KERYX BIOPHARMACEUTICALS INC
Form 10-K
March 16, 2007

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

FORM 10-K

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2006.

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)

Registrant's telephone number, including area code: (212) 531-5965

Securities registered pursuant to Section 12(b) of the Act:
Common Stock, Par Value $0.001 Per Share
(Title of Class)

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 x

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 x

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes x No £

Indicate by check mark 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 x Non-accelerated filer £

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

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 $557,961,054 as of June 30, 2006, based on the closing sale price of such stock as reported on the Nasdaq Global Market.

There were 43,518,008 shares of the registrant's common stock outstanding as of March 8, 2007.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2007 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, 2006

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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™, Zerenex™, KRX-0401, 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.

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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 III and Phase IV clinical program under a Special Protocol Assessment, or SPA, with the Food & Drug Administration, or FDA. Additionally, we are developing Zerenex™, an oral, inorganic, iron-based compound that has the capacity to bind to phosphorous and form non-absorbable complexes. Zerenex is currently in Phase II clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. We are also developing clinical-stage oncology compounds, including KRX-0401, a novel, first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth, and a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase II clinical development for multiple tumor types. We also have an active in-licensing and acquisition program designed to identify and acquire additional drug candidates. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

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

Product candidate	**Target indication**	**Development status**
Endocrine/Renal		
Sulonex™	Diabetic nephropathy	Phase III & Phase IV
Zerenex™	Hyperphosphatemia in patients with end-stage renal disease	Phase II
Oncology		
KRX-0401	Multiple forms of cancer	Phase II
KRX-0402	Brain cancer	Phase II
KRX-0601	Multiple forms of cancer	Phase II
KRX-0404	Multiple forms of cancer	Pre-clinical
Neurology		
KRX-0501	Neurological disorders	Pre-clinical

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 maximal shareholder value.

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

- continue our pivotal Phase III and Phase IV program for Sulonex;
- begin to establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA;
- 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 and KRX-0601; 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 info@keryx.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™

Overview

Our lead compound under development is Sulonex (sulodexide), which we previously referred to as KRX-101. We own the exclusive rights to use 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 demonstrated in multiple clinical trials conducted in Europe and the U.S., including two randomized, double-blind, placebo-controlled Phase II studies, that Sulonex can reduce urinary protein excretion in patients with diabetic nephropathy. Sulonex is in a pivotal Phase III and Phase IV 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.

We plan to develop Sulonex in the United States, and possibly other countries where we have exclusive rights under our license, 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. 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, which is the precursor of what will eventually be excreted as urine, flows into the next serial component, 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. As the glycosaminoglycan negative charge provides normal filtering selectivity to the glomerular membranes, their 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 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.

Sulonex belongs to a proposed new class of nephroprotective, or kidney protecting, drugs, known as the glycosaminoglycans. A variety of members of this chemical family have been shown to decrease pathological albumin excretion in diabetic nephropathy in humans. Some of the members of this chemical family include the following approved drugs: standard heparin, low molecular weight heparin and danaparoid. These agents all require therapy by injection and are all potent anticoagulants, which are blood thinners capable of inducing bleeding. Sulonex, on the other hand, is given orally and, in this form, has demonstrated little, if any, anticoagulant effects to date.

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 II 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. 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 recently completed, U.S.-based pilot Phase II 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. We announced the results of this study at the American Society of Nephrology's Renal Week in November 2005. The results of the study are presented below.

Design of the Phase II Study

The Phase II study was designed as a pilot for the fully-powered pivotal Phase III study, which is currently ongoing. In this Phase II study, two doses of Sulonex (200 mg and 400 mg) were compared to placebo in patients with diabetic microalbuminuria on maximal therapy with an angiotensin converting enzyme inhibitor, known as an ACEi, or a angiotensin receptor blocker, known as 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 II 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 III 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 20mg of albumin to 1g of creatinine).

Phase II Data Analysis

A total of 149 patients were randomized into the study. All patients evaluable for therapeutic success at six months (i.e. all patients with a baseline ACR and a six-month ACR) were included in the intent to treat analysis, for a total of 136 patients. All patients in the intent to treat population that at baseline were within the target eligibility range of microalbuminuria as defined in the protocol (ACR 20mg/G to 200mg/G) were included in the per protocol analysis, for a total population of 117 patients.

All of the primary and secondary analyses shown were pre-specified. For the primary endpoint analysis, statistical nominal p values have been provided for informational purposes only since this Phase II study, as a pilot study, had less than a 20% power to show statistically significant results for these endpoints.

The data is presented in two ways. First, the 200mg arm is compared to placebo because the 200mg is the dose being used in our Phase III and Phase IV clinical trials, as agreed to with the FDA under the SPA. Next, the data is presented as active (200mg and 400mg) vs. placebo; this was the primary endpoint defined by the Phase II protocol. Information on the effects of the 400mg arm alone can be found in the footnotes to the tables. The dose response relationship of Sulonex previously demonstrated up to 200mg was not observed from 200mg to 400mg in this study.

Table 1—Primary Endpoint Analysis (Therapeutic Success at six months) (200mg vs. Placebo)

	Number of Patients (Placebo/200mg)	Placebo	200mg	p value Fisher's Exact Test (2-sided)
Per Protocol	36/36	11.0%	33.0%	P=.045
Intent to Treat	42/44	14.0%	32.0%	P=.074

Table 2—Primary Endpoint Analysis (Therapeutic Success at six months) (200mg and 400mg[1] vs. Placebo)

	Number of Patients (Placebo/Active)	Placebo	Active (200mg and 400mg)[1]	p value Fisher's Exact Test (2-sided)
Per Protocol	36/81	11%	25%	P=.136
Intent to Treat	42/94	14%	26%	P=.180

1 For the 400mg group alone, the Therapeutic Success was 18% on a per protocol basis and 20% on intent to treat basis.

Table 3—Secondary Endpoint Analysis at Six months (Intent to Treat)

	Placebo n=42	200mg n=44	Active (200mg and 400mg[1]) N=94
>50 % reduction in ACR	12.0%	27.0%	22.0%
Normalization of ACR	9.0%	23.0%	17.0%

1 For the 400mg group alone, the 50% reduction and normalization were 18% and 10%, respectively.

Table 4—Average Changes of ACR Over Time (Intent to Treat)[1]

	200mg vs. Placebo	Placebo vs. Baseline	200mg vs. Baseline
Two months	-17.00%	-4.0%	-21.00%
Four months	-25.78%	7.5%	-18.28%
Six months	-28.03%	12.57%	-15.46%
Eight months (Two months off therapy)	-28.98%	18.5%	-10.48%

1 The average changes from baseline over time for the 400mg dose group were 3.4%, 3.24%, 5.59% and 12.59%, respectively.

On February 7, 2006, an independent Data Safety Monitoring Committee, or DSMC, met to review the safety data from the Phase II Pilot study as well as the follow-up Long-Term Open-Label Tolerability and Safety study. The DSMC concluded that (i) the risk/benefit ratio of Sulonex for the treatment of diabetic nephropathy was acceptable, (ii) the serious adverse event, or SAE, profile seen in either the Phase II Pilot and the Long-Term Open-Label

Tolerability and Safety studies were similar to placebo and were consistent with the patient's co-morbidities of diabetes, hypertension, and/or hyperlipidemia, (iii) no clinically relevant bleeding events were documented in either study and no changes in coagulation parameters assessed during the Phase II Pilot study were noted, (iv) further monitoring of coagulation parameters in either the Phase III (Micro) or Phase IV (Macro) studies are not warranted and the use of other anticoagulants such as warfarin, anti-platelet agents, etc. with Sulonex is permissible, and (v) based on a review of the safety data from both the Phase II Pilot and Open-Label Tolerability and Safety studies, both the Phase III (Micro) and Phase IV (Macro) studies should continue to randomize patients and no protocol amendments to either study are necessary. In the Phase II pilot study there were the following SAEs:

Placebo N=47		200 mg N=50		400 mg N=52	
No. of SAEs	No. of Patients	No. of SAEs	No. of Patients	No. of SAEs	No. of Patients
4	4 (8.5%)	23	16 (32%)	4	4 (7.7%)

All of the SAEs were considered by the Investigators to be unlikely to be related to study drug. The DSMC concluded that the SAE event rate appeared to be higher in the sulodexide 200mg/d group compared to both placebo and sulodexide 400mg/d groups (no dose dependent effect) and the pattern of SAE did not indicate any common trends. No additional safety signals emerged from a review of the adverse events, the biochemical data and the coagulation parameters. No abnormalities of coagulation were in any group and no excessive bleeding was seen in the patients receiving either the 200mg/d or 400mg/d dosage of sulodexide.

