our ability to resolve any such open questions might be complicated by the recent investigations into heparin manufacturing in China. All of those factors could affect the filing or ultimate approvability of Sulonex. Failure to obtain approval on a timely basis, or at all, would have a material adverse effect on us.

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

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

Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite positive results in initial clinical testing. There can be no assurance that the results from the Sulonex Phase 3 study will track the data from the pilot Collaborative Study Group Phase 2 study or the DiNAS Phase 2 study, or that the results from the Sulonex Phase 4 study will yield sufficient efficacy data. Results from these earlier Sulonex studies may not be indicative of results from future clinical trials and the risk remains that the pivotal program for Sulonex may generate efficacy data that will be insufficient for the approval of the drug, or may raise safety concerns that may prevent approval of the drug. Interpretation of the prior safety and efficacy data of Sulonex, or our other drug candidates, may be flawed and there can be no assurance that safety and/or efficacy concerns from the prior data were overlooked or misinterpreted, which in subsequent, larger studies appear and prevents approval of Sulonex or our other drugs candidates.

Clinical trials have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving what appeared to be promising results in earlier trials. If we experience delays in the testing or approval process or if we need to perform more or larger clinical trials than originally planned, our financial

results and the commercial prospects for our drug candidates may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the United States and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process. While we have engaged a clinical research organization with experience in conducting regulatory trials, errors in the conduct, monitoring and/or auditing could invalidate the results from a regulatory perspective.

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

We do not own any of our drug candidates. We have licensed the rights, patent or otherwise, to our drugs candidates from third parties. These license agreements require us to meet development milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates. From time to time, in the ordinary course of business, we may have disagreements with our licensors or collaborators regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our drug candidates or could require or result in litigation or arbitration, which would be time-consuming and expensive.

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

We have limited experience in manufacturing products for clinical or commercial purposes. We intend to continue, in whole or in part, to use third parties to manufacture and test our products for use in clinical trials and for future sales. We may not be able to enter into future contract agreements with these third-parties on terms acceptable to us, if at all.

Contract manufacturers often encounter difficulties in scaling up production, including problems involving 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 and unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with current Good Manufacturing Practices as well as other governmental regulations and corresponding foreign standards. The same issues apply to contract analytical services which we use for testing of our products. We will not have control over, other than by contract and periodic oversight, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple third-party contractors to produce our products may be difficult because the number of potential manufacturers is limited, particularly in the case of Sulonex, and the process by which multiple manufacturers make the drug substance must be identical at each manufacturing facility. It may be difficult for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. Moreover, if we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

If 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 SPL, a U.S.-based contract manufacturer, to manufacture Sulonex which we believe will be adequate to satisfy our current clinical trial and early commercial market needs. Manufacture will be conducted in a manufacturing suite built within their current facility by Keryx, which they will operate on our behalf. We believe this suite will be suitable to manufacture launch and initial commercialization (1 to 3 years) quantities of Sulonex. This new manufacturing suite has been completed and facility validation is in progress, with expected completion in 2008. As we move forward, we plan to build

additional manufacturing capacity to meet the future demands for Sulonex and create back-up manufacturing capabilities. As with all heparin-like compounds, the end product is sensitive to the manufacturing process utilized. Accordingly, as we scale-up we will need to accurately reproduce the established process on the larger scale to ensure successful commercialization of Sulonex. There can be no assurance that we will be successful in this endeavor. In addition, because we do not have a bioassay for Sulonex, we may have difficulty qualifying materials from multiple sources, including materials produced from our larger scale facility and/or from additional facilities, which could delay or impair our commercialization efforts. We have incurred, and will continue to incur, capital expenditures to develop commercial production capacity. Through December 31, 2007, we have spent approximately $11.2 million in capital expenditures building the current manufacturing suite. If we fail to obtain regulatory approval for Sulonex, we may incur significant losses disposing of the assets associated with our manufacturing suite.

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

Key raw materials for Sulonex, our lead product candidate, are derived from porcine mucosa. Long-term supplies for Sulonex could be affected by factors over which we have no control, for example, limitations in the supply of porcine mucosa and the demand for other heparin products. We estimate, in part, based on the number of pigs killed worldwide and estimates of projected supplies of porcine mucosa, that there is enough potential supply of this raw material to commercialize Sulonex. If our estimates of the potential supply of this key raw material are not accurate or we cannot secure adequate amounts of the potential supply of such material, then the market potential of Sulonex will not be realized. Diseases affecting the world supply of pigs, or safety issues associated with heparin products, generally, or specifically associated with heparin manufactured by our suppliers, including SPL, could also have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell Sulonex. Supply of heparin from China is important to all participants in the heparin business and, therefore, we are following closely the investigations into applicable controls and regulations in China to determine its impact, if any, on Keryx and Sulonex, or on our supplier, SPL, which, in turn, could have an adverse effect on us. If these investigations result in a reduction in the amount of porcine mucosa available from China, or any significant delay in obtaining those supplies, it could adversely affect the commercial success of Sulonex.

If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties, we may be unable to commercialize our products.

We do not possess all of the capabilities to fully commercialize our products on our own. From time to time, we may need to contract with third parties to:

- manufacture our product candidates;
- assist us in developing, testing and obtaining regulatory approval for and commercializing some of our compounds and technologies; and
- market and distribute our drug products.

We can provide no assurance that we will be able to successfully enter into agreements with such third parties on terms that are acceptable to us, if at all. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our products independently, which could result in delays. Furthermore, such failure could result in the termination of license rights to one or more of our products. If these manufacturing, development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we are unable to control whether such products will be scientifically or commercially successful. Additionally, if these third parties fail to perform their obligations under our agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor

and ensure the quality of such work, we may face delays in achieving the regulatory milestones required for commercialization of one or more drug candidates.

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

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

Other Risks Related to Our Business

If we are unable to develop adequate sales, marketing or distribution capabilities or enter into agreements with third parties to perform some of these functions, we will not be able to commercialize our products effectively.

In the event Sulonex is approved by the FDA, we currently plan to conduct our own sales and marketing effort to support the drug, and we may adopt this strategy with respect to future drug products. We currently have limited experience in sales, marketing or distribution. To directly market and distribute any products, we must build a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build such a sales and marketing organization on our own or with the assistance of a contract sales organization. For some market opportunities, we may need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our products. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

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

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

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

- perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidates;
- the rates of adoption of our products by medical practitioners and the target populations for our products;
- the potential advantages that our products offer over existing treatment methods;
- the cost-effectiveness of our products relative to competing products;
- the availability of government or third-party payor reimbursement for our products;
- the side effects or unfavorable publicity concerning our products or similar products; and
- the effectiveness of our sales, marketing and distribution efforts.

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

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

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our drug products obsolete or non-competitive. 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 February 22, 2008, we had 50 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. Although we have an employment agreement with Mr. Weiss, this agreement does not prevent him from terminating his employment with us.

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

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

Acquisitions involve a number of operational risks, including:

- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;
- our inability to retain the management, key personnel and other employees of the acquired business;
- our inability to maintain the acquired company's relationship with key third parties, such as alliance partners;
- exposure to legal claims for activities of the acquired business prior to the acquisition;
- the diversion of our management's attention from our core business; and
- the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

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

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

- government and health administration authorities;
- private health insurers;
- managed care programs; and
- other third-party payors.

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

Health care reform measures could adversely affect our business.

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

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

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

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

- decreased demand for a product;
- injury to our reputation;
- our inability to continue to develop a drug candidate;
- withdrawal of clinical trial volunteers; and
- loss of revenues.

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

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

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

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

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company with 50 full and part-time employees. We also have significantly fewer employees than many other companies that have a product candidate in late-stage clinical development, and we rely heavily on third parties to conduct many important functions. While we believe that our corporate compliance program is sufficient to ensure compliance with applicable regulations, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Related to Our Financial Condition

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

We believe that our $64.7 million in cash, cash equivalents, interest receivable and investment securities as of December 31, 2007 will be sufficient to enable us to meet our planned operating needs and capital expenditures through the date of the release of our Phase 3 Sulonex data, expected in the first quarter of 2008. Depending on the outcome of our Phase 3 study, our cash requirements will vary dramatically. In the event of a negative outcome, we believe our current capital resources will enable us to meet our revised operating needs and capital expenditures for at least 12 months from January 2008. Our forecast of the period of time through which our cash, cash equivalents, interest receivable, and investment securities will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the timing of completion and results from clinical trials for our drug candidates, especially Sulonex;
- the timing of expenses associated with manufacturing and product development of the proprietary drug candidates within our portfolio and those that may be in-licensed, partnered or acquired;
- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- our ability to achieve our milestones under our licensing arrangements; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

As of February 22, 2008, $12.0 million of our investment securities are invested in auction note securities. Our auction note securities are public securities with long-term nominal maturities for which the interest

rates are reset through a dutch auction each month. The monthly auctions historically have provided a liquid market for these securities. Our investments in auction note securities represent interests in student loan-backed securities. Consistent with our investment policy guidelines, our auction note securities all had "triple A" credit ratings at the time of purchase. Global credit and capital markets are increasingly experiencing liquidity issues. None of our auction note securities held at December 31, 2007, failed an auction in 2007 or 2008; however, a $3 million investment we made in January 2008 failed two auctions held in February 2008, as the amount of securities submitted for sale has exceeded the amount of purchase orders. We will continue to attempt to sell this $3 million investment security every seven days until an auction is successful. Our other $9 million of investments in auction note securities have their next scheduled auction dates in March 2008. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any ratings downgrades on the auction note securities in our portfolio, we may incur impairments to our investment portfolio, which could negatively affect our financial condition, cash flow and reported earnings, and the lack of liquidity of our auction note securities could have a material impact on our financial flexibility and ability to fund our operations.

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

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash, cash equivalents, interest receivable, and investment securities will be sufficient to fund our operating expenses and capital requirements through the date of the release of our Phase 3 Sulonex data, expected in the first quarter of 2008. Depending on the outcome of our Phase 3 study, our cash requirements will vary dramatically. In the event of a negative outcome, we believe our current capital resources will enable us to meet our revised operating needs and capital expenditures for at least 12 months from January 2008. However, the actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate, depending upon:

- the timing of completion and results from clinical trials for our drug candidates, especially Sulonex;
- the progress of our development activities;
- the progress of our research activities;
- the number and scope of our development programs;
- the costs associated with commercialization activities, including manufacturing, marketing and sales;
- our ability to establish and maintain current and new licensing or acquisition arrangements;
- our ability to achieve our milestones under our licensing arrangements;
- the costs involved in enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

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

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

In July 2003, Keryx (Israel) Ltd., one of our Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of our Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, our Chairman and Chief Executive Officer, and Robert Trachtenberg, a

former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,208,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. to vacate service of process outside of Israel was held in September 2006. On October 15, 2006, the Circuit Court of Jerusalem held that the service of process on Keryx was sustained. We appealed this holding. The appeal was denied on September 18, 2007, and we filed a petition for certiorari to the Supreme Court of Israel. Our motion for certiorari was denied as well. The next preliminary hearing is scheduled for February 28, 2008. We have not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

Risks Related to Our Intellectual Property

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

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

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

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

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

Risks Related to Our Common Stock

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

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

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders may be significantly diluted. We may be required to issue up to 3,372,422 shares of our common stock to former stockholders of ACCESS Oncology upon the achievement of certain milestones, of which 500,000 shares may be payable in 2008 upon the reaching of the first milestone. In addition, we may enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

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

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

- developments concerning our drug candidates;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in quarterly operating results;
- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies; and
- additions or departures of key personnel.

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

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

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the

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

Item 1B. Unresolved Staff Comments

None.

Item 2. Properties.

Our corporate and executive office is located in New York, New York. Our New York facility consists of approximately 11,700 square feet of leased space at 750 Lexington Avenue, New York, New York 10022. We are also currently leasing approximately 6,000 square feet of space in the San Francisco, California area, to accommodate our oncology and clinical operations groups.

Item 3. Legal Proceedings.

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

In July 2003, Keryx (Israel) Ltd., one of our Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of our Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, our Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,208,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd: filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. and Michael S. Weiss to vacate service of process outside of Israel was held in June 2006. On October 15, 2006, the Court held that the service of the claim against Mr. Weiss is vacated. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. However, the service against us was sustained. We appealed this holding. The appeal was denied on June 18, 2007, and we filed a petition for certiorari to the Supreme Court of Israel. Our motion for certiorari was denied as well. The next preliminary hearing is scheduled for February 28, 2008. We have not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

We are engaged in an arbitration proceeding with Alfa Wasserman concerning certain terms of the License Agreement related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. An arbitration proceeding was held in October 2007 and we are awaiting decision from the arbitrator. The outcome of the arbitration should not affect the validity of the license, but whether we are required to share data with Alfa Wasserman for that company's use outside of our licensed territories and our ongoing management of the licensed patent portfolio. Alfa Wasserman also seeks unspecified damages. If the arbitrator determines that we owe Alfa Wasserman the data, and that failure to deliver such data constitutes a material breach of the License Agreement, then we will have 28 days to cure such breach following the final arbitration decision by delivering any data required to be provided. Failure to cure would entitle Alfa Wasserman to terminate the License Agreement.

In November 2007, we initiated an action in the US District Court for the Southern District of New York against Panion to enjoin Panion from improperly terminating the November 2005 License Agreement for an alleged breach of contract by Keryx related to certain manufacturing provisions of the agreement, to enjoin Panion from interfering with Keryx's contractual relationships with certain third-parties, as well as to enforce Keryx's right with respect to the prosecution of certain patents. On November 27, 2007, the Court granted Keryx's motion for a preliminary injunction. Panion has since asserted counterclaims for breach of contract relating to certain manufacturing provisions of the license agreement and the parties have reached a tentative agreement to settle the litigation. If the parties are unable to resolve the matter by a settlement, we will proceed with the action to resolve the parties' respective claims, in which event Keryx will incur significant legal expenses. The matter is currently scheduled for trial in the second half of 2008. In the event that Keryx is found to be in breach of contract, it will have thirty days in which to cure such breach before Panion can terminate the agreement based on the alleged breach.

Item 4. Submission of Matters to a Vote of Security Holders.

We did not submit any matters to a vote of our security holders, through the solicitation of proxies or otherwise, during the fourth quarter of 2007.

PART II

Item 5. Market for Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities.

Market Information

Our common stock is listed on the Nasdaq Global Market and trades under the symbol "KERX." Trading of our common stock commenced on July 28, 2000, following the completion of our initial public offering.

The following table sets forth the high and low closing sale prices of our common stock for the periods indicated.

Fiscal Year Ended December 31, 2007	High	Low
Fourth Quarter	$11.14	$ 8.40
Third Quarter	$11.05	$ 8.27
Second Quarter	$11.64	$ 9.77
First Quarter	$13.27	$10.19
Fiscal Year Ended December 31, 2006	**High**	**Low**
Fourth Quarter	$14.77	$11.96
Third Quarter	$14.84	$ 9.60
Second Quarter	$18.19	$12.54
First Quarter	$19.16	$14.95

Holders

The number of record holders of our common stock as of February 21, 2008 was 41.

Dividends

We have never declared or paid any cash dividends on our common stock and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to pay dividends will be at the discretion of our board of directors.

Securities Authorized for Issuance Under Equity Compensation Plans

The following table provides information as of December 31, 2007, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1999 Stock Option Plan, as amended, the 2000 Stock Option Plan, as amended, the 2002 CEO Incentive Stock Option Plan, the 2004 President Incentive Plan, the 2004 Long-Term Incentive Plan, 2007 CAO Inducement Plan, 2007 General Counsel Incentive Stock Option Plan and the 2007 Incentive Plan.