In the Long-Term Open-Label Tolerability and Safety study, there have been twenty-seven SAEs in fourteen patients.

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 allows for the use of surrogate endpoints in Phase III trials to support the approval of an NDA with confirmatory studies completed post-approval, and could greatly reduce the development time to market.

In the third quarter of 2003, we announced that CSG would conduct the U.S.-based Phase II/III 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 II portion of our Phase II/III clinical program for Sulonex, and in the third quarter of 2004, we completed the target enrollment for the Phase II portion of the clinical program. The results of the Phase II are presented above under the caption "Phase II Data Analysis."

In January 2005, we announced that the CSG recommended that we proceed to the Phase III portion of our Phase II/III clinical program of Sulonex. This recommendation was based on the completion, by an independent DSMC, on January 4, 2005, of a safety evaluation of the first interim analysis from the 149 patient, randomized, double-blind, placebo-controlled Phase II clinical trial of 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 III and Phase IV clinical trials of Sulonex.

In June 2005, we announced the initiation of our pivotal Phase III and Phase IV 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 III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; supportive data from previously conducted clinical studies; and substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. The Phase III portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of Sulonex versus a placebo in patients with persistent microalbuminuria. The Phase IV portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of Sulonex versus a placebo in patients with persistent macroalbuminuria. The CSG is conducting the pivotal Phase III and Phase IV clinical program of Sulonex for the treatment of diabetic nephropathy.

In November 2005, we announced final results from our Phase II 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 II study is discussed above under "U.S.- based Clinical Data."

In November 2006, we announced that the DSMC responsible for monitoring Sulonex in the Phase III microalbuminuria and Phase IV macroalbuminuria studies recently 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 III clinical trial. We expect to complete the randomization of all patients by the end of the first half of 2007.

In March 2007, we announced that the DSMC responsible for monitoring Sulonex in the Phase III microalbuminuria and Phase IV 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.

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

Zerenex™

Overview

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

Market Opportunity

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 rquire 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 these type of binders 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.

Sevelamer, a polyallylamine-hydrochloride, nonabsorbed cationic polymers that binds phosphate anions through ion exchange and hydrogen binding has been developed as an alternative phosphate binder. Compared to calcium-type binder, fewer coronary and aortic calcifications have been documented, however, the non-specific binding of vitamins, nutrients, and concomitantly administered medications are of major concerns. In addition, the lowering of serum phosphorus levels with this polymer is debatable since a target serum phosphorus level <5.5 mg/dL cannot be achieved in a majority of patients when this polymer is used as monotherapy.

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 has been demonstrated in animals, particularly in bone and liver. 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 have long been recognized. Zerenex has the potential to be an effective and safe treatment in lowering and/or maintain 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 II multi- center study entitled: “A randomized, double-blind, placebo-controlled, dose ranging study of the effects of Zerenex on serum phosphate in patients with end stage renal disease (ESRD).” This Phase II study was conducted under an IND sponsored our licensors in both the United States and Taiwan.

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

The Phase II study was designed to determine the safety and efficacy of several doses of Zerenex in patients with 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 x phosphorous (Ca x P) product at day 28 (p=0.0158). In the 6g/day Zerenex group the mean decrease in Ca x P product when compared with placebo was statistically significant (p=0.0378) (See Table 2).

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

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

* mean (standard deviation)

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

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

*mean (standard deviation)

There were no deaths over the course of the 28 day study and there were no serious adverse events that were deemed by the investigators to be definitely related to Zerenex. The majority of adverse events were of mild severity. Seven (43.8%), 13 (39.4%), 9 (26.5%), and 14 (42.4%) patients in the placebo, 2, 4, and 6g treatment groups, respectively,

experienced no adverse events more severe than mild and 1 (6.3%), 0 (0.0%), 2 (5.9%), 1 (3.0%), of the placebo, 2,4, and 6 grams per day groups, respectively, experienced at least one severe 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, the efficacy of Zerenex has been demonstrated in two previous Phase II 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 was comparable to calcium based products which were used as control arms in those studies. 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 Phosphate		
	Baseline (mg/dL)	End-Point (Four Weeks) (mg/dL)	Change from Baseline
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)

Open Label, Randomized, Crossover, 2 sites

	Serum Phosphate		
	Baseline (mg/dL)	End-Point (Four Weeks) (mg/dL)	Change from Baseline
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 further development of Zerenex and Phase III study design and requirements prior to moving into Phase III. To support higher doses and longer duration of treatment in Phase III, 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. As a result of conversations with the leadership of the CSG as well as the FDA during 2006, we plan to run an additional Phase II, short-term exposure study (28-days) to evaluate the safety of higher doses of Zerenex. Prior to commencing this study, we wanted to complete chronic toxicology studies in rodents and non-rodents to evaluate the effect of higher doses in the human high-dose Phase II study. This evaluation is underway in rodents and we are currently trying to determine the most appropriate non-rodent model to assess the toxicology of an iron-based compound. We now plan to commence the high-dose exposure clinical trial in the second half of 2007. Consequently, we are now targeting commencement of the Phase III pivotal program in the first half of 2008.

Oncology

KRX-0401

Overview

We are also developing KRX-0401 (perifosine), which is a novel, first-in-class, oral anti-cancer agent that modulates the 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. 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.

The effects of KRX-0401 on Akt are of particular interest because of 1) the importance of this pathway in the development of most cancers; 2) the evidence that it is often activated in tumors that are resistant to other forms of anticancer therapy; and 3) and the difficulty encountered thus far in the discovery of drugs that will inhibit this pathway without causing excessive toxicity. It is plausible that KRX-0401 may be useful in combination to reduce the resistance to other cancer treatments.

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To date, over 1,200 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 doses that are known to induce tumor regression.

In Phase I/II trials, perifosine has induced tumor regressions and/or caused disease stabilization in a variety of tumor types. KRX-0401 has shown single agent partial responses or long term disease stabilizations in solid tumors including, renal, hepatocellular, sarcoma and prostate cancer. There is also evidence of activity in hematological malignancies, especially multiple myeloma. Responding patients, including stable disease, have been treated for months 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. In model systems the drug appears to be synergistic with radiotherapy and additive or synergistic with cytotoxics such as cisplatin, Adriamycin, and cyclophosphamide. In these experiments, the combination regimens were superior to chemotherapy alone and were well tolerated.

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, and it appeared to be synergistic when combined with bortezomib (Velcade®), dexamethasone and a number of other drugs used to treat multiple myeloma.

Six Phase I studies of KRX-0401 have been completed, three in Europe by Zentaris and three in the United States by the National Cancer Institute, or NCI, a department of the National Institutes of Health, or NIH, as part of a Cooperative Research and Development Agreement, or CRADA, 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 I studies was gastrointestinal: nausea, vomiting and diarrhea. In addition, some patients experienced fatigue, especially with prolonged administration. In these Phase I 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, 21 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 (2), ovarian cancer (1), salivary gland cancer (1), mesothelioma (2) and hepatoma (2). The meaning of disease stabilization in an individual patient in a Phase I 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 I data provides clinical evidence of the anti-cancer effects of KRX-0401.

The NCI has completed a number of Phase II clinical trials studying KRX-0401 as a single agent, including studies in prostate, breast, head and neck and pancreatic cancers, as well as melanoma and sarcomas. In total, nine NCI clinical

trials have been conducted across these six tumor types. The NCI and its collaborators have presented and/or published data from seven of their Phase II studies, including from Phase II studies involving prostate (2), sarcoma, head and neck, melanoma, pancreas and breast cancers. Findings from these studies led most of these investigators to conclude that the drug was safe and well-tolerated at the Phase II 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 or on days two to 21 of a four-week cycle. 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 I trials. However, studies using a single bolus dose of 600 mg to 900 mg on day one and continuous daily KRX-0401 at a dose of 100 mg per day appeared to be better tolerated than studies that used a larger bolus dose on day one of every 28-day cycle followed by 150 mg per day on days two to 21. In the published Phase II sarcoma study, the investigators reported a partial response (greater than 50% decrease in tumor mass) as well as several disease stabilizations. With the responses seen in the Phase I trials, there are now three sarcoma patients with durable partial responses. This has led us to consider exploring additional studies in sarcoma. On the Phase II breast cancer study, the investigators scored three of 15 evaluable patients as having stable disease. One of these patients had measurable tumor regression which 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 of the regimens employed in these NCI Phase II studies. 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.

In May 2005, we announced that Phase II data presented at the annual meeting of the American Society of Clinical Oncology in Orlando, Florida demonstrated the tolerability and potential efficacy of KRX-0401 in the treatment of patients with biochemically recurrent hormone-sensitive prostate cancer, or HSPC. The investigators concluded that KRX-0401 in the treatment of HSPC patients is feasible, well-tolerated, reduced prostate-specific antigen, or PSA, levels in some patients, and resulted in disease stabilization in approximately 80% of patients. Because of its inhibitory effects on the Akt and related pathways, we believe that further studies of KRX-0401 in combination with androgen ablation and chemotherapy are warranted. In a second study published by investigators at the NCI, there were no radiographic responses or PSA declines of 50% or greater related to KRX-0401, 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 June 2006, we announced data of KRX-0401 in patients with advanced renal cell carcinoma, or advanced RCC. These patients were a cohort of a Phase II, multi-center trial of KRX-0401 conducted by Keryx that included multiple tumor types. All patients in this study were to have had prior standard therapy. Although the extent of prior treatment varied with tumor type, most patients had received two chemotherapy regimens for metastatic disease. An interim analysis was performed at the end of the first year of accrual, and the results in the renal group met protocol requirements for expansion of this cohort. The study is ongoing.

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

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

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

In December 2006, we reported interim results from the Phase II study of KRX-0401 in patients with advanced relapsed and refractory multiple myeloma. The interim data analysis showed that KRX-0401 alone or in combination with dexamethasone has activity in patients with advanced, relapsed/refractory multiple myeloma, achieving response and/or stabilization of disease in 69% of evaluable patients to date. In this ongoing Phase II study, patients with relapsed or relapsed/refractory multiple myeloma are treated with KRX-0401 (150 mg oral daily dose) to assess the single agent activity of KRX-0401 in this patient population. If a patient progresses on KRX-0401 alone, dexamethasone (20mg twice weekly) is added to their KRX-0401 regimen.

A total of 55 patients (30 men and 25 women, median age 63 years, range 38-79) have been treated to date. All had relapsed and refractory multiple myeloma, with a median of four lines of prior treatment (range 2 - 11). Prior therapy included dexamethasone (95%), thalidomide (89%), bortezomib (78%), lenalidomide (31%) and stem cell transplant (73%). Among the 33 patients that were evaluable for response, best response (EBMT/Blade criteria) to single agent KRX-0401 after two cycles was stable disease (<25% reduction in M-protein) in 13 patients (39%). Dexamethasone was added in 30 of 55 patients with PD, with 23 patients evaluable for response on the combination, reported as follows:

Perifosine + Dex	**N (%)**	**Duration (wks)**
PR	2 (9%)	13+, 17+
MR	4 (17%)	4, 16+, 28+, 30+
Stable Disease	11 (48%)	6 - 20+ (median 18)*

*4 pts ongoing at 16, 18, 20 and 20 weeks

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The most common grade 3/4 adverse events were nausea (7%); vomiting (4%); diarrhea (2%); fatigue (2%), and increased creatinine (8% in the context of PD and light chain nephropathy). Dose reduction (150 to 100 or 50 mg/d) was required in 16 patients and seven patients discontinued treatment due to adverse events. Attributable toxicities otherwise proved manageable with appropriate supportive care. KRX-0401 was generally well tolerated, with no peripheral neuropathy or DVT seen.

Development Status

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

In December 2006, we announced the initiation of a multi-center Phase I clinical program to explore the convenient all-oral combination of KRX-0401, Revlimid® and dexamethasone for the treatment of relapsed or refractory multiple myeloma. KRX-0401 is also currently being evaluated in an ongoing multi-center Phase II study as a single agent and in combination with dexamethasone as a treatment for relapsed or relapsed/refractory multiple myeloma and in an ongoing multi-center Phase I/II clinical study in combination with Velcade® (bortezomib) for injection for the treatment for multiple myeloma.

In December 2006, we announced the initiation of a corporate-sponsored Phase II clinical program to evaluate KRX-0401 as a treatment for rare sarcomas. This Phase II study will be 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 II 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 will be treated with KRX-0401 until disease progression. This study follows previous Phase I and Phase II 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.

We plan to commence additional trials in 2007.

The ultimate clinical timeline, and consequent cost, for further development of KRX-0401 will depend, in part, on the successful completion of our Phase II trials, and ultimate approval by the FDA.

KRX-0402

KRX-0402 (O6-benzyl guanine or O6-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. Accordingly, we believe that KRX-0402 may have an important role in making cells more susceptible to the damaging effects of alkylating agents, and that

KRX-0402 may have utility in the treatment of multiple forms of cancer. KRX-0402 is administered intravenously. To date, approximately 400 patients have received KRX-0402 in multiple clinical studies. Dose limiting toxicity for KRX-0402 in combination with chemotherapy was bone marrow suppression. KRX-0402 alone has no identified dose limiting toxicity. Two company-sponsored, Phase II clinical trials for KRX-0402 are ongoing.

Investigators at Duke University led by Dr Henry Friedman performed a Phase I study of one day of temozolomide in combination with O6-BG. One patient with anaplastic astrocytoma previously resistant to temozolomide obtained a complete remission which has been ongoing for 3+ years. In a Phase II study of temozolomide resistant patients, 1/33 patients with glioblastoma and 3/32 patients with either anaplastic astrocytoma, or AA, or anaplastic oligodendroma, AO, obtained partial remissions to the combination of temozolomide and O6-BG. The dose of temozolomide was 200 mg/m^2 in the Phase I study and 472 mg/m^2 in the Phase II study.

The single day schedule for temozolomide was chosen at that time because data had only been generated on suppression of MGMT in tumors by O6-BG for up to 48 hours. However, pre-clinical models had suggested this may not be the optimum schedule for O6-BG and temozolomide. In a xenograft model, it was demonstrated that O6-BG did not significantly increase the growth delay induced by a single 200 mg/kg dose of temozolomide compared to temozolomide alone, but when the same dose was divided into five equal daily doses there was a significant increase in tumor growth delay. A Phase I study at Duke University evaluated a five day regimen of temozolomide in combination with O6-BG. All patients received 200 mg/m^2 of temozolomide on day one and four equal doses on days two through five. The maximum tolerated dose in that study was 200 mg/m^2 of temozolomide on day one and 50 mg/m^2/day for days two through five. This schedule is now being evaluated in a Phase II study being performed at 16 university and community sites to confirm the AA/AO results seen at Duke University. The study uses a two-stage design. The first stage of the design calls for up to 41 patients to be evaluated. The first patient was entered on the study in October 2006. Accrual to the study is continuing.

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 II 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 National Cancer Institute. 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 expect to continue exploring the potential utility of KRX-0601 over the next year.

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 expect to continue exploring the potential utility of KRX-0404 over the next year.

Neurology

KRX-0501

KRX-0501 is an orally available small molecule in pre-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. We expect to continue exploring the potential utility of KRX-0501 over the next year, currently with a goal of entering clinical development in 2007.

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 “Risk Factors Associated

with Our Product Development Efforts."

Sulonex is currently in Phase III and Phase IV clinical trials. We estimate that the cost to complete the Phase III will be approximately $10 million to $20 million, and we believe that the Phase III will be completed in the first half of 2008.

With respect to KRX-0401, KRX-0402, KRX-0601 and Zerenex, we are unable to estimate the cost to complete the current phase of each drug and also unable to project a time for the completion of the current phase. Each of KRX-0401, KRX-0402, KRX-0601 and Zerenex are in Phase II clinical development. Phase II clinical development is exploratory by design and looks at different doses and disease settings and thus is highly unpredictable, and the length of time required and results will vary based on patient enrollment, response rates in the trials, and the potential need for additional trials or increases in patients included, among other factors. Due to the nature of a Phase II and our inability to predict the results of such studies, we cannot estimate when such a program will end, and it is equally difficult to project the cost to complete such phase.

KRX-0404 and KRX-0501 are currently pre-clinical drug candidates. The timing and results of pre-clinical studies are highly unpredictable. Due to the nature of pre-clinical studies and our inability to predict the results of such studies, we cannot estimate when such pre-clinical development will end, and it is equally difficult to project the cost to complete such development.