Equity Compensation Plan Information

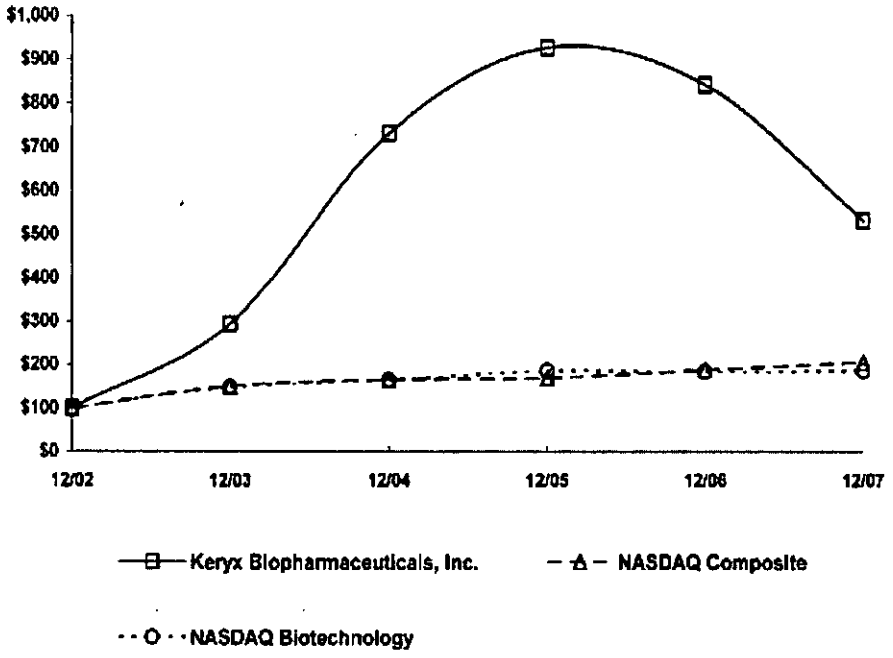
Plan Category	Number of Securities to be Issued upon Exercise of Outstanding Options	Weighted-Average Exercise Price of Outstanding Options	Number of Securities Remaining Available for Future issuance Under Equity Compensation Plans (Excluding Securities Reflected In Column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	7,616,516	$9.05	5,507,620
Equity compensation plans not approved by security holders	3,252,657	$4.49	—
Total	10,869,173	$7.69	5,507,620

For information about all of our equity compensation plans, see Note 9 to our Consolidated Financial Statements included in this report.

COMMON STOCK PERFORMANCE GRAPH

The following graph compares the cumulative total stockholder return on our common stock for the period from December 31, 2002 through December 31, 2007, with the cumulative total return over such period on (i) the United States Index of the Nasdaq Stock Market and (ii) the Biotechnology Index of the Nasdaq Stock Market. The graph assumes an investment of $100 on December 31, 2002, in our common stock (at the closing market price) and in each of the indices listed above, and assumes the reinvestment of all dividends. Measurement points are December 31 of each year.

COMPARISON OF 5 YEAR CUMULATIVE TOTAL RETURN*
Among Keryx Biopharmaceuticals, Inc., the NASDAQ Composite Index and the NASDAQ Biotechnology Index



* $100 invested on 12/31/02 in stock or index-including reinvestment of dividends. Fiscal year ending December 31.

Item 6. Selected Financial Data.

The following Statement of Operations Data for the years ended December 31, 2007, 2006, 2005, 2004 and 2003, and Balance Sheet Data as of December 31, 2007, 2006, 2005, 2004 and 2003, as set forth below are derived from our audited consolidated financial statements. This financial data should be read in conjunction with "Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations" and "Item 8. Financial Statements and Supplementary Data."

	Years Ended December 31,				
	2007	2006	2005	2004	2003
	(In Thousands, Except Per Share Data)				
Statement of Operations Data:					
License revenue	$ 204	$ —	$ —	$ —	$ —
Diagnostic revenue	66	103	—	—	—
Service revenue	52	431	574	809	—
Other revenue	727	—	—	—	—
Total revenue	1,049	534	574	809	—
Operating expenses:					
Cost of diagnostics sold	38	140	—	—	—
Cost of services	124	390	819	835	—
Research and development:					
Non-cash compensation	3,574	6,504	594	413	(486)
Non-cash acquired in-process research and development	—	—	—	18,800	—
Other research and development	74,889	56,139	24,182	9,805	5,996
Total research and development	78,463	62,643	24,776	29,018	5,510
Selling, general and administrative:					
Non-cash compensation	7,086	8,408	775	1,087	188
Other selling, general and administrative	9,919	9,110	3,416	3,581	3,684
Total selling, general and administrative	17,005	17,518	4,191	4,668	3,872
Total operating expenses	95,630	80,691	29,786	34,521	9,382
Operating loss	(94,581)	(80,157)	(29,212)	(33,712)	(9,382)
Other income (expense):					
Interest and other income, net	4,555	6,393	2,317	770	247
Income taxes	(36)	—	—	(1)	27
Net loss	$(90,062)	$(73,764)	$(26,895)	$(32,943)	$(9,108)
Net loss per common share					
Basic and diluted	$ (2.07)	$ (1.76)	$ (0.78)	$ (1.10)	$ (0.43)

	As of December 31,				
	2007	2006	2005	2004	2003
			(In Thousands)		
Balance Sheet Data:					
Cash, cash equivalents, interest receivable and investment securities	$64,682	$125,610	$100,733	$49,878	$31,414
Working capital	42,305	102,774	83,890	46,538	30,982
Total assets	81,061	140,313	105,097	50,862	32,223
Deferred revenue, net of current portion	11,022	—	—	—	—
Other liabilities	202	294	322	92	—
Contingent equity rights	4,004	4,004	4,004	4,004	—
Total stockholders' equity	44,422	123,821	94,678	42,804	31,226

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

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 "Item 1A. 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 "Item 6. Selected Financial Data," "Item 8. Financial Statements and Supplementary Data," and our consolidated financial statements beginning on page F-1 of this report.

Overview

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Our lead compound under development is Sulonex™ (sulodexide), which we previously referred to as KRX-101, a first-in-class, oral heparinoid compound for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes. Sulonex is in a pivotal Phase 3 and Phase 4 clinical program under a SPA with the FDA. Additionally, we are developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 2 clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. We are also developing clinical-stage oncology compounds, including KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth. KRX-0401 also modulates a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase 2 clinical development for multiple tumor types and we expect to move into a Phase 3 clinical program in 2008. 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 product sales from our drug candidates.

We are a development stage company and have no drug product sales to date. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, public offerings of our common stock, and, beginning in 2007, from the upfront payment from our licensing agreement with Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii") and miscellaneous payments from our other prior licensing activities. We have devoted substantially all of our efforts to the identification, in-licensing and development of drug candidates. We have incurred negative cash flow from operations each year since our inception. We anticipate incurring negative cash flows from operating activities for the foreseeable future. We have spent, and expect to continue to spend, substantial amounts in connection with implementing our business strategy, including our product development efforts, our clinical trials and in-licensing and acquisition activities.

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

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

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

Our other revenue currently consists of revenue from our license termination agreement with Yissum Research and Development Company of the Hebrew University of Jerusalem ("Yissum"). Payments from Yissum are recognized as earned since we have no responsibilities under the terminated license agreement or the termination agreement.

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

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

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

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred. Other research and development expenses, which excludes non-cash compensation and acquired in-process research and development expenses, for the years ended December 31, 2007, 2006 and 2005 were $74,889,000, $56,139,000, and $24,182,000, respectively.

The following table sets forth the other research and development expenses per project, for the periods presented.

	Years ended December 31,			
	2007	2006	2005	Amounts Accumulated During the Development Stage
Sulonex	$49,372,000	$41,533,000	$16,075,000	$121,184,000
KRX-0401	15,210,000	8,508,000	5,394,000	31,342,000
Zerenex	4,825,000	1,531,000	450,000	—
Other clinical stage compounds	3,990,000	2,410,000	1,143,000	14,972,000
Other	1,492,000	2,157,000	1,120,000	27,424,000
Total	$74,889,000	$56,139,000	$24,182,000	$194,922,000

Amounts accumulated during the development stage in the above table excludes acquired in-process research and development expenses.

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

Our results of operations include non-cash compensation expense as a result of the grants of stock options, restricted stock and warrants. Compensation expense for awards of options and restricted stock granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statements of operations. We expect to continue to incur significant non-cash compensation as a result of Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment" ("SFAS No. 123R"), which we adopted on January 1, 2006. For awards of options and warrants to consultants and other third-parties, compensation expense is determined at the "measurement date," in accordance with the fair value method prescribed by the provisions of Emerging Issues Task Force ("EITF") Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services" ("EITF 96-18"). The expense is recognized over the vesting period of

the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. These awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. In addition, because some of the options, restricted stock and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

For periods presented prior to our adoption of SFAS No. 123R, compensation expense for fixed award options and warrants granted to employees and directors represents the intrinsic value (the difference between the stock price of the common stock and the exercise price of the options or warrants) of the options and warrants at the date of grant. For variable awards, we considered the difference between the stock price at reporting date and the exercise price, in the case where a measurement date has not been reached. The compensation cost was recorded over the respective vesting periods of the individual stock options and warrants. The expense was included in the respective categories of expense in the statement of operations.

Our ongoing clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we will need to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA, which would result in us incurring additional expenses. As a result, our quarterly results may fluctuate and a quarter-by-quarter comparison of our operating results may not be a meaningful indication of our future performance.

Results of Operations

Years Ended December 31, 2007 and 2006

License Revenue. License revenue was $204,000 for the year ended December 31, 2007, as compared to no revenue for the year ended December 31, 2006. License revenue for the year ended December 31, 2007 was related to the amortization of a portion of an upfront payment of $12.0 million associated with our license agreement with JT and Torii. The upfront payment from JT and Torii will be recognized as license revenue on a straight-line basis over the life of the license agreement, which is through the expiration of the last-to-expire patent covered by the agreement in 2023, and represents the estimated period over which we will have significant responsibilities under the license agreement.

Diagnostic Revenue. Diagnostic revenue decreased by $37,000 to $66,000 for the year ended December 31, 2007, as compared to diagnostic revenue of $103,000 for the year ended December 31, 2006. The decrease in diagnostic revenue was primarily due to the timing and number of diagnostic kits sold offset by the inclusion of a full year of Accumin's results in the year ended December 31, 2007. The prior period included results from April 6, 2006, the acquisition date. We do not expect our diagnostic revenue to have a material impact on our financial results during the next fiscal year.

Service Revenue. Service revenue decreased by $379,000 to $52,000 for the year ended December 31, 2007, as compared to service revenue of $431,000 for the year ended December 31, 2006. The decrease in service revenue was primarily due to the timing and extent of services performed in accordance with our service contracts. We do not expect our service revenue to have a material impact on our financial results during the next fiscal year.

Other Revenue. Other revenue was $727,000 for the year ended December 31, 2007, as compared to no revenue for the year ended December 31, 2006. Other revenue for the year ended December 31, 2007 was related to a payment from Yissum under an October 2004 termination agreement whereby we received a portion of cash consideration earned by Yissum from the terminated license rights. Payments from Yissum are recognized as earned since we have no responsibilities under the terminated license agreement or the termination agreement.

Cost of Diagnostics Sold. Cost of diagnostics sold decreased by $102,000 to $38,000 for the year ended December 31, 2007, as compared to an expense of $140,000 for the year ended December 31, 2006. The decrease in cost of diagnostics sold was primarily due to the timing and number of diagnostic kits sold and a reduction of overhead associated with our diagnostics segment. We do not expect our cost of diagnostics sold expense to have a material impact on our financial results during the next fiscal year.

Cost of Services. Cost of services decreased by $266,000 to $124,000 for the year ended December 31, 2007, as compared to an expense of $390,000 for the year ended December 31, 2006. The decrease in cost of services was primarily due to the timing and extent of services performed in accordance with our service contracts. We do not expect our cost of service expense to have a material impact on our financial results during the next fiscal year.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option and restricted stock grants decreased by $2,930,000 to $3,574,000 for the year ended December 31, 2007, as compared to an expense of $6,504,000 for the year ended December 31, 2006. This difference was primarily attributable to, during the year ended December 31, 2006, approximately $1,128,000 of expense for the accelerated vesting of options due to the achievement of a financial milestone, and additionally, in the year ended December 31, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense (selling, general and administrative). This change accounted for approximately $2,458,000 of the difference. During the year ended December 31, 2007, we incurred expenses of approximately $869,000 related to the grant of 150,000 shares of restricted stock to our President upon the signing of a new employment agreement with us, which offsets the decrease discussed above.

Other Research and Development Expenses. Other research and development expenses increased by $18,750,000 to $74,889,000 for the year ended December 31, 2007, as compared to $56,139,000 for the year ended December 31, 2006. The increase in other research and development expenses was due primarily to a $7,839,000 increase in expenses related to our Sulonex pivotal Phase 3 and Phase 4 clinical programs. The comparative period last year included one-half, or $1,000,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone. In addition, the increase was due to a $6,702,000 increase in expenses related to KRX-0401 (including a $1,250,000 milestone), a $3,294,000 increase in expenses related to Zerenex (including a $2,500,000 license-related accrual for a contingent liability) and a $1,580,000 increase in expenses related to our other clinical compounds (including $997,000 of expenses relating to the in-licensing and purchase of related inventory for KRX-0701).

Depending on the outcome of our Phase 3 study for Sulonex, our other research and development costs will vary dramatically over the next year. In the event of a negative outcome, we would expect our other research and development costs to decrease. With a positive outcome, we would expect our other research and development costs to increase as a result of the continuation of the Phase 4 clinical program for Sulonex, as well as the acceleration of the clinical program for KRX-0401, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to stock option and restricted stock grants decreased by $1,322,000 to $7,086,000 for the year ended December 31, 2007, as compared to an expense of $8,408,000 for the year ended December 31, 2006. This difference was primarily attributable to, during the year ended December 31, 2006, approximately $1,636,000 of expense for the accelerated vesting of options due to the achievement of a financial milestone, and approximately $1,697,000 of expense for modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second quarter of 2006. In the year ended December 31, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense (selling, general and administrative), accounting for approximately $2,458,000 of increased expense, which offsets the decrease discussed above. In addition, during the year ended December 31, 2007, we recorded a reduction of

expense of approximately $780,000 associated with stock options and restricted stock issued to our former chief financial officer in 2006, who resigned in the second quarter of 2007.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $809,000 to $9,919,000 for the year ended December 31, 2007, as compared to an expense of $9,110,000 for the year ended December 31, 2006. Other selling, general and administrative expenses for the year ended December 31, 2007 included an impairment charge of approximately $600,000 related to certain intangibles associated with Accumin's diagnostic product. Additionally, there was an increase in legal fees of approximately $1,243,000 associated primarily with the Alfa Wasserman arbitration (see Legal Proceedings) and general maintenance of our products. The comparative period last year included one-half, or $1,000,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone. In addition, during the year ended December 31, 2007, we incurred additional expenses associated with the scale-up of our operations and infrastructure to prepare for commercialization of our drug candidates.

Depending on the outcome of our Phase 3 study for Sulonex, our other selling, general and administrative costs will vary dramatically over the next year. In the event of a negative outcome, we would expect our other selling, general and administrative costs to decrease. With a positive outcome, we would expect our other selling, general and administrative costs to increase as we scale-up our operations and infrastructure to prepare to commercialize Sulonex.

Interest and Other Income, Net. Interest and other income, net, decreased by $1,838,000 to $4,555,000 for the year ended December 31, 2007, as compared to income of $6,393,000 for the year ended December 31, 2006. The decrease resulted from a lower level of invested funds as compared to the comparable period last year.

Income Taxes. We recorded $36,000 in income tax expense for the year ended December 31, 2007, as a result of income tax withheld associated with the Yissum revenue as described above.

Years Ended December 31, 2006 and 2005

Diagnostic Revenue. Diagnostic revenue for the year ended December 31, 2006 was $103,000 as compared to no diagnostic revenue for the year ended December 31, 2005. Diagnostic revenue for the year ended December 31, 2006 was a result of our acquisition of Accumin during the second quarter of 2006.

Service Revenue. Service revenue decreased by $143,000 to $431,000 for the year ended December 31, 2006, as compared to service revenue of $574,000 for the year ended December 31, 2005. The decrease in service revenue was primarily due to the timing of services performed in accordance with our service contracts.

Cost of Diagnostics Sold Expense. Cost of diagnostics sold expense for the year ended December 31, 2006 was $140,000 as compared to no cost of diagnostics sold expense for the year ended December 31, 2005. Cost of diagnostics sold expense for the year ended December 31, 2006 was a result of our acquisition of Accumin during the second quarter of 2006.

Cost of Services Expense. Cost of services expense decreased by $429,000 to $390,000 for the year ended December 31, 2006, as compared to an expense of $819,000 for the year ended December 31, 2005. The decrease in cost of services was primarily due to a reduction in the amount of time necessary to service client contracts, as well as the timing of services performed in accordance with our service contracts.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants was $6,504,000 for the year ended December 31, 2006, as compared to an expense of $594,000 for the year ended December 31, 2005. The increase in non-cash compensation expense was due primarily to a $5,963,000 increase in expense related to the adoption of SFAS No. 123R on January 1, 2006. For the years ended December 31, 2006, and 2005, expenses of $502,000 and $464,000, respectively, were due to the adjustment to fair market value under EITF 96-18 "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," or EITF 96-18, of previously-issued options to consultants.