Accumin™

On April 6, 2006, Accumin Diagnostics, Inc., our wholly-owned subsidiary, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. We believe that the acquisition of Accumin may help increase our exposure to physicians that treat diabetes, the target market for Sulonex, by emphasizing the importance of early detection of microalbuminuria.

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 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 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

Pursuant to our license for Sulonex, 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 Sulonex 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.

Other Clinical-Stage Compounds, including KRX-0401

Pursuant to our acquisition of ACCESS Oncology, Inc., or ACCESS Oncology, 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 KRX-0401. 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 expiring in 2010 (with extension expected through 2015) and a series of United States patents and foreign counterparts directed to derivatives of KRX-0402 expiring in 2011 to 2019.

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 expires in June 2007. The method of use patents expire from 2013 to 2017.

Pursuant to our license for Zerenex 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 Zerenex. Panion holds one use patent expiring 2017 (with extensions expected through 2020) and two manufacturing process patents (expiring 2023).

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 to provide market exclusivity for certain of our drug candidates. The orphan drug regulations of the FDA 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 you 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 liable 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.

Collaborative Study Group

In June 2005, we announced that the CSG will be conducting our pivotal Phase III and Phase IV clinical program of Sulonex 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 (Sulonex) for a period of twelve years from the date of the first commercial sale of the product. Notwithstanding this right, Opocrin shall have the right to terminate the agreement on 60 days notice in the event that we have not submitted an NDA to the FDA by December 31, 2007.

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 KRX-0401 covering composition of matter and methods of treatment. This agreement grants us the exclusive rights to 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., or Procept, a wholly owned subsidiary of Paligent, Inc., relating to the development and marketing of KRX-0402. 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 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.

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. In addition, payment of AusAm liabilities by ADI under license agreements in the amount of $180,000 remains outstanding as of December 31, 2006, to be paid over the next 27 months.

COMPETITION

Competition in the pharmaceutical and biotechnology industries is intense. Our competitors include pharmaceuticals 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 pre-clinical 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 a U.S.-based contract manufacturer for Sulonex which we believe will be adequate to satisfy our current clinical supply needs. In addition, we have entered into an agreement with the same manufacturer to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture launch and initial commercialization (1 to 3 years) quantities of Sulonex. As we move forward, we plan to build additional manufacturing capacity to meet the future demands for Sulonex. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, as we scale-up, we will need to accurately reproduce the established process on the larger scale to ensure successful commercialization of Sulonex. There can be no assurance that we will be successful in this endeavor. Additionally, as we scale-up, we have incurred, and will continue to incur, capital expenditures to enable larger scale production. To date, we have spent over $9 million in capital expenditures building the current manufacturing suite.

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 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. 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, 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. We have submitted a subpart H clinical development plan to the FDA for the clinical development of Sulonex for diabetic nephropathy.

In March 2005, we announced that we had finalized an SPA agreement with the FDA for the Phase III and Phase IV 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 III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; (ii) supportive data from previously conducted clinical studies; and (iii) substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria.

The subpart H process is complex and requires careful execution. No assurance can be given that we will be able to meet the requirements set forth in the SPA. Even if we meet those requirements, the FDA is not obligated to grant approval of our NDA for Sulonex. If the FDA approves Sulonex for marketing on the basis of our Phase III trial, our Phase IV clinical trial may yield insufficient efficacy data or give rise to safety concerns, which could result in withdrawal of such approval or could cause us to withdraw the product from the market. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

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 I*: 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 II*: 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 III*: Studies establish safety and efficacy in an expanded patient population.

- *Phase IV*: The FDA may require Phase IV 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. 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 $9,805,000 in 2004, $24,182,000 in 2005, and $56,139,000 in 2006. “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 March 1, 2007, we had 40 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, 2006, we had an accumulated deficit of approximately $188.2 million. As we expand our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

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

Risks Associated with Our Product Development Efforts

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

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

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

complex and requires careful execution. No assurance can be given that we will be able to meet the requirements set forth in the SPA. Even if we meet those requirements, the FDA is not obligated to grant approval of our NDA for Sulonex. If the FDA approves Sulonex for marketing on the basis of our Phase III trial, our Phase IV clinical trial may yield insufficient efficacy data or give rise to safety concerns, which could result in withdrawal of such approval or could cause us to withdraw the product from the market. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

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

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

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

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

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

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

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

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

Contract manufacturers often encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and foreign regulations, production costs and development of advanced manufacturing techniques and process controls. Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidates. In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple manufacturers may be difficult because the number of potential manufacturers is limited and, particularly in the case of Sulonex, the process by which multiple manufacturers make the drug substance must be identical at each manufacturing facility. It may be difficult for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. Moreover, if we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to deliver the required quantities of our drug candidates on a timely basis and at commercially reasonable prices, we will not be able to commercialize our products as planned.

We have entered into a relationship with a U.S.-based contract manufacturer for Sulonex which we believe will be adequate to satisfy our current clinical supply needs. In addition, we have entered into an agreement with the same manufacturer to build a larger scale manufacturing suite within their current facility, which they will operate on our behalf. We believe this suite will be suitable to manufacture launch and initial commercialization (approximately one to three years) quantities of Sulonex. As we move forward, we plan to build additional manufacturing capacity to meet the future demands for Sulonex. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, as we scale-up we will need to accurately reproduce the established process on the larger scale to ensure successful commercialization of Sulonex. There can be no assurance that we will be successful in this endeavor. Additionally, as we scale-up, we have incurred, and will continue to incur, capital expenditures to enable larger scale production. Through December 31, 2006, we have spent over $8 million in capital expenditures building the current manufacturing suite.

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

Key raw materials for Sulonex, our lead product candidate, are derived from porcine mucosa. Long-term supplies for Sulonex could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products, over which we will have no control. We estimate, in part, based on the number of pigs killed worldwide and estimates of projected supplies of porcine mucosa, that there is enough potential supply of this raw material to commercialize Sulonex. If our estimates of the potential supply of this key raw material are not accurate or we cannot secure adequate amounts of the potential supply of such material, then the market potential of Sulonex will not be realized. Additionally, diseases affecting the world supply of pigs could have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell Sulonex. Such negative impact could materially affect the commercial success of Sulonex.

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

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

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

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

resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we are unable to control whether such products will be scientifically or commercially successful.

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

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

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

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

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

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

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

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

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

As of March 1, 2007, we had 40 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. 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 40 full and part-time employees. We also have significantly fewer employees than many other companies that have a product candidate in late-stage clinical development, and we rely heavily on third parties to conduct many important functions. While we believe that our corporate compliance program is sufficient to ensure compliance with applicable regulations, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Related to Our Financial Condition

Our current cash, cash equivalents and investment securities may not be adequate to support our operations for approximately the next 18 to 24 months as we have estimated.

We believe that our $125.6 million in cash, cash equivalents, interest receivable and investment securities as of December 31, 2006 will be sufficient to enable us to meet our planned operating needs and capital expenditures for approximately the next 18 to 24 months. Our forecast of the period of time through which our cash, cash equivalents, interest receivable and investment securities will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

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

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

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash, cash equivalents, interest receivable and investment securities will be sufficient to fund our operating expenses and capital requirements for approximately the next 18 to 24 months; however, the actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate, depending upon:

- the 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, our Israeli subsidiary vacated its Jerusalem facility, after giving advance notice to the landlord. On May 1, 2005, the landlord of the Jerusalem facility filed suit in Israel claiming that we were liable as a result of the alleged breach of the lease agreement by our subsidiary. The amount demanded by the landlord totals 4,345,313 New Israeli Shekels, or approximately $1,032,000, 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 filed an answer to the landlord's complaint. Generally, each answer challenges the merits of the landlord's cause of action as to each defendant. All defendants, except Keryx (Israel) Ltd., have also filed a motion to dismiss the complaint. The plaintiff has filed a response to each answer. At this time, the Circuit Court of Jerusalem has not issued a decision with respect to the motion to dismiss. A hearing on a motion by Keryx Biopharmaceuticals, Inc. to vacate service of process outside of Israel was held in June 2006. In October 2006, the Circuit Court of Jerusalem held that the service of process on Keryx was valid. We appealed this determination and the appeal is currently pending. To date, we have not yet recorded a charge to reflect any potential liability associated with this lawsuit as it is too early to accurately estimate the amount of the charge, if any.

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

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

We acquired the assets of the diagnostics business of AusAm Biotechnologies, Inc., a debtor in a pending Chapter 11 bankruptcy proceedings, in a court-approved transaction. Subsequent to the closing, disputes arose between the debtor and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, the debtor filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145. The parties have agreed to a settlement in principle of the matter, subject to documentation and Bankruptcy Court approval, pursuant to which Keryx will pay AusAm approximately $110,000.

Risks Related to Our Intellectual Property

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

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve

complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug products and technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

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

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

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

Risks Related to Our Common Stock

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

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

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

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

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

- developments concerning our drug candidates;
- announcements of technological innovations by us or our competitors;
- introductions or announcements of new products by us or our competitors;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in financial estimates by securities analysts;
- actual or anticipated variations in quarterly operating results;

- expiration or termination of licenses, research contracts or other collaboration agreements;
- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;
- changes in the market valuations of similar companies; and
- additions or departures of key personnel.

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

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

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

ITEM 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 group.

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 $1,032,000, 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. In October 2006, the Circuit Court of Jerusalem held that the service of process on Keryx Biopharmaceuticals, Inc. was valid. We appealed this determination and the appeal is currently pending. The Circuit Court of Jerusalem held that the service of process on Michael S. Weiss was invalid. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. To date, we have not yet recorded a charge to reflect any potential liability associated with this lawsuit, as it is too early to accurately estimate the amount of the charge, if any.

In April 2006, we acquired the assets of the diagnostics business of AusAm Biotechnologies, Inc., a debtor in a pending Chapter 11 proceeding, in a court-approved transaction. Subsequent to the closing, disputes arose between the debtor and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, the debtor filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145. (In re: AusAm Biotechnologies, Inc., Chapter 11 Case No. 06-10214 (RDD) (Bankr. S.D.N.Y.)). Keryx opposed the motion and asserted a counterclaim alleging fraud in connection with the acquisition. The parties have agreed to a settlement in principle of the matter, subject to documentation and Bankruptcy Court approval, pursuant to which Keryx will pay AusAm approximately $110,000.

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 2006.

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, 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

Fiscal Year Ended December 31, 2005	**High**	**Low**
Fourth Quarter	$ 17.90	$ 13.09
Third Quarter	$ 17.71	$ 13.23
Second Quarter	$ 14.49	$ 11.74
First Quarter	$ 15.38	$ 10.77

Holders

The number of record holders of our common stock as of March 8, 2007 was 37.

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, 2006, 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 Non-Plan, the 2002 CEO Incentive Stock Option Plan, the 2004 President Incentive Plan, the 2004 Long-Term Incentive Plan, and the 2006 CFO Incentive Plan.

Equity Compensation Plan Information

Plan Category	Number of securities to be issued upon exercise of outstanding options (a)	Weighted-average exercise price of outstanding options (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	7,187,056	$ 9.09	152,158
Equity compensation plans not approved by security holders	3,562,657	$ 5.48	—
Total	10,749,713	$ 7.90	152,158

For information about all of our equity compensation plans, see Note 7 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, 2001 through December 31, 2006, 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, 2001, 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.

ITEM 6. SELECTED FINANCIAL DATA.

The following Statement of Operations Data for the years ended December 31, 2006, 2005, 2004, 2003 and 2002, and Balance Sheet Data as of December 31, 2006, 2005, 2004, 2003 and 2002, 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,				
	2006	**2005**	**2004**	**2003**	**2002**
	(in thousands, except per share data)				
Statement of Operations Data:					
Diagnostic revenue	$ 103	$ —	$ —	$ —	$ —
Service revenue	431	574	809	—	—
Total revenue	534	574	809	—	—
Operating expenses:					
Cost of diagnostics sold	140	—	—	—	—
Cost of services	390	819	835	—	—
Research and development:					
Non-cash compensation	6,504	594	413	(486)	(1,382)
Non-cash acquired in-process research and development	—	—	18,800	—	—
Other research and development	56,139	24,182	9,805	5,996	9,523
Total research and development	62,643	24,776	29,018	5,510	8,141
Selling, general and administrative:					
Non-cash compensation	8,408	775	1,087	188	(4)
Other selling, general and administrative	9,110	3,416	3,581	3,684	4,108
Total selling, general and administrative	17,518	4,191	4,668	3,872	4,104
Total operating expenses	80,691	29,786	34,521	9,382	12,245
Operating loss	(80,157)	(29,212)	(33,712)	(9,382)	(12,245)
Other income (expense):					
Interest and other income, net	6,393	2,317	770	247	513
Income taxes	—	—	(1)	27	(51)
Net loss	$ (73,764)	$ (26,895)	$ (32,943)	$ (9,108)	$ (11,783)
Net loss per common share					
Basic and diluted	$ (1.76)	$ (0.78)	$ (1.10)	$ (0.43)	$ (0.59)

	As of December 31,

	2006	2005	2004	2003	2002
			(in thousands)		
Balance Sheet Data:					
Cash, cash equivalents, interest receivable and investment securities	$ 125,610	$ 100,733	$ 49,878	$ 31,414	$ 24,131
Working capital	102,774	83,890	46,538	30,982	22,350
Total assets	140,313	105,097	50,862	32,223	29,103
Other liabilities	294	322	92	—	256
Contingent equity rights	4,004	4,004	4,004	—	—
Total stockholders' equity	123,821	94,678	42,804	31,226	26,330

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 III and Phase IV clinical program under an SPA with the FDA. Additionally, we are developing Zerenex™, an oral, inorganic, iron-based compound that has the capacity to bind to phosphorous and form non-absorbable complexes. Zerenex is currently in Phase II clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with ESRD. We are also developing clinical-stage oncology compounds, including KRX-0401, a novel, first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth, and a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase II clinical development for multiple tumor types. We also have an active in-licensing and acquisition program designed to identify and acquire additional drug candidates. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any revenues from our drug candidates.

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

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

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

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

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

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

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, testing, and enhancement of our drug candidates and technologies, as well as expenses related to in-licensing of new product candidates. We expense our research and development costs as they are incurred. Other research and development expenses, which excludes non-cash compensation and acquired in-process research and development expenses, for the years ended December 31, 2006, 2005 and 2004 were $56,139,000, $24,182,000, and $9,805,000, respectively.

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

	Years ended December 31,			Amounts accumulated during the development stage
	2006	2005	2004	
Sulonex	$ 41,533,000	$ 16,075,000	$ 6,064,000	$ 71,812,000
KRX-0401	8,508,000	5,394,000	2,230,000	16,132,000
Other clinical stage compounds	3,941,000	1,593,000	623,000	6,157,000
Other	2,157,000	1,120,000	888,000	25,932,000
Total	$ 56,139,000	$ 24,182,000	$ 9,805,000	$ 120,033,000

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

Our results of operations include non-cash compensation expense as a result of the grants of stock options and warrants. Compensation expense for awards of options granted to employees and directors represents the fair value of the award recorded over the respective vesting periods of the individual stock options. The expense is included in the respective categories of expense in the statements of operations. For awards of options and warrants to consultants and other third-parties, compensation expense is determined at the “measurement date.” The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. These awards are then revalued, or the total compensation is recalculated based on the then current fair value, at each subsequent reporting date. We expect to 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. In addition, because some of the options and warrants issued to employees, consultants and other third-parties either do not vest immediately or vest upon the achievement of certain milestones, the total expense is uncertain.

For periods presented prior to our adoption of SFAS 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, 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. 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 $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. We do not expect our service revenue to have a material impact on our financial results during the next fiscal year.

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. 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 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. 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 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 III and Phase IV 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.

We expect our other research and development costs to increase over the next year as a result of the pivotal Phase III and Phase IV clinical program for Sulonex and the expansion of the clinical program for KRX-0401, as well as possible development programs for our other drug candidates.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to stock option and restricted stock grants was $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 is 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.

We expect our other selling, general and administrative costs to increase over the next year as we scale-up our operations and infrastructure to prepare to commercialize our drug candidates.

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.

Years Ended December 31, 2005 and 2004

Diagnostic Revenue. There was no diagnostic revenue for the years ended December 31, 2005, and 2004.

Service Revenue. Service revenue decreased by $235,000 to $574,000 for the year ended December 31, 2005, as compared to revenue of $809,000 for the year ended December 31, 2004. The decrease in service revenue was primarily due to a reduction in service contracts in 2005 as compared to 2004.

Cost of Diagnostics Sold Expense. There was no cost of diagnostics for the years ended December 31, 2005, and 2004.

Cost of Services Expense. Cost of services expense decreased by $16,000 to $819,000 for the year ended December 31, 2005, as compared to cost of services expense of $835,000 for the year ended December 31, 2004. The decrease in cost of services expense was primarily due to a reduction in service contracts in 2005 as compared to 2004.