Other Research and Development Expenses. Other research and development expenses increased by $31,957,000 to $56,139,000 for the year ended December 31, 2006, as compared to an expense of $24,182,000 for the year ended December 31, 2005. The increase in other research and development expenses was due primarily to a $25,458,000 increase in expenses related to our Sulonex pivotal Phase 3 and Phase 4 clinical program, which includes one-half, or $1,000,000, of a one-time bonus to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone, and a $5,462,000 increase in expenses related to our other clinical compounds, including a $500,000 milestone expense relating to Zerenex and a $600,000 expense relating to the in-licensing of KRX-0601.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to stock option and restricted stock grants was $8,408,000 for the year ended December 31, 2006, as compared to an expense of $775,000 for the year ended December 31, 2005. The increase in non-compensation expense was due primarily to a $5,704,000 increase in expense related to the adoption of SFAS No. 123R on January 1, 2006. In addition, modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second and third quarters resulted in additional expense of $1,803,000 for the year ended December 31, 2006. For the years ended December 31, 2006, and 2005, expenses of $475,000 and $306,000, respectively, were due to the adjustment to fair market value under EITF 96-18 of previously-issued options to consultants. Expenses during the year ended December 31, 2006 of $189,000 were due to the issuance of restricted stock.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $5,694,000 to $9,110,000 for the year ended December 31, 2006, as compared to an expense of $3,416,000 for the year ended December 31, 2005. The increase in selling, general and administrative expenses was due primarily to an increase of $1,746,000 in legal expenses associated with business development, option review, and patents costs, as well as, one-half, or $1,000,000, of a one-time bonus to our Chief Executive Officer for the achievement of a corporate milestone pursuant to his employment agreement. The compensation of our Chief Executive Officer was allocated equally between other research and development expenses and other selling, general and administrative expenses to reflect the allocation of his responsibilities and activities for Keryx. The increase was also due to $470,000 of expenses incurred in the first quarter of 2006 related to the acquisition of Accumin, $410,000 of sales and marketing expenses associated with Accumin and $400,000 of financial analyses expenses.

Interest and Other Income, Net. Interest and other income, net, increased by $4,076,000 to $6,393,000 for the year ended December 31, 2006, as compared to income of $2,317,000 for the year ended December 31, 2005. The increase resulted from a higher level of invested funds due to the completion of the registered direct offering that closed in March 2006, as well as due to the general increase in short-term market interest rates when compared to the comparable period last year.

Income Taxes. We did not record any income tax expense for the years ended December 31, 2006, and 2005.

Liquidity and Capital Resources

We have financed our operations from inception primarily through public offerings of our common stock, various private placement transactions, option and warrant exercises, and, beginning in 2007, from the upfront payment from our licensing agreement with JT and Torii and miscellaneous payments from our other prior licensing activities.

As of December 31, 2007, we had $64.7 million in cash, cash equivalents, interest receivable and investment securities, a decrease of $60.9 million from December 31, 2006. Cash used in operating activities for the year ended December 31, 2007 was $57.6 million, as compared to $52.2 million for the year ended December 31, 2006. This increase was due primarily to increased expenditures associated with the execution of our business plan, including costs associated with our pivotal Phase 3 and Phase 4 clinical program for Sulonex and the expansion of our other clinical programs, partially offset by an increase of approximately $11.8 million in deferred revenue associated with unamortized portion of an upfront payment of $12.0 million associated with our license agreement with JT and Torii. For the year ended December 31, 2007, net cash provided by investing activities of $27.9 million was primarily the result of the maturity and sale of marketable securities in our investment portfolio, net of purchases, of approximately $31.0 million, partially offset by

purchases of property, plant and equipment, net of disposals, of approximately $3.1 million. For the year ended December 31, 2007, net cash provided by financing activities of $3,000 was primarily the result of $271,000 of proceeds from the exercise of options, offset by the surrendering to Keryx of 23,848 shares of common stock, at a cost of approximately $268,000, by our President and former Chief Financial Officer, in order to satisfy tax withholding obligations upon the vesting of their restricted stock.

We have entered into a relationship with SPL, a U.S.-based contract manufacturer, for Sulonex to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture and produce initial commercialization quantities of Sulonex (for approximately one to three years from launch). As of December 31, 2007, we have spent approximately $11.2 million in capital expenditures building our manufacturing suite for Sulonex. We anticipate that in the first half of 2008, after equipment validation has been completed, the facility will be ready for its intended use.

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

We believe that our $64.7 million in cash, cash equivalents, interest receivable and investment securities as of December 31, 2007 will be sufficient to enable us to meet our planned operating needs and capital expenditures through the date of the release of our Phase 3 Sulonex data, which is expected in the first quarter of 2008. Depending on the outcome of our Phase 3 study, our cash requirements will vary dramatically. In the event of a negative outcome, we believe our current capital resources will enable us to meet our revised operating needs and capital expenditures for at least 12 months from January 2008.

As of December 31, 2007, $42.2 million of our $64.7 million in cash, cash equivalents, interest receivable and investment securities are invested in highly liquid investments such as cash, money market accounts and short-term and long-term U.S. government debt securities. As of December 31, 2007, we are unaware of any known trends or any known demands, commitments, events, or uncertainties that will, or that are reasonably likely to, result in a material increase or decrease in our liquidity related to these investments. We expect that our liquidity needs throughout 2008 will continue to be funded from existing cash, cash equivalents, and these short-term marketable securities.

As of December 31, 2007, $22.2 million of our $64.7 million in cash, cash equivalents, interest receivable and investment securities are invested in auction note securities. Our auction note securities are public securities with long-term nominal maturities for which the interest rates are reset through a dutch auction each month. The monthly auctions historically have provided a liquid market for these securities. Our investments in auction note securities represent interests in student loan-backed securities. Consistent with our investment policy guidelines, our auction note securities all had "triple A" credit ratings at the time of purchase.

As of February 22, 2008, $12.0 million of our investment securities are invested in auction note securities. Global credit and capital markets are increasingly experiencing liquidity issues. None of our auction note securities held at December 31, 2007, failed an auction in 2007 or 2008; however, a $3 million investment we made in January 2008 failed two auctions held in February 2008, as the amount of securities submitted for sale has exceeded the amount of purchase orders. We will continue to attempt to sell this $3 million investment security every seven days until an auction is successful. Our other $9 million of investments in auction note securities have their next scheduled auction dates in March 2008. As of December 31, 2007, we have not recorded any losses or impairment charges related to our auction note securities since there was no temporary or other-than-temporary decline in value in the securities in either 2007 or 2008.

If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any ratings downgrades on the auction note securities in our portfolio, we may incur impairments to our

investment portfolio, which could negatively affect our financial condition, cash flow and reported earnings, and the lack of liquidity of our auction note securities could have a material impact on our financial flexibility and ability to fund our operations.

Off-Balance Sheet Arrangements

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

Obligations and Commitments

As of December 31, 2007, we have known contractual obligations, commitments and contingencies of $48,309,000. Of this amount, $46,529,000 relates to research and development agreements (primarily relating to our pivotal Phase 3 and Phase 4 clinical program for Sulonex), of which $23,910,000 is due within the next year, with the remaining balance due as per the schedule below. The additional $1,780,000 relates to our operating lease obligations, of which $724,000 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 . . .	$46,529,000	$23,910,000	$22,619,000	$—	$—
Operating leases	1,780,000	724,000	1,056,000	—	—
Total	$48,309,000	$24,634,000	$23,675,000	$—	$—

The table above includes certain commitments that are contingent upon our continuing development of our drug candidates.

We have undertaken to make contingent milestone payments to certain of our licensors of up to approximately $93.8 million over the life of the licenses, of which approximately $74.5 million will be due upon or following regulatory approval of the licensed drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, we remain obligated to pay three licensors $50,000, $75,000, and $22,500, respectively, annually until the licenses expire. We have also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights (up to 3,372,422 shares of our common stock) if its drug candidates meet certain development milestones, of which 500,000 shares may be payable in 2008 upon the reaching of the first milestone. We have also entered into a royalty arrangement under which our wholly-owned subsidiary may be required to pay up to a maximum of $16.1 million to AusAm on revenue from a next generation product following FDA marketing approval, as part of our acquisition of Accumin. The uncertainty relating to the timing of the commitments described in this paragraph prevents us from including them in the table above.

Critical Accounting Policies

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

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

Stock Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. In applying SFAS No. 123R, the value of each option

award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock; however, this estimate is neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those options expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

In accordance with EITF 96-18 "Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services," total compensation expense for options issued to consultants is determined at the "measurement date." The expense is recognized over the vesting period for the options. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record option compensation based on the fair value of the options at the reporting date. These options are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. This results in a change to the amount previously recorded in respect of the option grant, and additional expense or a reversal of expense may be recorded in subsequent periods based on changes in the assumptions used to calculate fair value, such as changes in market price, until the measurement date is reached and the compensation expense is finalized.

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred to date in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance and expense in any accounting period. In addition, administrative costs related to external CROs are recognized on a straight-line basis over the estimated contractual period. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful recruitment of patients, the completion of portions of the clinical trial or similar conditions. The objective of our policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on our estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Revenue Recognition. We recognize license revenue consistent with the provisions of Staff Accounting Bulletin ("SAB") No. 104 and EITF Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." We analyze each element of our licensing agreement to determine the appropriate revenue recognition. We recognize revenue on upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones and royalties that are deferred will be recognized when earned under the agreements.

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

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

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

As of December 31, 2007, there was approximately $3.2 million of goodwill on our consolidated balance sheet. SFAS No. 142, "Goodwill and Other Intangible Assets," or SFAS No. 142, addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. This statement also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. SFAS No. 142 requires goodwill be tested using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests under SFAS No. 142 annually and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable. For all of our acquisitions, various analyses, assumptions and estimates were made at the time of each acquisition specifically regarding cash flows that were used to determine the valuation of goodwill and intangibles. When we perform impairment tests in future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in impairment charges.

Impairment. In accordance with SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," the Company recognizes an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, the Company makes certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized. The Company continues to derive revenue from the sale of the Accumin diagnostic tool. During the first quarter of 2007, management reviewed both its original and projected revenue estimates associated with the diagnostic tool. As a result of this analysis, the Company concluded that the asset was impaired and recorded an impairment charge of approximately $600,000 to write-down identifiable intangible long-lived assets associated with Accumin. The charge was recorded in other selling, general and administrative expenses within the Diagnostics segment. Prior to the impairment charge taken in the first quarter of 2007, we amortized our identifiable intangible assets associated with Accumin over their estimated economic lives, which was 12 years, the life of the patents, using the straight-line method.

Accounting For Income Taxes. In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To

the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our U.S. deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in establishing the valuation allowance. In prior periods, our wholly-owned Israeli subsidiaries had generated taxable income in respect of services provided within the group, and therefore we believed in the past that our deferred tax assets relating to the Israeli subsidiaries would be realized. With the cessation of operating activities in Israel during 2003 and the resulting absence of taxable income from the Israeli subsidiaries, the deferred tax asset was written off in 2003. We recorded $36,000 in income tax expense for the year ended December 31, 2007, as a result of income tax withheld associated with the payment from Yissum relating to a terminated license agreement.

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

Accounting For Our Manufacturing Suite. We have entered into a relationship with SPL, a U.S.-based contract manufacturer, for Sulonex to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture and produce initial commercialization quantities of Sulonex (for approximately one to three years from launch). As of December 31, 2007, we have spent approximately $11.2 million in capital expenditures building the suite. We anticipate that in the first half of 2008, after equipment validation has been completed, the facility will be ready for its intended use and we will begin to depreciate this asset at that time. Significant estimates and judgments were made, and will continue to be made, relating to the appropriate in-service date of these assets and the related asset retirement obligation.

Recently Issued Accounting Standards

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS No. 141R") which replaces SFAS No. 141. SFAS No. 141R changes the accounting for business combinations, including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance and income tax uncertainties. SFAS No. 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years. Early application is prohibited.

In December 2007, the FASB issued SFAS No. 160 "Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB 51," ("SFAS No. 160") which changes the accounting and reporting for minority interests. Minority interests will be recharacterized as noncontrolling interests and will be reported as a component of equity separate from the parent's equity, and purchases or sales of equity interests that do not result in a change in control will be accounted for as equity transactions. In addition, net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement and, upon a loss of control, the interest sold, as well as any interest retained, will be recorded at fair value with any gain or loss recognized in earnings. SFAS No. 160 is effective for fiscal years (including interim periods within those fiscal years) beginning on or after December 15, 2008. Earlier adoption is prohibited. The statement shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. We expect that the adoption of SFAS No. 160 will not have a material impact on our results of operations and financial position.

In December 2007, the FASB ratified EITF Issue No. 07-1, "Accounting for Collaborative Arrangements" ("EITF 07-1"). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. EITF 07-1 shall be applied using modified version of retrospective transition for those arrangements in place at the effective date. An entity should report the effects of applying this Issue as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects the change retrospectively. We are currently assessing the impact that EITF 07-1 may have on our results of operations and financial position.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. The provisions of EITF 07-3 will be effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Early application is prohibited. The provisions of this EITF are applicable for new contracts entered into on or after the effective date. We expect that the adoption of EITF 07-3 will not have a material impact on our results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities - including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 is expected to expand the use of fair value accounting, but does not affect existing standards which require certain assets or liabilities to be carried at fair value. The objective of SFAS 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS 159, a company may choose, at its initial application or at other specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Were we to elect the fair value option for our existing assets and liabilities, the effect as of the adoption date, shall be reported as a cumulative-effect adjustment to the opening balance of retained earnings. We do not expect to elect the fair value option to our existing assets and liabilities and thus the adoption of SFAS 159 will not have a material impact on our results of operations and financial position.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which provides guidance for using fair value to measure assets and liabilities. SFAS 157 will apply whenever another standard requires (or permits) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value to any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB deferred the effective date of SFAS 157 for one year for certain non financial assets and non financial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis. We do not expect the adoption of SFAS 157 to have a material impact on our results of operations and financial position.

Item 7A. Quantitative and Qualitative Disclosure 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 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 December 31, 2007, our portfolio of financial instruments consists of cash equivalents

and short-term and long-term interest bearing securities, including money market funds, government debt and auction note securities. The average duration of all of our held-to-maturity investments held as of December 31, 2007, was less than 12 months. Additionally, the re-pricing of our auction notes within thirty days allows these securities to function as short-term investments. Due to the short-term nature of our investments, we believe we have no material exposure to interest rate risk arising from our investments.

As of February 22, 2008, $12.0 million of our investment securities are invested in auction note securities. Global credit and capital markets are increasingly experiencing liquidity issues. None of our auction note securities held at December 31, 2007, failed an auction in 2007 or 2008; however, a $3 million investment we made in January 2008 failed two auctions held in February 2008, as the amount of securities submitted for sale has exceeded the amount of purchase orders. We will continue to attempt to sell this $3 million investment security every seven days until an auction is successful. Our other $9 million of investments in auction note securities have their next scheduled auction dates in March 2008. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any ratings downgrades on the auction note securities in our portfolio, we may incur impairments to our investment portfolio, which could negatively affect our financial condition, cash flow and reported earnings, and the lack of liquidity of our auction note securities could have a material impact on our financial flexibility and ability to fund our operations.

Item 8. Financial Statements and Supplementary Data

Our consolidated financial statements and the notes thereto, included in Part IV, Item 15(a), part 1, are incorporated by reference into this Item 8.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial disclosure.

Not applicable.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2007, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Accounting Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Accounting Officer concluded that, as of December 31, 2007, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting. Our management is responsible for establishing and maintaining adequate internal control over financial reporting (as defined in Rule 13a-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2007. In making this assessment, our management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission, known as COSO, in Internal Control-Integrated Framework. Our management has concluded that, as of December 31, 2007, our internal control over financial reporting was effective based on these criteria. KPMG LLP, our independent registered public accounting firm has audited the financial statements included in this annual report and has issued an attestation report on our internal control over financial reporting. Such reports are found beginning on page F-1.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2007, that have materially affected, or are reasonably likely to materially affect our internal control over financial reporting.

Limitations on the Effectiveness of Controls. Our management, including our Chief Executive Officer and Chief Accounting Officer, does not expect that our disclosure controls and procedures or our internal control 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.

Item 9B. Other Information

Not Applicable.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2008 Annual Meeting of Stockholders.

Item 11. Executive Compensation

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2008 Annual Meeting of Stockholders.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2008 Annual Meeting of Stockholders.

Item 13. Certain Relationships and Related Transactions and Director Independence.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2008 Annual Meeting of Stockholders.

Item 14. Principal Accountant Fees and Services.

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2008 Annual Meeting of Stockholders.