Non-Cash Compensation Expense (Research and Development). Non-cash compensation expense related to stock option grants was $594,000 for the year ended December 31, 2005, as compared to an expense of $413,000 for the year ended December 31, 2004. For the year ended December 31, 2005 and 2004, adjustment to fair market value under EITF 96-18 of previously-issued options to consultants accounted for expenses of $464,000 and $276,000, respectively, and the issuance of options to consultants, requiring the use of the fair value method of accounting, resulted in expenses of $130,000 and $137,000, respectively.

Non-Cash Acquired In-Process Research and Development Expense. We did not record a charge for the year ended December 31, 2005. As required by Financial Accounting Standards Board, or FASB, Interpretation No. 4, “Applicability of FASB Statement No. 2 to Business Combinations Accounted for by the Purchase Method," or FIN 4, we recorded a charge of $18,800,000 for the year ended December 31, 2004, for the estimate of the portion of the purchase price of ACCESS Oncology allocated to acquired in-process research and development. A project-by-project valuation was performed with the assistance of independent valuation specialists to determine the fair value of research and development projects of ACCESS Oncology, which were in-process, but not yet completed.

Other Research and Development Expenses. Other research and development expenses increased by $14,377,000 to $24,182,000 for the year ended December 31, 2005, as compared to expenses of $9,805,000 for the year ended December 31, 2004. The increase in other research and development expenses was due primarily to a $10,011,000 increase in expenses related to our Sulonex clinical program, including costs associated with our pivotal Phase III and Phase IV clinical trials, a $3,164,000 increase in expenses related to our KRX-0401 clinical program, and a $970,000 increase in expenses related to our other clinical stage compounds (the $970,000 increase includes $159,000 for the purchase of additional license rights and interests covering patent rights for KRX-0402). The comparative period last year included one-half, or $500,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense related to stock option grants was $775,000 for the year ended December 31, 2005, as compared to an expense of $1,087,000 for the year ended December 31, 2004. For the year ended December 31, 2005 and 2004, adjustment to fair market value under EITF 96-18 of previously-issued options to consultants accounted for expenses of $306,000 and $175,000, respectively, and the issuance of options to consultants, requiring the use of fair value method of accounting, resulted in expenses of $24,000 and $245,000, respectively, and the continued vesting of options granted to certain directors below market value on the date of issuance (but equal to market price at grant date) accounted for expenses of $445,000 and $667,000, respectively.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses decreased by $165,000 to $3,416,000 for the year ended December 31, 2005, as compared to expenses of $3,581,000 for the year ended December 31, 2004. The decrease in general and administrative expenses in 2005 was due primarily to the absence of payroll expenses incurred in 2004 relating to one-half, or $500,000, of a one-time bonus to our Chief Executive Officer for the achievement of a corporate milestone pursuant to his employment agreement, partially offset by a $127,000 increase in insurance expenses and a $120,000 increase in facility expenses. The compensation of our Chief Executive Officer is 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.

Interest and Other Income, Net. Interest and other income, net, increased by $1,547,000 to $2,317,000 for the year ended December 31, 2005, as compared to income of $770,000 for the year ended December 31, 2004. The increase resulted from a higher level of invested funds due to the completion of a public offering of our common stock that closed in July 2005, as well as due to the general increase in short-term market interest rates when compared to the comparable period last year.

Income Taxes. We did not record any income tax expense for the year ended December 31, 2005. For the year ended December 31, 2004, income tax expense was $1,000. Our income tax expense for the year ended December 31, 2004 resulted from state taxes imposed on our capital.

LIQUIDITY AND CAPITAL RESOURCES

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

As of December 31, 2006, we had $125.6 million in cash, cash equivalents, interest receivable, and short-term and long-term securities, an increase of $24.9 million from December 31, 2005. Cash used in operating activities for the year ended December 31, 2006 was $52.2 million, as compared to $25.8 million for the year ended December 31, 2005. This increase in cash used in operating activities was due primarily to increased expenditures associated with the execution of our business plan, including costs associated with our pivotal Phase III and Phase IV clinical program for Sulonex and the expansion of our other clinical programs. For the year ended December 31, 2006, net cash used in investing activities of $51.9 million was primarily the result of the investment of a portion of the proceeds of our registered direct offering that closed in March 2006 in marketable securities, as well as $7.6 million of manufacturing capital expenditures relating to the scale-up for larger scale production of Sulonex. For the year ended December 31, 2006, net cash provided by financing activities of $84.7 million was the result of our $82.7 million registered direct offering of our common stock completed in March 2006, and $2.0 million of proceeds from the exercise of options.

In March 2006, we completed a registered direct offering of 4,500,000 shares of our common stock to two institutional investors at $18.40 per share. We received approximately $82.7 million in proceeds, net of offering expenses of approximately $104,000.

We believe that our $125.6 million in cash, cash equivalents, interest receivable and investment securities as of December 31, 2006 will be sufficient to enable us to meet our planned operating needs and capital expenditures for approximately the next 18 to 24 months. Additionally, we also believe that our cash position provides us with added flexibility in our in-licensing and product acquisition program to potentially strengthen our portfolio with additional clinical-stage drug candidates.

Our cash and cash equivalents and investment securities as of December 31, 2006 are invested in highly liquid investments such as cash, money market accounts and short-term and long-term U.S. corporate and government debt and auction note securities. As of December 31, 2006, we are unaware of any known trends or any known demands,

commitments, events, or uncertainties that will, or that are reasonably likely to, result in a material increase or decrease in our required liquidity. We expect that our liquidity needs throughout 2007 will continue to be funded from existing cash, cash equivalents, and short-term marketable securities.

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

OFF-BALANCE SHEET ARRANGEMENTS

We do not have any unconsolidated entities, and accordingly, 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, 2006, we have known contractual obligations, commitments and contingencies of $73,098,000. Of this amount, $70,530,000 relates to research and development agreements (primarily relating to our pivotal Phase III and Phase IV clinical program for Sulonex), of which $31,205,000 is due within the next year, with the remaining balance due as per the schedule below. The additional $2,568,000 relates to our operating lease obligations, of which $788,000 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	$ 70,530,000	$ 31,205,000	$ 39,183,000	$ 142,000	$ —
Operating leases	2,568,000	788,000	1,321,000	459,000	—
Total	$ 73,098,000	$ 31,993,000	$ 40,504,000	$ 601,000	$ —

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 $77.4 million over the life of the licenses, of which approximately $58.8 million will be due upon or following regulatory approval of the licensed drugs. In certain cases, such payments will reduce any royalties due on sales of related products. In the event that the milestones are not achieved, we remain obligated to pay one licensor $50,000 annually until the license expires. We have also committed to pay to the former stockholders of ACCESS Oncology certain contingent equity rights (up to 3,372,422 shares of our common stock) if its drug candidates meet certain development milestones. 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 options to employees, directors and consultants, as well as warrants to other third parties. In December 2004, the FASB issued SFAS No. 123R. SFAS No. 123R is a revision of SFAS No. 123 "Accounting for Stock-Based Compensation" and amends SFAS No. 95 "Statement of Cash Flows." SFAS No. 123R supersedes APB Opinion No. 25 "Accounting for Stock Issued to Employees," and its related implementation guidance. SFAS No. 123R covers a wide range of share-based compensation arrangements including stock options, restricted share plans, performance-based awards, share appreciation rights, and employee share purchase plans. We adopted SFAS No. 123R effective January 1, 2006. See Note 1 to our consolidated financial statements.

In applying SFAS No. 123R, the value of each option award is estimated on the date of grant using the Black-Scholes option-pricing model. The Black-Scholes model takes into account volatility in the price of our stock, the risk-free interest rate, the estimated life of the option, the closing market price of our stock and the exercise price. We base our estimates of our stock price volatility on the historical volatility of our common stock and our assessment of future volatility; however, this estimate is neither predictive nor indicative of the future performance of our stock. For purposes of the calculation, we assumed that no dividends would be paid during the life of the options and warrants. The estimates utilized in the Black-Scholes calculation involve inherent uncertainties and the application of management judgment. In addition, we are required to estimate the expected forfeiture rate and only recognize expense for those options expected to vest. As a result, if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported.

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

Accruals for Clinical Research Organization and Clinical Site Costs. We make estimates of costs incurred to date in relation to external clinical research organizations, or CROs, and clinical site costs. We analyze the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Significant judgments and estimates must be made and used in determining the accrued balance in any accounting period. In addition, administrative costs related to external CROs are recognized on a straight-line basis over the estimated contractual period.

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

- revenue that is likely to result from the asset, including estimated selling price, estimated market share and year-over-year growth rates;
- operating margin; and

- sales and marketing and general and administrative expenses using historical and industry or other sources of market data;

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

As of December 31, 2006, there was approximately $3.2 million of net goodwill and $0.6 million of net other intangible assets on our consolidated balance sheet. We amortize our identifiable intangible assets over their estimated economic lives, which is 12 years, the life of the patents, using the straight-line method.

Accounting Related to the Valuation of Acquired In-Process Research and Development. As required by FIN 4, we recorded a charge of $18,800,000 for the estimate of the portion of ACCESS Oncology purchase price allocated to acquired in-process research and development.

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

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

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

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

The valuations are based on information that was available as of the acquisition date and the expectations and assumptions deemed reasonable by our management. No assurance can be given, however, that the underlying assumptions or events associated with such assets will occur as projected. For example, the following changes in our assumptions would have yielded the indicated change in the total amount of the acquired in-process research and development charge:

- if the growth rate regarding the revenue assumptions for the three drugs under development and included in the assumptions on future cash flows were increased by 10%, the result on the aggregate amount of the charge would have been approximately $4,500,000, yielding a total charge of approximately $23,300,000, or if the growth rate were decreased by 5%, the result on the aggregate amount of the charge would have been approximately $2,200,000, yielding a total charge of approximately $16,600,000;
- if the discount rate used to bring the estimated future cash flows to a present value amount (which was based on a 55% rate) were reduced by 10%, the total charge would have increased to approximately $33,000,000, and if the discount rate were increased by 10%, the total charge would have decreased to approximately $11,000,000.

Additionally, if it was assumed that the research and development activity of the least developed of the three drugs under development acquired with ACCESS Oncology was going to be terminated for any reason and had no alternative future use, including inconclusive clinical results, the amount of the in-process research and development charge would have been reduced, possibly creating a situation where we would have recognized goodwill.

In each of the above scenarios, the change in the in-process research and development charge would have required an equal change in contingent equity rights, or if a significant decrease, goodwill would have been recorded. Contingent equity rights represent the lesser of negative goodwill and the maximum value of the contingent consideration at the date of the acquisition. Changes in the acquired in-process research and development charge do not change the amount or the value of the contingent consideration that could ultimately be paid.

Impairment. SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," or SFAS No. 144, requires that long-lived assets be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized. Assets to be disposed of are reported at the lower of the carrying amount or fair value less costs to sell.

SFAS No. 142, “Goodwill and Other Intangible Assets,” or SFAS No. 142, requires periodic tests of goodwill for impairment and that other intangible assets be amortized over their useful lives unless these lives are determined to be indefinite. SFAS No. 142 requires goodwill be tested using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit’s goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit’s goodwill is compared with the carrying amount of the unit’s goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. We determine the implied fair value by discounting, to present value, the estimated future cash flow of the reporting unit, which includes various analyses, assumptions and estimates including discount rates, projected results and estimated cash flows.

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

Accounting For Income Taxes. In preparing our consolidated financial statements, we are required to estimate our income taxes in each of the jurisdictions in which we operate. This process involves management estimation of our actual current tax exposure and assessment of temporary differences resulting from differing treatment of items for tax and accounting purposes. These differences result in deferred tax assets and liabilities. We must then assess the likelihood that our deferred tax assets will be recovered from future taxable income and, to the extent we believe that recovery is not likely, we must establish a valuation allowance. To the extent we establish a valuation allowance or increase this allowance in a period, we must include an expense within the tax provision in the statement of operations. Significant management judgment is required in determining our provision for income taxes, our deferred tax assets and liabilities and any valuation allowance recorded against our net deferred tax assets. We have fully offset our U.S. deferred tax assets with a valuation allowance. Our lack of earnings history and the uncertainty surrounding our ability to generate taxable income prior to the reversal or expiration of such deferred tax assets were the primary factors considered by management in establishing the valuation allowance. In prior periods, our wholly-owned Israeli subsidiaries had generated taxable income in respect of services provided within the group, and therefore we believed in the past that our deferred tax assets relating to the Israeli subsidiaries would be realized. With the cessation of operating activities in Israel during 2003 and the resulting absence of taxable income from the Israeli subsidiaries, the deferred tax asset was written off in 2003.

RECENTLY ISSUED ACCOUNTING STANDARDS

In September 2006, the SEC staff issued Staff Accounting Bulletin Topic 1N, “Financial Statements — Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements,” or SAB 108, which is effective for calendar-year companies as of December 31, 2006. SAB 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the financial statements are materially misstated. SAB 108 requires that public companies utilize a “dual-approach” to assessing the quantitative effects of financial misstatements, whereby companies should take into account both the effect of a misstatement on the current year balance sheet as well as the impact upon the current year income statement in assessing the materiality of a current year misstatement. Once a current year misstatement has been quantified, the guidance in SAB Topic 1M, “Financial Statements — Materiality,” or SAB 99, should be applied to determine whether the misstatement is material. The adoption of SAB 108 did not have a material impact on our financial condition, results of operations or cash flows.

The FASB issued Statement of Financial Accounting Standards No. 157, “Fair Value Measurements,” or SFAS No. 157, in September 2006. The new standard provides guidance on the definition of and how to measure fair value and what sources of information are to be used in such measurements. It also prescribes expanded disclosures about fair value measurements contained in the financial statements. The pronouncement, including the new disclosures, is effective for us as of the first quarter of 2008. We are evaluating the potential impact of the new standard on our consolidated financial statements or results of operations; however, we do not expect the adoption of this standard will have a material effect on our consolidated financial statements.

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 may have market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the prevailing interest rate later rises, the principal amount of our investment will probably decline. As of December 31, 2006, our portfolio of financial instruments consisted of cash equivalents and short-term and long-term interest bearing securities, including corporate debt, money market funds, government debt and auction note securities. The average duration of all of our held-to-maturity investments held as of December 31, 2006, was less than ten months. Additionally, the re-pricing of our auction notes within thirty days allows these securities to function as short-term investments. Due to the short-term nature of our investments, we believe we have no material exposure to interest rate risk arising from our investments.

ITEM 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, 2006, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the 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 Financial Officer concluded that, as of December 31, 2006, 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, 2006. 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, 2006, our internal control over financial reporting is effective based on these criteria. Our independent registered public accounting firm, KPMG LLP, issued an attestation on our assessment of our internal control over financial reporting, which is included in this report.

Changes in Internal Control Over Financial Reporting. There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2006, 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 Financial 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 2007 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 2007 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 2007 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 2007 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 2007 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 (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 (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.

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
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†	Employment Agreement with I. Craig Henderson, M.D., dated as of January 31, 2004. filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2004, filed on May 14, 2004 (File No. 000-30929), and incorporated herein by reference.
10.2!	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.
10.3!	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.
10.4	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.
10.5†	Employment Agreement between Ron Bentsur and Keryx Biopharmaceuticals, Inc., dated as of June 23, 2003, filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q for the quarter ended June 30, 2003 filed on August 14, 2003 (File No. 000-30929), and incorporated herein by reference.
10.6†	

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.

10.7† 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.

10.8† 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.

10.9† 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.

10.10 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.

10.11 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.

10.12 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.

10.13 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.

10.14 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.

10.15! 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. .

10.16! 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.

10.17! 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.

10.18 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.

10.19 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.

10.20† Employment Agreement between Ronald C. Renaud, Jr. and Keryx Biopharmaceuticals, Inc., dated as of February 14, 2006, filed as Exhibit 10.20 to the Registrant's Annual Report on

Form 10-K for the year ended December 31, 2005, filed on March 8, 2006, and incorporated herein by reference.

10.21! 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.

10.22* 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.

10.23	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.
10.24†	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.
10.25†	CFO Incentive Stock Option Agreement dated February 14, 2006.
10.26†	President Incentive Stock Option Agreement dated February 5, 2004.
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 March 16, 2007.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 16, 2007.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 16, 2007.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 16, 2007.

! 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, 2006

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Financial Statements as of December 31, 2006

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, 2006 and 2005, 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, 2006, and for the period from December 3, 1996 to December 31, 2006. 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, a development stage company, as of December 31, 2006 and 2005, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2006, and for the period from December 3, 1996 to December 31, 2006, 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 effectiveness of the Company's internal control over financial reporting as of December 31, 2006, 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 March 14, 2007 expressed an unqualified opinion on management's assessment of, and the effective operation of, internal control over financial reporting.