PART IV

Item 15. Exhibits and Financial Statement Schedules

(a) 1. Consolidated Financial Statements

The following consolidated financial statements of Keryx Biopharmaceuticals, Inc. are filed as part of this report.

2. Consolidated Financial Statement Schedules

All schedules are omitted as the information required is inapplicable or the information is presented in the consolidated financial statements or the related notes.

3. Exhibits

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger by and among Keryx Biopharmaceuticals, Inc., AXO Acquisition Corp., and ACCESS Oncology, Inc. dated as of January 7, 2004, filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K dated January 8, 2004, filed on January 15, 2004 (File No. 000-30929), and incorporated herein by reference.
2.2	First Amendment to the Agreement and Plan of Merger by and among Keryx Biopharmaceuticals, Inc., AXO Acquisition Corp., and ACCESS Oncology, Inc. dated as of February 5, 2004, filed as Exhibit 2.2 to the Registrant's Current Report on Form 8-K dated February 5, 2004, filed on February 20, 2004 (File No. 000-30929), and incorporated herein by reference.
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.
3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007, filed as Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 and incorporated herein by reference.
4.1	Specimen Common Stock Certificate, filed as Exhibit 4.1 to the Registrant's First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein by reference.
4.2	Form of Warrant for the Purchase of Shares of Common Stock between certain holders of Series A Preferred Stock and Keryx Biopharmaceuticals, Inc., dated as of December 14, 1999, filed as Exhibit 4.9 to the Registrant's Registration Statement on Form S-1 filed on May 19, 2000 (File No. 333-37402), and incorporated herein by reference.
4.3	Form of Common Stock Purchase Warrant dated November 20, 2003, issued to the purchasers under the Securities Purchase Agreement, filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.
4.4	Securities Purchase Agreement dated November 12, 2003 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.
4.5	Registration Rights Agreement dated November 17, 2003 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.
4.6	Securities Purchase Agreement dated February 12, 2004 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed on March 16, 2004 (File No. 333-113654), and incorporated herein by reference.

Exhibit Number	Exhibit Description
4.7	Registration Rights Agreement dated February 17, 2004 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on March 16, 2004 (File No. 333-113654), and incorporated herein by reference.
10.1!	License Agreement between Alfa Wassermann S.p.A. and Partec Ltd., dated as of November 12, 1998, filed as Exhibit 10.7 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on July 24, 2000 (File No. 333-37402), and incorporated by reference.
10.2!	License Agreement between Opocrin S.p.A. and Keryx Biopharmaceuticals, Inc., dated September 25, 2002, filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 filed on November 12, 2002 (File No. 000-30929), and incorporated herein by reference.
10.3	Form of Sulonex™ (KRX-101) Scientific Advisory Board Agreement, filed as Exhibit 10.20 to the Registrant's First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein be reference.
10.4†	Employment Agreement between Keryx Biopharmaceuticals, Inc. and Michael S. Weiss dated as of December 23, 2002, filed as Exhibit 10.1 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929), and incorporated herein by reference.
10.5†	1999 Stock Option Plan, as amended, filed as Exhibit 10.2 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.
10.6†	2000 Stock Option Plan, as amended, filed as Exhibit 10.3 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.
10.7†	2002 CEO Incentive Stock Option Plan, filed as Exhibit 10.4 to the Registrant's Quarterly Report of Form 10-Q for the quarter ended March 31, 2003 filed on May 15, 2003 (File No. 000-30929) and incorporated herein by reference.
10.8	Sub-license Agreement dated October 13, 2000 between Procept, Inc. and AOI Pharmaceuticals, Inc., filed as Exhibit 10.32 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.9	Amendment to Sub-license agreement dated February 28, 2002 between AOI Pharmaceuticals, Inc. and Procept, Inc., filed as Exhibit 10.33 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.10	Patent License Agreement dated February 28, 2002 between Procept, Inc. and United State Public Health Services, as amended, filed as Exhibit 10.34 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.11	Release Agreement dated February 28, 2002 among AOI Pharmaceuticals, Inc., Procept, Inc., and United States Public Health Services, filed as Exhibit 10.35 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.12	Comprehensive Release Agreement dated May 29, 2002 among AOI Pharmaceuticals, Inc., Procept, Inc., United States Public Health Services and the University of Chicago, filed as Exhibit 10.36 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.

Exhibit Number	Exhibit Description
10.13!	Sub-license Agreement between Prescient NeuroPharma, Inc. and ACCESS Oncology, Inc. dated December 24, 2001, filed as Exhibit 10.37 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.14!	License Agreement dated September 18, 2002 between Zentaris AG and AOI Pharma, Inc, filed as Exhibit 10.38 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.15!	Addendum Agreement to License and Cooperation Agreement for Perifosine dated December 3, 2003 between Zentaris AG and AOI Pharma, Inc., filed as Exhibit 10.39 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10.16	Cooperative Research and Development Agreement between the National Cancer Institute and ASTA Medica Inc., as amended, filed as Exhibit 10.40 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2003, filed on March 30, 2004, and incorporated herein by reference.
10. 17†	Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan, filed with the Registrant's Definitive Proxy Statement for the Annual Meeting of Stockholders on June 10, 2004, filed on April 29, 2004, and incorporated herein by reference.
10.18†	Employment Agreement between Mark Stier and Keryx Biopharmaceuticals, Inc., dated as of March 23, 2007, filed as Exhibit 10.1 to the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 7, 2007, and incorporated herein by reference.
10.19!	License Agreement between Keryx Biopharmaceuticals, Inc. and Panion & BF Biotech, Inc. dated as of November 7, 2005, filed as Exhibit 10.21 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2005, filed on March 8, 2005, and incorporated herein by reference.
10.20*	License Agreement by and between Kyowa Hakko Kogyo Co., Ltd. and Keryx Biopharmaceuticals, Inc. dated as of September 29, 2006, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, filed on November 8, 2006, and incorporated herein by reference.
10.21	Assignment and Assumption Agreement (related to the License Agreement by and between Kyowa Hakko Kogyo Co., Ltd. and Keryx Biopharmaceuticals, Inc. dated as of September 29, 2006) by and among Keryx Biopharmaceuticals, Inc. and AOI Pharmaceuticals, Inc. dated as of October 25, 2006, filed as Exhibit 10.2 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2006, filed on November 8, 2006, and incorporated herein by reference.
10.22†	Amendment to the Keryx Biopharmaceuticals, Inc. 2004 Long-Term Incentive Plan dated April 11, 2006, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2006, filed on August 9, 2006, and incorporated herein by reference.
10.23*	Sub-license Agreement by and among Keryx Biopharmaceuticals, Inc., Japan Tobacco Inc., and Torii Pharmaceutical Co., Ltd. dated September 26, 2007, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 31, 2007, filed on November 9, 2007, and incorporated herein by reference.
10.24†	Employment Agreement between Beth F. Levine and Keryx Biopharmaceuticals, Inc., dated as of April 25, 2007, filed as Exhibit 10.2 to the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 7, 2007, and incorporated herein by reference.
10.25†	Employment Agreement between Dr. I. Craig Henderson and Keryx Biopharmaceuticals, Inc. dated April 25, 2007, filed as Exhibit 10.3 to the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 7, 2007, and incorporated herein by reference.

Exhibit Number	Exhibit Description
10.26†	2007 Chief Accounting Officer Inducement Stock Option Plan dated March 23, 2007, filed as Exhibit 10.4 to the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 7, 2007, and incorporated herein by reference.
10.27†	2007 General Counsel Incentive Stock Option Plan dated April 25, 2007, filed as Exhibit 10.5 to the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 7, 2007, and incorporated herein by reference.
21.1	List of subsidiaries of Keryx Biopharmaceuticals, Inc.
23.1	Consent of KPMG LLP.
24.1	Power of Attorney of Director and Officers of Keryx Biopharmaceuticals, Inc. (included herein).
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 February 27, 2008.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated February 27, 2008.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated February 27, 2008.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated February 27, 2008.

! Confidential treatment has been granted with respect to the omitted portions of this exhibit.

† Indicates management contract or compensatory plan or arrangement.

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED FINANCIAL STATEMENTS
As of December 31, 2007

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED FINANCIAL STATEMENTS
As of December 31, 2007

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Keryx Biopharmaceuticals, Inc.:

We have audited the accompanying consolidated balance sheets of Keryx Biopharmaceuticals, Inc. and subsidiaries (the "Company"), a development stage company, as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2007, and for the period from December 3, 1996 to December 31, 2007. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2007, and for the period from December 3, 1996 to December 31, 2007, in conformity with U.S. generally accepted accounting principles.

As discussed in the notes to the consolidated financial statements, effective January 1, 2006, the Company adopted Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment."

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the Company's internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO), and our report dated February 27, 2008 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

New York, New York
February 27, 2008

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders
Keryx Biopharmaceuticals, Inc.:

We have audited Keryx Biopharmaceuticals, Inc. and subsidiaries' (the "Company"), a development stage company, internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). The Company's management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying "Management's Report on Internal Control over Financial Reporting" in item 9A. Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

In our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2007, based on criteria established in Internal Control Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2007 and 2006, and the related consolidated statements of operations, stockholders' equity, and cash flows for each of the years in the three-year period ended December 31, 2007, and for the period from December 3, 1996 to December 31, 2007, and our report dated February 27, 2008 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

New York, New York
February 27, 2008

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED BALANCE SHEETS
As of December 31
(In Thousands, Except Share and Per Share Amounts)

	2007	2006
ASSETS		
Current assets		
Cash and cash equivalents	$ 19,065	$ 48,736
Short-term investment securities	43,038	63,659
Accrued interest receivable	283	525
Other current assets	1,330	2,048
Total current assets	63,716	114,968
Long-term investment securities	2,296	12,690
Property, plant and equipment, net	11,497	8,489
Goodwill	3,208	3,208
Other assets, net	344	958
Total assets	$ 81,061	$ 140,313
LIABILITIES AND STOCKHOLDER'S EQUITY		
Current liabilities		
Accounts payable and accrued expenses	$ 19,134	$ 10,460
Accrued compensation and related liabilities	1,254	1,534
Current portion of deferred revenue	1,023	200
Total current liabilities	21,411	12,194
Deferred revenue, net of current portion	11,022	—
Contingent equity rights	4,004	4,004
Other liabilities	202	294
Total liabilities	36,639	16,492
Commitments and contingencies (Note 13)		
Stockholders' equity		
Common stock, $0.001 par value per share (95,000,000 and 60,000,000 shares authorized, 43,751,101 and 43,516,669 shares issued, 43,671,153 and 43,460,569 shares outstanding at December 31, 2007, and 2006, respectively)	44	44
Additional paid-in capital	323,009	312,078
Treasury stock, at cost, 79,948 and 56,100 shares at December 31, 2007, and 2006, respectively	(357)	(89)
Deficit accumulated during the development stage	(278,274)	(188,212)
Total stockholders' equity	44,422	123,821
Total liabilities and stockholders' equity	$ 81,061	$ 140,313

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF OPERATIONS
For the Year Ended December 31
(In Thousands, Except Share and Per Share Amounts)

	2007	2006	2005	Amounts Accumulated During the Development Stage
Revenue:				
License revenue	$ 204	$ —	$ —	$ 204
Diagnostic revenue	66	103	—	169
Service revenue	52	431	574	1,866
Other revenue	727	—	—	1,027
Total revenue	1,049	534	574	3,266
Operating expenses:				
Cost of diagnostics sold	38	140	—	178
Cost of services	124	390	819	2,168
Research and development:				
Non-cash compensation	3,574	6,504	594	17,812
Non-cash acquired in-process research and development	—	—	—	18,800
Other research and development	74,889	56,139	24,182	194,922
Total research and development	78,463	62,643	24,776	231,534
Selling, general and administrative:				
Non-cash compensation	7,086	8,408	775	20,935
Other selling, general and administrative	9,919	9,110	3,416	44,115
Total selling, general and administrative	17,005	17,518	4,191	65,050
Total operating expenses	95,630	80,691	29,786	298,930
Operating loss	(94,581)	(80,157)	(29,212)	(295,664)
Interest and other income, net	4,555	6,393	2,317	17,917
Net loss before income taxes	(90,026)	(73,764)	(26,895)	(277,747)
Income taxes	36	—	—	527
Net loss	$ (90,062)	$ (73,764)	$ (26,895)	$ (278,274)
Basic and diluted loss per common share	$ (2.07)	$ (1.76)	$ (0.78)	$ (12.34)
Weighted average shares used in computing basic and diluted net loss per common share	43,583,950	41,919,741	34,384,576	22,543,474

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(In Thousands, Except Share Amounts)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-in Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2004	—	$—	31,373,280	$ 31	$132,643
Changes during the year:					
Issuance of common stock in public offering (net of issuance expenses of $5,419)	—	—	5,780,000	6	75,784
Exercise of warrants	—	—	157,647	1	946
Exercise of options	—	—	520,969	—*	663
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	—	—	722
Net loss	—	—	—	—	—
Balance at December 31, 2005	—	$—	37,831,896	$ 38	$210,758

	Treasury Stock		Unearned Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balance at December 31, 2004	56,100	$(89)	$(2,228)	$ (87,553)	$ 42,804
Changes during the year:					
Issuance of common stock in public offering (net of issuance expenses of $5,419)	—	—	—	—	75,790
Exercise of warrants	—	—	—	—	947
Exercise of options	—	—	—	—	663
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	647	—	1,369
Net loss	—	—	—	(26,895)	(26,895)
Balance at December 31, 2005	56,100	$(89)	$(1,581)	$(114,448)	$ 94,678

* Amount less than one thousand dollars.

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY — (continued)
(In Thousands, Except Share Amounts)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2005	—	$—	37,831,896	$ 38	$210,758
Changes during the year:					
Issuance of common stock in public offering (net of issuance expenses of $104)	—	—	4,500,000	5	82,692
Issuance of common stock in connection with acquisition	—	—	245,024	—*	3,310
Issuance of common stock held in escrow	—	—	15,646	—*	—
Issuance of restricted stock	—	—	100,000	—*	—
Exercise of options	—	—	824,103	1	1,987
Reclassification of unearned compensation upon adoption of SFAS No. 123R	—	—	—	—	(1,581)
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	14,912
Net loss	—	—	—	—	—
Balance at December 31, 2006	—	$—	43,516,669	$ 44	$312,078

	Treasury Stock		Unearned Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balance at December 31, 2005	56,100	$(89)	$(1,581)	$(114,448)	$ 94,678
Changes during the year:					
Issuance of common stock in public offering (net of issuance expenses of $104)	—	—	—	—	82,697
Issuance of common stock in connection with acquisition	—	—	—	—	3,310
Issuance of common stock held in escrow	—	—	—	—	—*
Issuance of restricted stock	—	—	—	—	—*
Exercise of options	—	—	—	—	1,988
Reclassification of unearned compensation upon adoption of SFAS No. 123R	—	—	1,581	—	—
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	14,912
Net loss	—	—	—	(73,764)	(73,764)
Balance at December 31, 2006	56,100	$(89)	$ —	$(188,212)	$123,821

* Amount less than one thousand dollars.

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY — (continued)
(In Thousands, Except Share Amounts)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Balance at December 31, 2006	—	$—	43,516,669	$ 44	$312,078
Changes during the year:					
Cancellation of common stock held in escrow	—	—	(15,646)	(—)*	—
Issuance of restricted stock	—	—	195,000	—*	—
Forfeiture of restricted stock	—	—	(83,334)	(—)*	—
Surrender of common stock for tax withholding	—	—	—	—	—
Exercise of options	—	—	138,412	—*	271
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	10,660
Net loss	—	—	—	—	—
Balance at December 31, 2007	—	$—	43,751,101	$ 44	$323,009

	Treasury Stock		Unearned Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Balance at December 31, 2006	56,100	$ (89)	$—	$(188,212)	$123,821
Changes during the year:					
Cancellation of common stock held in escrow	—	—	—	—	(—)*
Issuance of restricted stock	—	—	—	—	—*
Forfeiture of restricted stock	—	—	—	—	(—)*
Surrender of common stock for tax withholding	23,848	(268)	—	—	(268)
Exercise of options	—	—	—	—	271
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	10,660
Net loss	—	—	—	(90,062)	(90,062)
Balance at December 31, 2007	79,948	$(357)	$—	$(278,274)	$ 44,422

* Amount less than one thousand dollars.

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY — (continued)
(In Thousands, Except Share Amounts)

	Series A Convertible Preferred Stock		Common Stock		Additional Paid-In Capital
	Shares	Amount	Shares	Amount	
Amounts accumulated during the development stage (December 3, 1996 to December 31, 2007):					
Contributed capital	—	$ —	—	$ —	$ 3,181
Conversion of convertible notes of Partec into stock in Keryx	—	—	—	—	2,973
Issuance of Series A convertible preferred stock to investors at $100 per share for cash (net of issuance expenses of $552)	89,180	—*	—	—	8,338
Issuance of Series A convertible preferred stock at $0.001 par value to note holders in exchange for note of predecessor	29,465	—*	—	—	—
Issuance of common stock to technology licensors for technology license	—	—	1,256,797	2	358
Issuance of common stock in public offering (net of issuance expenses of $5,523)	—	—	10,280,000	11	158,476
Issuance of common stock in private placement (net of issuance expenses of $1,205)	—	—	6,729,412	6	45,789
Issuance of common stock in connection with acquisition	—	—	868,169	1	9,634
Issuance of common stock held in escrow	—	—	15,646	—*	—
Cancellation of common stock held in escrow	—	—	(15,646)	(—)*	—
Issuance of restricted stock	—	—	295,000	—*	—
Forfeiture of restricted stock	—	—	(83,334)	(—)*	—
Receipt on account of shares issued in prior years	—	—	6,900,000	7	—
Conversion of Series A convertible preferred stock to common stock	(118,645)	(—)*	6,114,962	6	(6)
Issuance of common stock in initial public offering, including exercise of overallotment (net of issuance expenses of $5,702)	—	—	5,200,000	5	46,293
Purchase of common stock	—	—	—	—	—
Surrender of common stock for tax withholding	—	—	—	—	—
Exercise of warrants	—	—	753,897	1	3,050
Exercise of options	—	—	5,436,198	5	6,064
Reclassification of unearned compensation upon adoption of SFAS No. 123R	—	—	—	—	(1,581)
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	39,738
Warrants of common stock issued to related party as finder's fee in private placement	—	—	—	—	114
Warrants for common stock issued to note holders in exchange for note of predecessor	—	—	—	—	588
Net loss	—	—	—	—	—
Balance at December 31, 2007	—	$ —	43,751,101	$ 44	$323,009

* Amount less than one thousand dollars.

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY — (continued)
(In Thousands, Except Share Amounts)

	Treasury Stock		Unearned Compensation	Deficit Accumulated During the Development Stage	Total
	Shares	Amount			
Amounts accumulated during the development stage (December 3, 1996 to December 31, 2007):					
Contributed capital	—	$ —	$ —	$ —	$ 3,181
Conversion of convertible notes of Partec into stock in Keryx	—	—	—	—	2,973
Issuance of Series A convertible preferred stock to investors at $100 per share for cash (net of issuance expenses of $552)	—	—	—	—	8,338
Issuance of Series A convertible preferred stock at $0.001 par value to note holders in exchange for note of predecessor	—	—	—	—	—*
Issuance of common stock to technology licensors for technology license	—	—	—	—	360
Issuance of common stock in public offering (net of issuance expenses of $5,523)	—	—	—	—	158,487
Issuance of common stock in private placement (net of issuance expenses of $1,205)	—	—	—	—	45,795
Issuance of common stock in connection with acquisition	—	—	—	—	9,635
Issuance of common stock held in escrow	—	—	—	—	—*
Cancellation of common stock held in escrow	—	—	—	—	(—)*
Issuance of restricted stock	—	—	—	—	—*
Forfeiture of restricted stock	—	—	—	—	(—)*
Receipt on account of shares issued in prior years	—	—	—	—	7
Conversion of Series A convertible preferred stock to common stock	—	—	—	—	(—)*
Issuance of common stock in initial public offering, including exercise of overallotment (net of issuance expenses of $5,702)	—	—	—	—	46,298
Purchase of common stock	56,100	(89)	—	—	(89)
Surrender of common stock for tax withholding	23,848	(268)	—	—	(268)
Exercise of warrants	—	—	—	—	3,051
Exercise of options	—	—	—	—	6,069
Reclassification of unearned compensation upon adoption of SFAS No. 123R	—	—	1,581	—	—
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	(1,581)	—	38,157
Warrants of common stock issued to related party as finder's fee in private placement	—	—	—	—	114
Warrants for common stock issued to note holders in exchange for note of predecessor	—	—	—	—	588
Net loss	—	—	—	(278,274)	(278,274)
Balance at December 31, 2007	79,948	$(357)	$ —	$(278,274)	$ 44,422

* Amount less than one thousand dollars.

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Year Ended December 31
(In Thousands)

	2007	2006	2005	Amounts Accumulated During the Development Stage
Cash Flows From Operating Activities				
Net loss	$(90,062)	$(73,764)	$(26,895)	$(278,274)
Adjustments to reconcile net loss to cash flows used in operating activities:				
Acquired in-process research and development	—	—	—	18,800
Stock compensation expense	10,660	14,912	1,369	38,747
Issuance of common stock to technology licensor	—	—	—	359
Interest on convertible notes settled through issuance of preferred shares	—	—	—	253
Depreciation and amortization	151	224	190	2,986
(Gain) loss on disposal of property, plant and equipment	(1)	—	2	171
Impairment charges	600	—	—	3,082
Exchange rate differences	—	—	—	94
Changes in assets and liabilities, net of effects of acquisitions:				
Decrease (increase) in other current assets	718	1,253	(2,578)	(858)
Decrease (increase) in accrued interest receivable	242	(189)	(192)	(283)
(Increase) in security deposits	—	(255)	(8)	(263)
Increase in accounts payable and accrued expenses	8,674	4,974	1,975	17,389
(Decrease) increase in accrued compensation and related liabilities	(280)	575	193	659
(Decrease) increase in other liabilities	(92)	(28)	230	47
Increase (decrease) in deferred revenue	11,845	97	(37)	11,589
Net cash used in operating activities	(57,545)	(52,201)	(25,751)	(185,502)
Cash Flows From Investing Activities				
Purchases of property, plant and equipment	(3,159)	(7,597)	(964)	(16,147)
Proceeds from disposals of property, plant and equipment	15	—	1	440
(Increase) in note and accrued interest receivable from related party	—	—	—	(356)
Payments of transaction costs	—	(231)	—	(231)
Decrease (increase) in other assets	—	27	(23)	(1,192)
Investment in held-to-maturity short-term securities	(6,136)	(4,080)	(1,122)	(55,049)
Proceeds from maturity of held-to-maturity short-term securities	24,020	8,275	15,045	76,041
Investment in available-for-sale short-term securities	(56,700)	(38,375)	(13,700)	(114,800)
Proceeds from sale of available-for-sale short-term securities	76,200	6,725	8,675	92,600
Investment in held-to-maturity long-term securities	(6,372)	(16,677)	(21,270)	(44,319)
Proceeds from maturity of held-to-maturity long-term securities	3	5	185	193
Net cash provided by (used in) investing activities	27,871	(51,928)	(13,173)	(62,820)

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

KERYX BIOPHARMACEUTICALS, INC.
(A Development Stage Company)

CONSOLIDATED STATEMENTS OF CASH FLOWS
For the Year Ended December 31
(In Thousands)

	2007	2006	2005	Amounts Accumulated During the Development Stage
Cash Flows From Financing Activities				
Proceeds from short-term loans	$ —	$ —	$ —	$ 500
Proceeds from long-term loans	—	—	—	3,251
Payment of assumed notes payable and accrued interest in connection with the ACCESS Oncology acquisition	—	—	—	(6,322)
Issuance of convertible note, net	—	—	—	2,150
Issuance of preferred shares, net	—	—	—	8,453
Receipts on account of shares previously issued	—	—	—	7
Proceeds from initial public offering, net	—	—	—	46,298
Proceeds from subsequent public offerings, net	—	82,697	75,790	158,487
Proceeds from private placements, net	—	—	—	45,795
Proceeds from exercise of options and warrants	271	1,988	1,610	9,120
Purchase of treasury stock	(268)	—	—	(357)
Net cash provided by financing activities	3	84,685	77,400	267,382
Cash acquired in acquisition	—	5	—	99
Effect of exchange rate on cash	—	—	—	(94)
Net (Decrease) Increase in Cash and Cash Equivalents	(29,671)	(19,439)	38,476	19,065
Cash and cash equivalents at beginning of year	48,736	68,175	29,699	—
Cash and Cash Equivalents at End of Year	$ 19,065	$ 48,736	$68,175	$ 19,065
Non-Cash Transactions				
Issuance of common stock in connection with acquisition	$ —	$ 3,310	$ —	$ 9,635
Contingent equity rights in connection with acquisition	—	—	—	4,004
Assumption of liabilities in connection with acquisition	—	345	—	9,068
Conversion of short-term loans into contributed capital	—	—	—	500
Conversion of long-term loans into contributed capital	—	—	—	2,681
Conversion of long-term loans into convertible notes of Partec	—	—	—	570
Conversion of convertible notes of Partec and accrued interest into stock in Keryx	—	—	—	2,973
Issuance of warrants to related party as finder's fee in private placement	—	—	—	114
Declaration of stock dividend	—	—	—	3
Supplementary Disclosures of Cash Flow Information				
Cash paid for interest	$ —	$ —	$ —	$ 1,166
Cash paid for income taxes	$ 36	$ —	$ —	$ 468

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

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Summary of Significant Accounting Policies

Description of Business

Keryx Biopharmaceuticals, Inc. ("Keryx" or the "Company") is a biopharmaceutical company focused on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. The Company was incorporated in Delaware in October 1998 (under the name Paramount Pharmaceuticals, Inc., which was later changed to Lakaro Biopharmaceuticals, Inc. in November 1999, and finally to Keryx Biopharmaceuticals, Inc. in January 2000). The Company commenced activities in November 1999, focusing on the development and commercialization of clinical compounds and core technologies for the life sciences.

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

The Company owns a 100% interest in each of ACCESS Oncology, Inc., Neryx Biopharmaceuticals, Inc., and Accumin Diagnostics, Inc., all U.S. corporations incorporated in the State of Delaware, and Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd., each organized in Israel. In 2003, the Company's subsidiaries in Israel ceased operations and are currently in the process of being closed down. Most of the Company's biopharmaceutical development and substantially all of its administrative operations during 2007 and 2006 were conducted in the United States of America.

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

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

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.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

Principles of Consolidation

The consolidated financial statements include the financial statements of the Company and its wholly owned subsidiaries. Intercompany transactions and balances have been eliminated in consolidation.

Use of Estimates

The preparation of financial statements in conformity with U.S. generally accepted accounting principles ("GAAP") requires management to make estimates and judgments that affect the reported amounts of assets and liabilities and the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the applicable reporting period. Actual results could differ from those estimates. Such differences could be material to the financial statements.

Cash and Cash Equivalents

The Company considers all highly liquid investments with maturities of three months or less from the date of purchase to be cash equivalents.

Investment Securities

Investment securities at December 31, 2007 and 2006 consist of short-term and long-term government and auction note securities. The Company classifies its short-term and long-term debt securities as held-to-maturity, with the exception of auction notes securities, which are classified as available-for-sale. Held-to-maturity securities are those securities in which the Company has the ability and intent to hold the security until maturity. Held-to-maturity securities are recorded at amortized cost, adjusted for the amortization or accretion of premiums or discounts.

A decline in the market value of any held-to-maturity security below cost, that is deemed to be other than temporary, results in a reduction in the carrying amount to fair value. The impairment is charged to earnings and a new cost basis for the security is established. Premiums and discounts are amortized or accreted over the life of the related held-to-maturity security as an adjustment to yield using the effective interest method. Dividend and interest income are recognized when earned.

Property, Plant and Equipment

Property, plant and equipment are stated at historical cost. Depreciation is computed using the straight-line method over the estimated useful lives of the assets:

	Estimated Useful Life (Years)
Lab equipment	4
Office furniture and equipment	3 – 7
Computers, software and related equipment	3

Leasehold improvements are amortized over the shorter of their useful life or the remaining term of the lease exclusive of renewal options. The Company has incurred, and will continue to incur, manufacturing capital expenditures relating to the scale-up for larger scale production. Accordingly, the Company's manufacturing suite and equipment are not yet in production and are not amortized or depreciated until they are ready for their intended use.

As of December 31, 2007, the Company has spent approximately $11.2 million in capital expenditures building its manufacturing suite for Sulonex. The Company anticipates that in the first half of 2008, after equipment validation has been completed, the facility will be ready for its intended use, and the Company will begin to depreciate this asset at that time.

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

Patent Costs

The Company expenses patent maintenance costs as incurred. Through March 31, 2006, the Company classified its patent expenses in other research and development. Effective April 1, 2006, the Company has classified its patent expenses in other selling, general and administrative. The results of prior periods have not been reclassified because they were not significant.

Revenue Recognition

The Company recognizes license revenue consistent with the provisions of Staff Accounting Bulletin ("SAB") No. 104 and Emerging Issues Task Force ("EITF") Issue No. 00-21, "Revenue Arrangements with Multiple Deliverables." The Company analyzes each element of its licensing agreement to determine the appropriate revenue recognition. The Company recognizes revenue on upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. The Company recognizes milestone payments upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones and royalties that are deferred will be recognized when earned under the agreements.

Diagnostic revenue consists of the sale of diagnostic products for the direct measurement of total, intact urinary albumin. Diagnostic revenue is recognized when persuasive evidence of an arrangement exists, the product has been shipped, title and risk of loss have passed to the customer and collection from the customer is reasonably assured. Service revenue consists of clinical trial management and site recruitment services. Revenues generated from providing clinical trial management and site recruitment services are recognized at the time such services are provided. Deferred revenue is incurred when the Company receives a deposit or prepayment for services to be performed at a later date. Management fees accumulated during the development stage arose from provision of management services to a related company and were recognized ratably over the period for which the services were provided.

Cost of Diagnostics Sold and Cost of Services

Cost of diagnostics sold consist specifically of costs associated with the manufacture of the diagnostic products such as payments to third-party vendors and systems, material costs and other support facilities associated with delivering of the diagnostics to our customers. Cost of diagnostics sold is recognized as diagnostic revenue is recognized. Cost of services consist of all costs specifically associated with client programs such as salary, benefits paid to personnel, payments to third-party vendors and systems and other support facilities associated with delivering services to the Company's clients. Cost of services are recognized at the time such services are performed.

Research and Development Costs

Research and development costs are expensed as incurred. The Company makes estimates of costs incurred to date in relation to external clinical research organizations, or CROs, and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Additionally, administrative costs related to external CROs are recognized on a straight-line basis over the estimated contractual period. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful accrual of patients, the completion of portions of the clinical trial or similar conditions. The objective of the Company's policy is

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on the Company's estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to temporary and permanent differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carryforwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax assets and liabilities of a change in tax rates is recognized in income in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than "more likely than not," a valuation allowance is then created.

On January 1, 2007, the Company adopted Financial Accounting Standards Board ("FASB") Interpretation No. 48, "Accounting for Uncertainty in Income Taxes" ("FIN 48"). FIN 48 clarifies the criteria for recognizing tax benefits related to uncertain tax positions under SFAS No. 109, "Accounting for Income Taxes" ("SFAS No. 109"), and requires additional financial statement disclosure. FIN 48 requires that the Company recognize, in its consolidated financial statements, the impact of a tax position if that position is more likely than not to be sustained upon examination, based on the technical merits of the position. Adoption of FIN 48 had no impact on the Company's consolidated results of operations and financial position. Upon adoption, the Company believed there were no uncertain tax positions that failed to meet the more likely than not recognition threshold under FIN 48 to be sustained upon examination.

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

The Company files income tax returns in the U.S. and the statue of limitations has expired for years prior to 2003. In 2006, the Internal Revenue Service commenced an examination of the Company's U.S. Federal income tax returns for tax years 2004, 2005 and 2006. The Company believes that the ultimate resolution of this tax matter will not have a material impact on the Company's results of operations or financial condition.

The Company has filed inactive returns in Israel for its subsidiaries in Israel since 2004. These subsidiaries in Israel had ceased operations and are currently in the process of being closed down. In 2007, the Israeli tax authorities commenced and completed an examination of the Israeli tax returns of one of the Company's subsidiaries in Israel for the tax years 2003 through 2006, which resulted in a reclassification of the Company's net operating loss carryforwards to a capital loss and a corresponding decrease in valuation allowance.

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

Stock-Based Compensation

In December 2004, the FASB issued Statement of Financial Accounting Standards ("SFAS") No. 123R, "Share-Based Payment" ("SFAS No. 123R"). SFAS No. 123R requires all share-based payments to employees, or to non-employee directors as compensation for service on the Board of Directors, to be recognized as compensation expense in the consolidated financial statements based on the fair values of such payments.

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

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

Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company's pro forma disclosures required under SFAS No. 123 for periods prior to 2006, the Company accounted for forfeitures as they occurred. Upon adoption of SFAS No. 123R, the Company elected to use the Black-Scholes model to value share-based payments granted to employees subsequent to January 1, 2006 and elected to attribute the value of stock-based compensation expense using the straight-line single option method. These methods were previously used for the Company's pro forma information required under SFAS No. 123. For additional information, see Note 9 — Stockholders' Equity.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value method prescribed by the provisions of EITF Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services" ("EITF 96-18"). Unvested options are revalued at every reporting period and amortized over the vesting period in order to determine the compensation expense.

Prior to January 1, 2006, the Company applied the intrinsic value-based method of accounting prescribed by the Accounting Principles Board Opinion No. 25, "Accounting for Stock Issued to Employees" ("APB 25"), and related interpretations, including 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 was recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price.

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 exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options and warrants outstanding as of December 31, 2007, 2006 and 2005, which are not included in the computation of net loss per share amounts, were 11,191,149, 11,071,689 and 8,346,628, respectively.

Business Acquisitions

The Company accounts for acquired businesses using the purchase method of accounting which requires that the assets acquired and liabilities assumed be recorded at the date of acquisition at their respective fair values. Our consolidated financial statements and results of operations reflect an acquired business after the completion of the acquisition and are not retroactively restated. The cost to acquire a business, including transaction costs, is allocated to the underlying net assets of the acquired business in proportion to their respective fair values. Any excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill. Any excess of the net assets acquired over the purchase price represents negative goodwill.

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

The acquisition of ACCESS Oncology (see Note 8 — Contingent Equity Rights) resulted in negative goodwill. Since the negative goodwill was a result of not recognizing contingent consideration (i.e., the contingent equity rights), the lesser of the negative goodwill and the maximum value of the contingent equity rights at the date of the acquisition was recorded as if it were a liability, thereby eliminating the negative goodwill.

Impairment

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

The Company accounts for impairment of goodwill using the provisions of SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). This statement addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. This Statement also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. SFAS No. 142 requires goodwill be tested using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. As of December 31, 2007, management concluded that there is no impairment to its goodwill.

Concentrations of Credit Risk

The Company does not have significant off-balance-sheet risk or credit risk concentrations. The Company maintains its cash and cash equivalents and short-term and long-term investments with multiple financial institutions and invests in investment-grade securities with average maturities of less than twenty-four months. The Company also maintains short-term investments in auction note securities. See "Note 3 — Investment Securities."

Recently Issued Accounting Standards

In December 2007, the FASB issued SFAS No. 141 (revised 2007), "Business Combinations" ("SFAS No. 141R") which replaces SFAS No. 141. SFAS No. 141R changes the accounting for business combinations, including the measurement of acquirer shares issued in consideration for a business combination, the recognition of contingent consideration, the accounting for contingencies, the recognition of capitalized in-process research and development, the accounting for acquisition-related restructuring cost accruals, the

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

treatment of acquisition related transaction costs and the recognition of changes in the acquirer's income tax valuation allowance and income tax uncertainties. SFAS No. 141R applies prospectively to business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008, and interim periods within those fiscal years. Early application is prohibited.

In December 2007, the FASB issued SFAS No. 160 "Noncontrolling Interests in Consolidated Financial Statements, an amendment of ARB 51," ("SFAS No. 160") which changes the accounting and reporting for minority interests. Minority interests will be recharacterized as noncontrolling interests and will be reported as a component of equity separate from the parent's equity, and purchases or sales of equity interests that do not result in a change in control will be accounted for as equity transactions. In addition, net income attributable to the noncontrolling interest will be included in consolidated net income on the face of the income statement and, upon a loss of control, the interest sold, as well as any interest retained, will be recorded at fair value with any gain or loss recognized in earnings. SFAS No. 160 is effective for fiscal years (including interim periods within those fiscal years) beginning on or after December 15, 2008. Earlier adoption is prohibited. The statement shall be applied prospectively as of the beginning of the fiscal year in which it is initially applied, except for the presentation and disclosure requirement which shall be applied retrospectively for all periods presented. The Company expects that the adoption of SFAS No. 160 will not have a material impact on its results of operations and financial position.

In December 2007, the FASB ratified EITF Issue No. 07-1, "Accounting for Collaborative Arrangements" ("EITF 07-1"). EITF 07-1 defines collaborative arrangements and establishes reporting requirements for transactions between participants in a collaborative arrangement and between participants in the arrangement and third parties. EITF 07-1 also establishes the appropriate income statement presentation and classification for joint operating activities and payments between participants, as well as the sufficiency of the disclosures related to these arrangements. EITF 07-1 is effective for fiscal years beginning after December 15, 2008. EITF 07-1 shall be applied using a modified version of retrospective transition for those arrangements in place at the effective date. An entity should report the effects of applying this Issue as a change in accounting principle through retrospective application to all prior periods presented for all arrangements existing as of the effective date, unless it is impracticable to apply the effects the change retrospectively. The Company is currently assessing the impact that EITF 07-1 may have on its results of operations and financial position.

In June 2007, the EITF reached a consensus on EITF Issue No. 07-3, "Accounting for Nonrefundable Advance Payments for Goods or Services Received to Be Used in Future Research and Development Activities" ("EITF 07-3"). EITF No. 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. The provisions of EITF 07-3 will be effective for financial statements issued for fiscal years beginning after December 15, 2007, and interim periods within those fiscal years. Early application is prohibited. The provisions of this EITF are applicable for new contracts entered into on or after the effective date. The Company expects that the adoption of EITF 07-3 will not have a material impact on its results of operations and financial position.

In February 2007, the FASB issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities — including an amendment of FASB Statement No. 115" ("SFAS 159"). SFAS 159 is expected to expand the use of fair value accounting, but does not affect existing standards which require certain assets or liabilities to be carried at fair value. The objective of SFAS 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently without having to apply complex hedge accounting provisions. Under SFAS 159, a company may choose, at its initial application or at other specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial

Note 1 — Organization and Summary of Significant Accounting Policies – (continued)

statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. Were the Company to elect the fair value option for its existing assets and liabilities, the effect as of the adoption date, shall be reported as a cumulative-effect adjustment to the opening balance of retained earnings. The Company does not expect to elect the fair value option to its existing assets and liabilities and thus the adoption of SFAS 159 will not have a material impact on its results of operations and financial position.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurements" ("SFAS 157"), which provides guidance for using fair value to measure assets and liabilities. SFAS 157 will apply whenever another standard requires (or permits) assets or liabilities to be measured at fair value. The standard does not expand the use of fair value to any new circumstances. SFAS 157 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. In February 2008, the FASB deferred the effective date of SFAS 157 for one year for certain non financial assets and non financial liabilities that are recognized or disclosed at fair value in the financial statements on a nonrecurring basis. The Company does not expect the adoption of SFAS 157 to have a material impact on its results of operations and financial position.

Note 2 — Cash and Cash Equivalents

(In Thousands)	December 31, 2007	December 31, 2006
Money market funds	$14,457	$14,733
Checking and bank deposits	4,608	34,003
Total	$19,065	$48,736

Note 3 — Investment Securities

The following tables summarize the Company's investment securities at December 31, 2007 and December 31, 2006 (regarding assumptions used for estimating fair value, see "Note 10 — Fair Value of Financial Instruments."):

	December 31, 2007			
(In Thousands)	Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Short-term investments:				
Obligations of domestic governmental agencies (mature between April and October 2008) (Held-to-maturity)	$20,838	$91	$—	$20,929
Auction notes (Available-for-sale)*	22,200	—	—	22,200
	$43,038	$91	$—	$43,129
Long-term investments:				
Obligations of domestic governmental agencies (mature May 2009) (Held-to-maturity)	$ 2,296	$54	$—	$ 2,350

Note 3 — Investment Securities – (continued)

(in thousands)	December 31, 2006 Amortized Cost	Gross Unrealized Holding Gains	Gross Unrealized Holding Losses	Estimated Fair Value
Short-term investments:				
Obligations of domestic governmental agencies (mature between January and October 2007) (Held-to-maturity) . . .	$21,959	$—	$(73)	$21,886
Auction notes (Available-for-sale)*	41,700	—	—	41,700
	$63,659	$—	$(73)	$63,586
Long-term investments:				
Obligations of domestic governmental agencies (mature between April and May 2008) (Held-to-maturity)	$12,690	$ 2	$(19)	$12,673
	$12,690	$ 2	$(19)	$12,673

* Amortized cost approximates fair value. Unrealized gains and losses are not material.

As of December 31, 2007, $22.2 million of the Company's investment securities are invested in auction note securities. The Company's auction note securities are public securities with long-term nominal maturities for which the interest rates are reset through a dutch auction each month. The monthly auctions historically have provided a liquid market for these securities. The Company's investments in auction note securities represent interests in student loan-backed securities. Consistent with the Company's investment policy guidelines, its auction note securities all had "triple A" credit ratings at the time of purchase.

As of February 22, 2008, $12.0 million of the Company's investment securities are invested in auction note securities, $5.0 million of which were held at December 31, 2007 and have repriced in successful auctions. Global credit and capital markets are increasingly experiencing liquidity issues. None of the Company's auction note securities held at December 31, 2007, failed an auction in 2007 or 2008; however, a $3 million investment the Company made in January 2008 failed two auctions held in February 2008, as the amount of securities submitted for sale has exceeded the amount of purchase orders. The Company will continue to attempt to sell this $3 million investment security every seven days until an auction is successful. The Company's other $9 million of investments in auction note securities have their next scheduled auction dates in March 2008. As of December 31, 2007, the Company has not recorded any losses or impairment charges related to its auction note securities since there was no temporary or other-than-temporary decline in value in the securities in either 2007 or 2008.

If uncertainties in the credit and capital markets continue, these markets deteriorate further or the Company experiences any ratings downgrades on the auction note securities in its portfolio, the Company may incur impairments to its investment portfolio, which could negatively affect its financial condition, cash flow and reported earnings, and the lack of liquidity of its auction note securities could have a material impact on the Company's financial flexibility and ability to fund its operations.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 4 — Property, Plant and Equipment

(In Thousands)	December 31, 2007	December 31, 2006
Manufacturing suite and equipment	$11,224	$8,162
Lab equipment	19	38
Leasehold improvements	36	16
Office furniture and equipment	315	311
Computers, software and related equipment	391	318
	11,985	8,845
Accumulated depreciation and amortization	(488)	(356)
Net book value	$11,497	$8,489

The Company has incurred, and will continue to incur, manufacturing capital expenditures relating to the scale-up for larger scale production. Accordingly, the Company's manufacturing suite and equipment costs is not yet in production and is not amortized or depreciated until it is ready for its intended use.

Depreciation expense for the years ended December 31, 2007, 2006 and 2005 was approximately $137,000, $139,000 and $102,000, respectively. The following table summarizes depreciation expense for the years ended December 31, 2007, 2006 and 2005.

	For the Year Ended December 31		
(In Thousands)	2007	2006	2005
Depreciation expense:			
Cost of services	$ —	$ 2	$ 4
Research and development	92	90	72
General and administrative	45	47	26
Total	$137	$139	$102

Note 5 — Other Assets

(In Thousands)	December 31, 2007	December 31, 2006
Patents and other intangible assets	$ 352	$1,007
Long-term deposits	322	322
Deferred registration fees	22	22
	696	1,351
Accumulated amortization	(352)	(393)
	$ 344	$ 958

Amortization expense for the years ended December 31, 2007, 2006 and 2005 was approximately $14,000, $84,000 and $88,000, respectively. The Company does not expect to record amortization expenses going forward, as all intangible assets are fully amortized. In addition, for the year ended December 31, 2007, the Company recorded an impairment charge in the amount of $600,000 related to certain intangibles associated with Accumin's diagnostic product.

Note 6 — Acquisition

On April 6, 2006, Accumin Diagnostics, Inc. ("ADI"), a wholly-owned subsidiary of the Company, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. ("AusAm"). The Company believes that the

Note 6 — Acquisition – (continued)

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

The purchase price of Accumin was $3,996,000, which included the issuance of 245,024 shares of the Company's common stock, the assumption of certain liabilities of AusAm equal to approximately $345,000 and transaction costs and cash settlement costs of approximately $341,000. ADI also entered into a royalty arrangement under which ADI may be required to pay up to a maximum of $16.1 million to AusAm on revenue from a next generation product following Food and Drug Administration marketing approval. Keryx filed a registration statement on Form S-3 with the SEC on April 6, 2006 with respect to the shares issued to AusAm which was declared effective on June 23, 2006 (the "Effective Date"). On the Effective Date, 245,024 shares were released from escrow to AusAm.

Subsequent to the closing, disputes arose between AusAm and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, AusAm filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145. (In re: AusAm Biotechnologies, Inc., Chapter 11 Case No. 06-10214 (RDD) (Bankr. S.D.N.Y.)). The matter has been settled pursuant to a settlement agreement approved by the Bankruptcy Court on April 10, 2007. In April 2007, under the settlement, Keryx paid AusAm $110,075 in full settlement of all claims made by AusAm in the action. Following completion of the settlement, 15,646 shares of the Company's common stock, which were issued and outstanding and held in escrow, were canceled.

The Accumin transaction has been accounted for as a purchase by the Company. Under the purchase method of accounting, the assets and liabilities assumed from AusAm are recorded at the date of acquisition at their respective fair values. The consolidated financial statements and reported results of operations of the Company issued after completion of the transaction reflect these values.

The following represents the purchase price for Accumin:

(In Thousands, Except Share and Per Share Amounts)		
Assumed liabilities		$ 345
Number of shares of Keryx common stock issued	245,024	
Multiplied by Keryx's average closing bid price per share as quoted on NASDAQ over a period of 5 trading days (2 days prior to the Effective Date, the Effective Date, and 2 days after the Effective Date)	$ 13.51	3,310
Other transaction costs and cash settlement costs		341
Total purchase price		$3,996

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

Note 6 — Acquisition – (continued)

The purchase price allocation, which is considered final, is based on an estimate of the fair value of net assets acquired.

(In Thousands)	
Allocation of purchase price:	
Tangible assets acquired	$ 132
Amortizable intangibles (over 12 years — patent life)	656
Goodwill	3,208
Purchase price	$3,996

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

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

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

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

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

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

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

Note 7 — License Agreements

In September 2007, the Company entered into a licensing agreement with Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii"), JT's pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive rights for the development and commercialization of Zerenex in Japan. JT and Torii will be responsible for the future development and commercialization costs in Japan. An upfront payment of $12.0 million, which was received in October 2007, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last-to-expire patent covered by the agreement in 2023, and represents the estimated period over which the Company will have significant responsibilities under the license agreement. As of December 31, 2007, the Company has recognized approximately $204,000 of license revenue. At December 31, 2007, the Company had deferred revenue of approximately $11.8 million (approximately $774,000 of which has been classified as a current liability) associated with this license agreement. The Company may receive up to an additional $88.0 million in up-front license fees and payments upon the achievement of pre-specified milestones. In addition, upon commercialization, JT and Torii will make royalty payments to the Company on net sales of Zerenex in Japan.

In October 2004, the Company entered into a termination agreement with Yissum Research and Development Company of the Hebrew University of Jerusalem ("Yissum"), whereby in consideration for the Company's agreement to a termination of certain license rights, Yissum agreed to pay the Company thirty three and one-third percent of any cash consideration received by Yissum relating to the terminated license rights, up to $6.0 million. In December 2007, the Company recognized $726,600 of other revenue, which was received net of $36,330 of income tax withheld, related to this termination agreement. Payments from Yissum are recognized as earned since the Company has no responsibilities under the terminated license agreement or the termination agreement.

Note 8 — Contingent Equity Rights

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 former 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 3 (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

Note 8 — Contingent Equity Rights – (continued)

- 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. The excess of the net assets acquired over the purchase price represented negative goodwill of approximately $4,004,000. Since the negative goodwill is a result of not recognizing contingent consideration (i.e., the contingent equity rights), the lesser of the negative goodwill ($4,004,000) and the maximum value of the contingent equity rights at the date of the acquisition ($34,275,000) has been recorded as a liability, thereby eliminating the negative goodwill. The value of the contingent equity rights of $34,275,000 was based on the volume-adjusted weighted average closing price per share of the Company's common stock measured over the last seven trading days immediately preceding the closing of the acquisition ($10.15 per share) multiplied by 3,376,855 shares, which consist of the sum of the unissued amount of the Company's common stock deliverable to the ACCESS Oncology stockholders as milestone consideration (3,372,422 shares) and to those preferred stockholders of ACCESS Oncology who have yet to provide the necessary documentation to receive shares of the Company's common stock (4,433 shares).

Note 9 — Stockholders' Equity

Preferred Stock

The Company's amended and restated certificate of incorporation allows it to issue up to 5,000,000 shares of preferred stock, $0.001 par value, with rights senior to those of the common stock.

Common Stock

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

On March 29, 2006, the Company completed a registered direct offering of 4,500,000 shares of its common stock to two institutional investors at $18.40 per share. Total proceeds to the Company from this public offering were approximately $82.7 million, net of offering expenses of approximately $0.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-130809) filed with the Securities and Exchange Commission, or SEC, on December 30, 2005, and declared effective by the SEC on January 13, 2006, covering shares of the Company's Common Stock having a value not to exceed $150 million.

The Company may offer the remaining securities under its shelf registration from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interest of the Company and its stockholders. The Company believes that the shelf registration provides it with the flexibility to raise additional capital to finance its operations as needed.

During 2006, the Company issued 245,024 shares of its common stock, valued at approximately $3,310,000, to AusAm, in connection with the Company's purchase of Accumin, which closed on April 6, 2006. (See Note 6 above).

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

Note 9 — Stockholders' Equity – (continued)

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.

In June 2004, the Company's stockholders approved an amendment to the Company's amended and restated certificate of incorporation increasing by 20 million the number of shares of authorized common stock to 60 million shares.

In June 2004, the Company's stockholders approved the delisting of the Company's common stock from the Alternative Investment Market of the London Stock Exchange, which became effective on August 10, 2004.

During 2004, the Company issued 623,145 shares of its common stock, valued at approximately $6,325,000, to the preferred stockholders of ACCESS Oncology, in connection with the Company's merger with ACCESS Oncology, which closed on February 5, 2004. 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. In addition, up to 3,372,422 shares of the Company's common stock are deliverable to the ACCESS Oncology stockholders as contingent milestone consideration pursuant to the merger agreement. The Company's stockholders approved the issuance of shares of its common stock payable as contingent milestone consideration in June 2004 (see Note 8 above).

On February 17, 2004, the Company completed a private placement of approximately 3.2 million shares of its common stock to institutional investors at $10.00 per share. Total net proceeds of this private placement were approximately $31.7 million, net of offering expenses of approximately $0.3 million. In connection with this private placement, the Company filed a Registration Statement on Form S-3 (File No. 333-113654) on March 16, 2004, and Amendment No. 1 to the Registration Statement on Form S-3/A on April 1, 2004, which was declared effective by the SEC on May 3, 2004.

On November 20, 2003, the Company completed a private placement of approximately 3.5 million shares of its common stock together with warrants for the purchase of an aggregate of 705,883 shares of its common stock at an exercise price of $6.00 per share. Total proceeds of this private placement were approximately $14.1 million, net of offering expenses of approximately $0.9 million. In addition, the Company issued to the placement agent a warrant to purchase 50,000 shares of its common stock at an exercise price of $6.00. In connection with the private placement, the Company filed a Registration Statement of Form S-3 (File No. 333-111133) on December 12, 2003, and Amendment No. 1 to the Registration Statement on Form S-3/A on December 19, 2003, which was declared effective by the SEC on December 19, 2003.

During 2002, the Company issued a total of 48,491 unregistered shares of its common stock with a fair value at issue date of $7.40 per share, or approximately $359,000, to third parties.

The Company completed its initial public offering of 4.6 million shares of its common stock at $10.00 per share pursuant to a Registration Statement on Form S-1 (File No. 333-37402), which was effective on July 28, 2000. Additionally, the underwriters exercised their over-allotment option and purchased an additional 600,000 shares of the Company's common stock, at $10.00 per share, on August 30, 2000. Total proceeds of this offering, including the exercise of the over-allotment option, were approximately $46.3 million, net of underwriting fees and offering expenses of approximately $5.7 million.

Note 9 — Stockholders' Equity – (continued)

Treasury Stock

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

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

The Company repurchased 9,800 shares of its common stock at an aggregate cost of approximately $12,000 and 46,300 shares of its common stock at an aggregate cost of approximately $77,000 during the years ended December 31, 2003 and 2002, respectively, pursuant to the stock repurchase program approved by the Company's Board of Directors in November 2002. At December 31, 2003, the stock repurchase program ended.

Equity Incentive Plans

The Company has in effect the following stock option and incentive plans.

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

b. The 2000 Stock Option Plan was adopted in June 2000. Under the 2000 Stock Option Plan the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants and employees. The 2000 plan authorizes grants to purchase up to 4,455,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 10 years from the date of the grant, unless authorized by the board. As of December 31, 2007, up to 64,379 additional shares may be issued under the 2000 Stock Option Plan.

c. The 2002 CEO Incentive Stock Option Plan was adopted in December 2002. Under the 2002 CEO Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed Chief Executive Officer of the Company to purchase up to 2,002,657 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Executive Officer was part of a total grant of options issued pursuant to the 1999 Stock Option Plan, the 2000 Stock Option Plan and the 2002 CEO Incentive Stock Option Plan, to purchase a total of 4,050,000 shares of the Company's common stock. As of December 31, 2007, the option granted under the 2002 CEO Incentive Stock Option Plan has fully vested. In the event of a merger, acquisition or other change of control or in the event that the Company terminates the Chief Executive Officer's employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or December 24, 2012. No additional shares of our common stock may be issued under the 2002 CEO Incentive Stock Option Plan.

Note 9 — Stockholders' Equity – (continued)

d. The 2004 President Incentive Stock Option Plan was adopted in February 2004. Under the 2004 President Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed President of the Company to purchase up to 1,000,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed President was made pursuant to an employment agreement following the acquisition of ACCESS Oncology in February 2004. Of this option, 166,667 vests over a three-year period and 833,333 vests upon the earlier of the achievement of certain performance-based milestones or February 5, 2011. As of December 31, 2007, 500,000 options have vested under this plan. In addition, in the event of a merger, acquisition or other change of control or in the event that the Company terminates the President's employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the exercisability of any of the options described in this paragraph that are unexercisable at the time of such event or termination shall accelerate and the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or February 5, 2014. Additionally, the Company's board of directors shall have the discretion to accelerate all or a portion of these options at any time. No additional shares of our common stock may be issued under the 2004 President Incentive Stock Option Plan.

e. The 2004 Long-Term Incentive Plan was adopted in June 2004 by our stockholders. Under the 2004 Long-Term Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants and employees. The 2004 plan authorizes grants to purchase up to 4,000,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 10 years from the date of their grant. As of December 31, 2007, up to an additional 222,810 shares may be issued under the 2004 Long-Term Incentive Plan.

f. The 2007 Chief Accounting Officer Inducement Stock Option Plan (the "2007 CAO Plan") was adopted in March 2007. Under the 2007 CAO Plan, the Company's board of directors granted an option to the newly-appointed Chief Accounting Officer of the Company to purchase up to 100,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Accounting Officer was made pursuant to an employment arrangement. Of these options, 25,000 vest on the one-year anniversary of employment and 6,250 vest every three months following the one-year anniversary of employment, until the 48th month of employment. No additional shares of our common stock may be issued under the 2007 CAO Plan.

g. The 2007 General Counsel Incentive Stock Option Plan (the "2007 GC Plan") was adopted in April 2007. Under the 2007 GC Plan, the Company's board of directors granted an option to the newly-appointed General Counsel of the Company to purchase up to 150,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed General Counsel was made pursuant to an employment arrangement. Of these options, 37,500 vest on the one-year anniversary of employment and 9,375 vest every three months following the one-year anniversary of employment, until the 48th month of employment. No additional shares of our common stock may be issued under the 2007 GC Plan.

h. The 2007 Incentive Plan was adopted in June 2007 by our stockholders. Under the 2007 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2007 Incentive Plan authorizes grants to purchase up to 6,000,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of their grant. As of December 31, 2007, up to an additional 5,220,431 shares may be issued under the 2007 Incentive Plan.

Note 9 — Stockholders' Equity – (continued)

The following table summarizes stock option activity for the year ended December 31, 2007:

	Number of Shares	Weighted-Average Exercise Price	Weighted-Average Contractual Term	Aggregate Intrinsic Value
			(In Years)	(In Millions)
Outstanding at December 31, 2006	10,784,713	$ 7.87		
Granted	1,235,769	9.67		
Exercised	(138,412)	1.96		$ 1.3
Forfeited	(544,730)	14.48		
Expired	(468,167)	11.31		
Outstanding at December 31, 2007	10,869,173	$ 7.69	6.9	$31.1
Vested and expected to vest at December 31, 2007	10,768,822	$ 7.65	6.9	$31.1
Exercisable at December 31, 2007	7,306,546	$ 5.71	6.2	$31.1

The following table summarizes information about stock options outstanding at December 31, 2007:

	Options Outstanding			Options Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighed-Average Exercise Price	Number Exercisable	Weighed-Average Exercise Price
$ 0.10 – $ 2.14	4,175,987	5.7	$ 1.24	4,175,987	$ 1.24
3.01 – 8.98	926,599	8.3	7.18	346,911	5.02
9.25 – 12.81	2,890,878	7.1	10.47	1,432,998	10.64
13.00 – 18.06	2,875,709	8.2	14.42	1,350,650	14.50
$ 0.10 – $18.06	10,869,173	6.9	$ 7.69	7,306,546	$ 5.71

Upon the exercise of stock options, the Company issues new shares. As of December 31, 2007, 3,453,833 options issued to employees and directors, and 93,000 options issued to consultants, are milestone-based, of which 3,218,833 options issued to employees and directors, and 43,000 options issued to consultants, are vested and exercisable.

Certain employees and consultants have been awarded restricted stock under the 2004 Long-Term Incentive Plan and 2007 Incentive Plan. The restricted stock vests primarily over a period of two to four years. The following table summarizes restricted share activity for the year ended December 31, 2007:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
			(In Millions)
Outstanding at December 31, 2006	100,000	$15.30	
Granted	195,000	10.28	
Vested	(73,332)	11.77	$0.8
Forfeited	(83,334)	15.30	
Outstanding at December 31, 2007	138,334	$10.09	$1.2

Note 9 — Stockholders' Equity – (continued)

Shares available for the issuance of stock options or other stock based awards under our stock option and incentive plans were 5,507,620 at December 31, 2007.

Warrants

	Warrants	Weighted-Average Exercise Price	Aggregate Intrinsic Value
			(In Millions)
Outstanding at December 31, 2006	321,976	$4.65	
Issued	—	—	
Exercised	—	—	$—
Canceled	—	—	
Outstanding at December 31, 2007	321,976	$4.65	$1.2

As of December 31, 2007, 753,893 warrants have been exercised and no warrants have been cancelled as part of cashless exercises. The terms of outstanding warrants as of December 31, 2007 are as follows:

	Warrants Outstanding			Warrants Exercisable	
Range of Exercise Prices	Number Outstanding	Weighted-Average Remaining Contractual Life (Years)	Weighed-Average Exercise Price	Number Exercisable	Weighed-Average Exercise Price
$0.01	72,564	2.0	$0.01	72,564	$0.01
6.00	249,412	0.9	6.00	249,412	6.00
	321,976	1.1	$4.65	321,976	$4.65

Stock-Based Compensation

The fair value of stock options granted was estimated at the date of grant using the Black-Scholes model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of the Company's common stock and the Company's assessment of its future volatility. The risk-free interest rate is based on the U.S. Treasury yield for a period consistent with the expected term of the option in effect at the time of the grant. The Company has assumed no expected dividend yield, as dividends have never been paid to stock or option holders and will not be for the foreseeable future.

Black-Scholes Option Valuation Assumptions	2007	2006	2005
Risk-free interest rates	4.1%	4.7%	3.7%
Dividend yield	—	—	—
Volatility	68.4%	78.3%	84.9%
Weighted-average expected term	4.8 years	3.1 years	4.9 years

The weighted average grant date fair value of options granted was $5.69, $7.79 and $7.84 for the years ended December 31, 2007, 2006 and 2005, respectively. The Company used historical information to estimate forfeitures within the valuation model. As of December 31, 2007, there was $17.3 million and $1.1 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over a weighted-average period of 2.5 years and 1.8 years, respectively.

Note 9 — Stockholders' Equity – (continued)

The amounts do not include, as of December 31, 2007, 285,000 options outstanding, which are milestone-based and vest upon certain corporate milestones, such as FDA approval of our drug candidates and market capitalization targets. Stock-based compensation will be measured and recorded if and when a milestone occurs.

The following table summarizes stock-based compensation expense information about stock options, restricted stock and warrants for the years ended December 31, 2007 and 2006:

(In Thousands)	Year Ended December 31, 2007	Year Ended December 31, 2006
Stock-based compensation expense associated with restricted stock	$ 1,028	$ 189
Stock-based compensation expense associated with option grants+	9,632	14,723
Stock-based compensation expense associated with warrants	—	—
	$10,660	$14,912

\+ Includes additional non-cash compensation expense during the year ended December 31, 2006 of $1,697, relating to previous grants made to a former officer and two former directors. The Board of Directors agreed to modify their option agreements in 2006 such that their vesting and exercisability has been extended beyond the terms of their original agreements.

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

(In Thousands, Except Per Share Amounts)	For the Year Ended December 31, 2005	Amounts Accumulated During the Development Stage through December 31, 2005
Net loss, as reported	$(26,895)	$(114,448)
Add: Stock-based compensation expense to employees and directors determined under the intrinsic value-based method, as included in reported net loss	445	10,179
Deduct: Stock-based compensation expense to employees and directors determined under fair value based method	(3,797)	(20,216)
Pro forma net loss	$(30,247)	$(124,485)
Basic and diluted loss per common share:		
As reported	$ (0.78)	$ (6.34)
Pro forma	$ (0.88)	$ (6.89)

Note 9 — Stockholders' Equity – (continued)

For the year ended December 31, 2005, the Company did not record any stock-based compensation expense related to its warrants or restricted stock, as all warrants were vested and no shares of restricted stock were outstanding. Unvested warrants are revalued at every reporting period and amortized over the vesting period in order to determine the compensation expense. The value of these warrants had been estimated using the Black-Scholes model. No warrants or shares of restricted stock were issued in 2005.

Note 10 — Fair Value of Financial Instruments

The Company's financial instruments at December 31, 2007 and 2006 consisted of cash and cash equivalents, investment securities, accrued interest receivable, and accounts payable and accrued expenses.

The carrying amounts of all the financial instruments noted above, except for investment securities, approximate fair value for all years presented due to the relatively short maturity of these instruments. The carrying amount for investment securities (held-to-maturity) are based on the amortized cost for these investments at the reporting date. The difference between the carrying value and fair value of investment securities held-to-maturity is set forth in Note 3 above. The carrying amount of available-for-sale investment securities (auction notes) is based on cost, which approximates fair value due to the rate re-pricing mechanism.

Note 11 — Income Taxes

As of December 31, 2007, the Company has U.S. net operating loss carryforwards of approximately $210 million which expire from 2019 through 2027. In addition, as of the date of the acquisition, ACCESS Oncology had U.S. net operating loss carryforwards of $14.9 million that start to expire in December 2019. Deferred tax assets of Partec were lost upon assumption of operations by the Company (see Note 1 — Organization and Summary of Significant Accounting Policies).

The Company has established a valuation allowance against its net deferred tax assets due to the Company's pre-tax losses and the resulting likelihood that the deferred tax assets are not realizable. The valuation allowance for deferred tax assets was $119.2 million and $95.0 million as of December 31, 2007 and 2006, respectively. At December 31, 2007, deferred tax assets have not been recorded on net operating loss carryforwards for certain stock option deductions of $4.7 million. If the entire deferred tax asset were realized, $15.1 million would be allocated to paid-in-capital related to the tax effect of compensation deductions from the exercise of employee and consultant stock options. Due to the Company's various equity transactions, the utilization of certain tax loss carryforwards could be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision.

Note 11 — Income Taxes – (continued)

The tax expense reported during the development stage primarily related to the subsidiaries in Israel. The Company recorded $36,000 in income tax expense for the year ended December 31, 2007, as a result of income tax withheld associated with the Yissum revenue (see Note 7). No income tax expense was attributable to income from continuing operations for the years ended December 31, 2006 and 2005, respectively, and differed from amounts computed by applying the US federal income tax rate of 35% to pretax loss.

	For the Year Ended December 31,		
(In Thousands)	2007	2006	2005
Losses before taxes on income, as reported in the consolidated statements of operations	$(90,026)	$(73,764)	$(26,895)
Computed "expected" tax benefit	(31,509)	(25,817)	(9,413)
Increase (decrease) in income taxes resulting from:			
Expected benefit from state & local taxes	(4,624)	(8,154)	(3,379)
Change in state and local effective tax rate	4,555	(831)	(3,130)
Unrecognized compensation deduction	7,053	—	—
Permanent differences	447	1,067	(571)
Witholding tax	36	—	—
Other	159	—	—
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	23,919	33,735	16,493
	$ 36	$ —	$ —

The significant components of deferred income tax expense (benefit) attributable to loss from operations are as follows:

	For the Year Ended December 31,		
(In Thousands)	2007	2006	2005
Deferred tax benefit	$(24,186)	$(37,129)	$(18,931)
Federal deferred tax benefit relating to the exercise of stock options	267	3,394	2,438
Increase in the valuation allowance for deferred tax assets	23,919	33,735	16,493
	$ —	$ —	$ —

Note 11 — Income Taxes – (continued)

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2007 and 2006 are presented below.

(In Thousands)	December 31, 2007	December 31, 2006
Deferred tax assets/(liabilities):		
Net operating loss carryforwards	$ 94,315	$ 78,235
Net operating loss carryforwards (ACCESS Oncology)	6,128	6,128
Non-cash compensation	10,980	7,843
Deferred revenue	5,069	—
Research and development	1,397	1,977
Intangible assets due to different amortization methods	1,203	730
Accrued compensation	30	19
Other temporary differences	67	72
Net deferred tax asset, excluding valuation allowance	119,189	95,004
Less valuation allowance	(119,189)	(95,004)
Net deferred tax assets	$ —	$ —

The Company's tax returns for the fiscal years ended December 31, 2004, 2005, and 2006 are currently under examination by the IRS. The Company is also subject to audits by various state and foreign taxing authorities. The Company regularly reevaluates its tax positions and the associated interest and penalties, if applicable, resulting from audits of federal, state and foreign income tax filings, as well as changes in tax law that would reduce the technical merits of the position to below more likely than not. Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken, or expected to be taken, in a tax return because of the uncertainties described above. The Company's balance of unrecognized tax benefits is $7.05 million at December 31, 2007 and relates primarily to deductions taken in 2004 and 2005 for compensation expense of certain former foreign employees. If recognized, these unrecognized tax benefits would have no net impact, as they would be fully reserved by a valuation allowance. The Company expects a settlement of its December 31, 2007 uncertain tax benefit balance within the next twelve months.

The Company accounts for interest and penalties related to uncertain tax positions, if any, in selling, general and administrative expense. As of December 31, 2007 the Company has not accrued any interest and penalties.

Note 12 — Interest and Other Income, Net

The components of interest and other income, net are as follows:

	For the Year Ended December 31,		
(In Thousands)	2007	2006	2005
Interest income	$4,550	$6,378	$2,317
Other income	5	15	—
	$4,555	$6,393	$2,317

In 2007 and 2006, other income consisted of rental income from a related-party that terminated in 2007.

Note 13 — Commitments and Contingencies

Research & Development Agreements

The Company has entered into various research and development agreements (primarily relating to the Company's pivotal Phase 3 and Phase 4 clinical program for Sulonex) under which it is obligated to make payments of approximately $46,529,000 through December 2010. The following table shows future research and development payment obligations by period as of December 31, 2007.

(In Thousands)	2008	2009	2010	2011	2012
Research and development agreements	$23,910	$19,210	$3,409	—	—

The table above includes certain commitments that are contingent upon our continuing development of our drug candidates.

Leases

The Company leases its office space under lease agreements that expire through 2010. Total rental expense was approximately $723,000, $658,000 and $514,000 for the years ended December 31, 2007, 2006, and 2005, respectively.

Future minimum lease commitments as of December 31, 2007, in the aggregate total approximately $1,780,000 through 2010. The following table shows future minimum lease commitments by period as of December 31, 2007.

(In Thousands)	2008	2009	2010	2011	2012
Operating leases	$724	$597	$459	—	—

During 2004, the Company entered into a lease arrangement with its President, Dr. Craig Henderson, for the utilization of part of his residence for office space associated with the Company's employees in San Francisco, California. The Company has expensed $65,000, $49,000 and $48,000 in 2007, 2006 and 2005, respectively, pursuant to the terms of this arrangement, which $28,000 and $44,000 have been included in accounts payable and accrued expenses in the accompanying balance sheets as of December 31, 2007 and 2006, respectively. The 2005 and 2006 amounts have been paid. Of the 2007 amount, $28,000 is yet to be paid.

Royalty and Contingent Milestone Payments

The Company has licensed the patent rights to its drug candidates from others. These license agreements require the Company to make contingent milestone payments to certain of its licensors. In addition, under these agreements, the Company must pay royalties on sales of products resulting from licensed technologies.

The Company has undertaken to make contingent milestone payments to certain of our licensors of up to approximately $93.8 million over the life of the licenses, of which approximately $74.5 million will be due upon or following regulatory approval of the licensed drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, the Company remains obligated to pay three licensors $50,000, $75,000, and $22,500, respectively, annually until the licenses expire. As of December 31, 2007, the Company has recorded a total of approximately $8.1 million in license and milestone payments in regard to these license agreements since inception.

The Company has also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights (up to 3,372,422 shares of the Company's common stock) if its drug candidates meet certain development milestones (see Note 8 — Contingent Equity Rights). The Company has also entered into a royalty arrangement under which its wholly-owned subsidiary may be required to pay up to a maximum of $16.1 million to AusAm.

Note 14 — Bonus to Officer

Pursuant to his employment agreement, the Chief Executive Officer of the Company was entitled to receive a one-time $2 million cash bonus due to the achievement of a corporate milestone that occurred, and was expensed and paid in 2006. Of this amount, $1,000,000 was included in other research and development expenses and $1,000,000 was included in other selling, general and administrative expenses for the year ended December 31, 2006.

Note 15 — Segment Information

The Company has three reportable segments: Diagnostics, Services and Products. The Diagnostics business sells diagnostic products for the direct measurement of total, intact urinary albumin. The Services business provides clinical trial management and site recruitment services to other biotechnology and pharmaceutical companies. The Products business focuses on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer, and also includes license revenue, other revenue and associated costs.

Segment information for the years ended December 31, 2007, 2006 and 2005 was as follows:

	Revenue			
(In Thousands)	2007	2006	2005	Amounts Accumulated During the Development Stage
Diagnostics	$ 66	$103	$ —	$ 169
Services	52	431	574	1,866
Products	931	—	—	931
Total	$1,049	$534	$574	$2,966

	Operating Loss			
(In Thousands)	2007	2006	2005	Amounts Accumulated During the Development Stage
Diagnostics	$ (756)	$ (1,016)	$ —	$ (1,772)
Services	(72)	41	(245)	(302)
Products	(93,753)	(79,182)	(28,967)	(293,590)
Total	$(94,581)	$(80,157)	$(29,212)	$(295,664)

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

	Net Loss			
(In Thousands)	2007	2006	2005	Amounts Accumulated During the Development Stage
Operating losses of reportable segments	$(94,581)	$(80,157)	$(29,212)	$(295,664)
Interest and other income	4,555	6,393	2,317	17,917
Income taxes	(36)	—	—	(527)
Consolidated net loss	$(90,062)	$(73,764)	$(26,895)	$(278,274)

Note 15 — Segment Information – (continued)

(In Thousands)	Assets[1] As of December 31, 2007	2006
Diagnostics	$ 87	$ 734
Services	—	116
Products	16,293	13,853
Total assets of reportable segments	16,380	14,703
Cash and cash equivalents[2]	64,681	125,610
Consolidated total assets	$81,061	$140,313

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

(2) Includes cash, cash equivalents, interest receivable and investment securities.

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

(In Thousands)	Goodwill December 31, 2007	December 31, 2006
Diagnostics	—	—
Services	—	—
Products	$3,208	$3,208
Total	$3,208	$3,208

As of December 31, 2007, management concluded that there is no impairment to its goodwill.

Note 16 — Litigation

In July 2003, Keryx (Israel) Ltd., one of the Company's Israeli subsidiaries, vacated its Jerusalem facility, after giving advance notice to RMPA Properties Ltd., the landlord. On May 1, 2005, the landlord filed suit in the Circuit Court of Jerusalem in Jerusalem, Israel, claiming that Keryx (Israel) Ltd., among other parties, was liable as a result of the alleged breach of the lease agreement. In addition to Keryx (Israel) Ltd., the landlord brought suit against Keryx Biomedical Technologies Ltd., another of the Company's Israeli subsidiaries, Keryx Biopharmaceuticals, Inc., Michael S. Weiss, the Company's Chairman and Chief Executive Officer, and Robert Trachtenberg, a former employee of Keryx. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,208,000, and includes rent for the entire remaining term of the lease, as well as property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. The Company intends to vigorously defend the suit. In July 2005, Keryx (Israel) Ltd. and Keryx Biomedical Technologies Ltd. filed an answer to the landlord's complaint. In October 2005, Keryx Biopharmaceuticals, Inc. filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. and Michael S. Weiss to vacate service of process outside of Israel was held in June 2006. On October 15, 2006, the Court held that the service of the claim against Mr. Weiss is vacated. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. However, the service against the Company was sustained. The Company appealed this holding. The appeal was denied on

Note 16 — Litigation – (continued)

June 18, 2007, and the Company filed a petition for certiorari to the Supreme Court of Israel. The Company's motion for certiorari was denied as well. The next preliminary hearing is scheduled for February 28, 2008. The Company has not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

The Company is engaged in an arbitration proceeding with Alfa Wasserman concerning certain terms of the License Agreement related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. An arbitration proceeding was held in October 2007 and the Company is awaiting decision from the arbitrator. The outcome of the arbitration should not affect the validity of the license, but whether the Company is required to share data with Alfa Wasserman for that company's use outside of the Company's licensed territories and its ongoing management of the licensed patent portfolio. Alfa Wasserman also seeks unspecified damages. If the arbitrator determines that the Company owes Alfa Wasserman the data, and that failure to deliver such data constitutes a material breach of the License Agreement, then the Company will have 28 days to cure such breach following the final arbitration decision by delivering any data required to be provided. Failure to cure would entitle Alfa Wasserman to terminate the License Agreement.

In November 2007, the Company initiated an action in the US District Court for the Southern District of New York against Panion to enjoin Panion from improperly terminating the November 2005 License Agreement for an alleged breach of contract by Keryx related to certain manufacturing provisions of the agreement, to enjoin Panion from interfering with Keryx's contractual relationships with certain third-parties, as well as to enforce Keryx's right with respect to the prosecution of certain patents. On November 27, 2007, the Court granted Keryx's motion for a preliminary injunction. Panion has since asserted counterclaims for breach of contract relating to certain manufacturing provisions of the license agreement and the parties have reached a tentative agreement to settle the litigation. If the parties are unable to resolve the matter by a settlement, the Company will proceed with the action to resolve the parties' respective claims, in which event Keryx will incur significant legal expenses. The matter is currently scheduled for trial in the second half of 2008. In the event that Keryx is found to be in breach of contract, it will have thirty days in which to cure such breach before Panion can terminate the agreement based on the alleged breach.

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 17 — Quarterly Consolidated Financial Data (Unaudited)

	2007			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(In Thousands, Except Per Share Data)			
Revenue:				
License revenue	$ —	$ —	$ 41	$ 163
Diagnostic revenue	30	36	—	—
Service revenue	12	14	11	15
Other revenue	—	—	—	727
Total revenue	42	50	52	905
Operating expenses:				
Cost of diagnostics sold	22	16	—	—
Cost of services	32	30	28	34
Research and development:				
Non-cash compensation	995	1,178	735	666
Other research and development	17,446	15,685	15,967	25,791
Total research and development	18,441	16,863	16,702	26,457
Selling, general and administrative:				
Non-cash compensation	2,006	1,407	1,780	1,893
Other selling, general and administrative	2,795	2,394	2,087	2,643
Total selling, general and administrative	4,801	3,801	3,867	4,536
Total operating expenses	23,296	20,710	20,597	31,027
Operating loss	(23,254)	(20,660)	(20,545)	(30,122)
Other income (expense)				
Interest and other income, net	1,441	1,200	1,017	897
Income taxes	—	—	—	36
Net loss	$(21,813)	$(19,460)	$(19,528)	$(29,261)
Net loss per common share				
Basic and diluted	$ (0.50)	$ (0.45)	$ (0.45)	$ (0.67)

NOTES TO THE CONSOLIDATED FINANCIAL STATEMENTS

Note 17 — Quarterly Consolidated Financial Data (Unaudited) – (continued)

	2006			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(In Thousands, Except Per Share Data)			
Revenue:				
Diagnostic revenue	$ —	$ 23	$ 35	$ 45
Service revenue	112	224	39	56
Total revenue	112	247	74	101
Operating expenses:				
Cost of diagnostics sold	—	19	50	71
Cost of services	171	98	29	92
Research and development:				
Non-cash compensation	2,724	2,104	1,378	298
Other research and development	12,333	12,352	14,950	16,504
Total research and development	15,057	14,456	16,328	16,802
Selling, general and administrative:				
Non-cash compensation	2,817	3,541	1,481	569
Other selling, general and administrative	2,645	1,860	2,041	2,564
Total selling, general and administrative	5,462	5,401	3,522	3,133
Total operating expenses	20,690	19,974	19,929	20,098
Operating loss	(20,578)	(19,727)	(19,855)	(19,997)
Other income (expense)				
Interest and other income, net	982	1,899	1,862	1,650
Net loss	$(19,596)	$(17,828)	$(17,993)	$(18,347)
Net loss per common share				
Basic and diluted	$ (0.51)	$ (0.41)	$ (0.42)	$ (0.42)

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) 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: February 27, 2008

By: /s/ Michael S. Weiss
Michael S. Weiss
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael S. Weiss and Mark Stier, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments to this annual report on Form 10-K, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Form 10-K has been signed by the following persons on behalf of the Registrant on February 27, 2008, and in the capacities indicated:

Signatures	Title
/s/ Michael S. Weiss Michael S. Weiss	Chairman and Chief Executive Officer (principal executive officer)
/s/ Mark Stier Mark Stier	Chief Accounting Officer (principal financial officer)
/s/ I. Craig Henderson, M.D. I. Craig Henderson, M.D.	President and Director
/s/ Kevin Cameron Kevin Cameron	Director
/s/ Senator Wyche Fowler, Jr. Senator Wyche Fowler, Jr.	Director
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director
/s/ Jack Kaye, CPA Jack Kaye, CPA	Director
/s/ Eric A. Rose, M.D. Eric A. Rose, M.D.	Director
/s/ Michael P. Tarnok Michael P. Tarnok	Director

EXHIBIT INDEX

Exhibit Number	Exhibit Description
21.1	List of subsidiaries of Keryx Biopharmaceuticals, Inc.
23.1	Consent of KPMG LLP.
24.1	Power of Attorney of Director and Officers of Keryx Biopharmaceuticals, Inc. (included herein).
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 February 27, 2008.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated February 27, 2008.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated February 27, 2008.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated February 27, 2008.

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Weiss, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008

/s/ Michael S. Weiss
Michael S. Weiss
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2007 as filed with the Securities and Exchange Commission (the "Report"), I, Mark Stier, Chief Accounting Officer, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2008

/s/ Mark Stier

Mark Stier
Chief Accounting Officer
(Principal Financial Officer)

Exhibit 31.1

CERTIFICATION OF PERIODIC REPORT
PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael S. Weiss, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008

/s/ Michael S. Weiss

Michael S. Weiss
Chief Executive Officer
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATION OF PERIODIC REPORT PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002

I, Mark Stier, certify that:

1. I have reviewed this annual report on Form 10-K of Keryx Biopharmaceuticals, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the consolidated financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: February 27, 2008

/s/ Mark Stier

Mark Stier
Chief Accounting Officer
(Principal Financial Officer)

Exhibit 32.1

STATEMENT OF CHIEF EXECUTIVE OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2007 as filed with the Securities and Exchange Commission (the "Report"), I, Michael S. Weiss, Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2008

/s/ Michael S. Weiss

Michael S. Weiss
Chief Executive Officer
(Principal Executive Officer)

Exhibit 32.2

STATEMENT OF CHIEF FINANCIAL OFFICER OF
KERYX BIOPHARMACEUTICALS, INC.
PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the annual report of Keryx Biopharmaceuticals, Inc. (the "Company") on Form 10-K for the period ended December 31, 2007 as filed with the Securities and Exchange Commission (the "Report"), I, Mark Stier, Chief Accounting Officer, certify, pursuant to 18 U.S.C. §1350, as adopted pursuant to §906 of the Sarbanes-Oxley Act of 2002, that, based on my knowledge:

1) The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

2) The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: February 27, 2008

/s/ Mark Stier

Mark Stier
Chief Accounting Officer
(Principal Financial Officer)

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END