/s/ KPMG LLP

New York, New York
March 14, 2007

Report of Independent Registered Public Accounting Firm

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

We have audited management's assessment, included in the accompanying Management's Report on Internal Control Over Financial Reporting, that Keryx Biopharmaceuticals, Inc. and subsidiaries (the "Company"), a development stage company, maintained effective internal control over financial reporting as of December 31, 2006, 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. Our responsibility is to express an opinion on management's assessment and an opinion on the effectiveness of 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, evaluating management's assessment, testing and evaluating the design and operating effectiveness of internal control, and 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, management's assessment that the Company maintained effective internal control over financial reporting as of December 31, 2006, is fairly stated, in all material respects, based on criteria established in Internal Control—Integrated Framework issued by the COSO. Also, in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2006, based on criteria established in Internal Control—Integrated Framework issued by the COSO.

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, 2006 and 2005, 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, 2006, and for the period from December 3, 1996 to December 31, 2006, and our report dated March 14, 2007 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

New York, New York
March 14, 2007

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Consolidated Balance Sheets as of December 31

(in thousands, except share and per share amounts)

	2006	2005
Assets		
Current assets		
Cash and cash equivalents	$ 48,736	$ 68,175
Short-term investment securities	63,659	18,272
Accrued interest receivable	525	336
Other receivables, inventory and prepaid expenses	2,048	3,200
Total current assets	114,968	89,983
Long-term investment securities	12,690	13,950
Property, plant and equipment, net	8,489	1,004
Goodwill	3,208	—
Other assets (primarily intangible assets), net	958	160
Total assets	$ 140,313	$ 105,097
Liabilities and stockholders' equity		
Current liabilities		
Accounts payable and accrued expenses	$ 10,460	$ 5,054
Accrued compensation and related liabilities	1,534	936
Deferred revenue	200	103
Total current liabilities	12,194	6,093
Contingent equity rights	4,004	4,004
Other liabilities	294	322
Total liabilities	16,492	10,419
Stockholders' equity		
Common stock, $0.001 par value per share (60,000,000 and 60,000,000 shares authorized, 43,516,669 and 37,831,896 shares issued, 43,460,569 and 37,775,796 shares outstanding at December 31, 2006, and 2005, respectively)	44	38
Additional paid-in capital	312,078	209,177
Treasury stock, at cost, 56,100 shares at December 31, 2006, and 2005, respectively	(89)	(89)
Deficit accumulated during the development stage	(188,212)	(114,448)
Total stockholders' equity	123,821	94,678
Total liabilities and stockholders' equity	$ 140,313	$ 105,097

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)

	2006	2005	2004	Amounts accumulated during the development stage
Revenue:				
Diagnostic revenue	$ 103	$ —	$ —	$ 103
Service revenue	431	574	809	1,814
Management fees from related party	—	—	—	300
Total revenue	534	574	809	2,217
Operating expenses:				
Cost of diagnostics sold	140	—	—	140
Cost of services	390	819	835	2,044
Research and development:				
Non-cash compensation	6,504	594	413	14,238
Non-cash acquired in-process research and development	—	—	18,800	18,800
Other research and development	56,139	24,182	9,805	120,033
Total research and development	62,643	24,776	29,018	153,071
Selling, general and administrative:				
Non-cash compensation	8,408	775	1,087	13,849
Other selling, general and administrative	9,110	3,416	3,581	34,196
Total selling, general and administrative	17,518	4,191	4,668	48,045
Total operating expenses	80,691	29,786	34,521	203,300
Operating loss	(80,157)	(29,212)	(33,712)	(201,083)
Interest and other income, net	6,393	2,317	770	13,362
Net loss before income taxes	(73,764)	(26,895)	(32,942)	(187,721)
Income taxes	—	—	1	491
Net loss	$ (73,764)	$ (26,895)	$ (32,943)	$ (188,212)
Basic and diluted loss per common share	$ (1.76)	$ (0.78)	$ (1.10)	$ (9.21)
Weighted average shares used in computing basic and diluted net loss per common share	41,919,741	34,384,576	30,053,647	20,440,585

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, 2003	—	$ —	25,016,873	$ 25	$ 86,042
Changes during the year:					
Issuance of common stock in private placement (net of issuance expenses of $338)	—	—	3,200,000	3	31,659
Issuance of common stock in connection with acquisition	—	—	623,145	1	6,324
Exercise of warrants	—	—	348,824	—*	2,093
Exercise of options	—	—	2,184,438	2	2,939
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	—	—	3,586
Net loss	—	—	—	—	—
Balance at December 31, 2004	—	$ —	31,373,280	$ 31	$ 132,643

	Treasury stock		Unearned compensation	Deficit accumulated during the development stage	Total
	Shares	Amount			
Balance at December 31, 2003	56,100	$ (89)	$ (142)	$ (54,610)	$ 31,226
Changes during the year:					
Issuance of common stock in private placement (net of issuance expenses of $338)	—	—	—	—	31,662
Issuance of common stock in connection with acquisition	—	—	—	—	6,325
Exercise of warrants	—	—	—	—	2,093
Exercise of options	—	—	—	—	2,941
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	(2,086)	—	1,500
Net loss	—	—	—	(32,943)	(32,943)
Balance at December 31, 2004	56,100	$ (89)	$ (2,228)	$ (87,553)	$ 42,804

* 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, 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 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	—	—
	—	—	—	—	14,912

Compensation in respect of options and warrants granted to employees, directors and third-parties					
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	
Amounts accumulated during the development stage (December 3, 1996 to December 31, 2006):					
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	* —	—
Issuance of restricted stock	—	—	100,000	* —	—
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	—	—	—	—	—
Exercise of warrants	—	—	753,897	1	3,050
Exercise of options	—	—	5,297,786	5	5,793
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	—	—	—	—	29,078
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, 2006	— $	—	43,516,669 $	44 $	312,078

* 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, 2006):					
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	—	—	—	—	* —
Issuance 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)
Exercise of warrants	—	—	—	—	3,051
Exercise of options	—	—	—	—	5,798
	—	—	1,581	—	—

Reclassification of unearned compensation upon adoption of SFAS No. 123R					
Compensation in respect of options and warrants granted to employees, directors and third-parties	—	—	(1,581)	—	27,497
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	—	—	—	(188,212)	(188,212)
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 Cash Flows for the Year Ended December 31

(in thousands)

	2006	2005	2004	Amounts accumulated during the development stage
CASH FLOWS FROM OPERATING ACTIVITIES				
Net loss	$ (73,764)	$ (26,895)	$ (32,943)	$ (188,212)
Adjustments to reconcile cash flows used in operating activities:				
Acquired in-process research and development	—	—	18,800	18,800
Stock compensation expense	14,912	1,369	1,500	28,087
Issuance of common stock to technology licensor	—	—	—	359
Interest on convertible notes settled through issuance of preferred shares	—	—	—	253
Depreciation and amortization	224	190	155	2,835
Loss on disposal of property, plant and equipment	—	2	—	172
Impairment charges	—	—	—	2,482
Exchange rate differences	—	—	(3)	94
Changes in assets and liabilities, net of effects of acquisitions:				
Decrease (increase) in other receivables, inventory and prepaid expenses	1,253	(2,578)	(43)	(1,576)
(Increase) in accrued interest receivable	(189)	(192)	(33)	(525)
(Increase) in security deposits	(255)	(8)	—	(263)
Increase in accounts payable and accrued expenses	4,974	1,975	874	8,715
Increase in accrued compensation and related liabilities	575	193	68	939
(Decrease) increase in other liabilities	(28)	230	(63)	139
Increase (decrease) in deferred revenue	97	(37)	(316)	(256)
Net cash used in operating activities	(52,201)	(25,751)	(12,004)	(127,957)
CASH FLOWS FROM INVESTING ACTIVITIES				
Purchases of property, plant and equipment	(7,597)	(964)	(24)	(12,988)
Proceeds from disposals of property, plant and equipment	—	1	—	425

(Increase) in note and accrued interest receivable from related party	—	—	(4)	(356)
Payments of transaction costs	(231)	—	—	(231)
Decrease (increase) in other assets	27	(23)	(8)	(1,192)
Investment in held-to-maturity short-term securities	(4,080)	(1,122)	(16,838)	(48,913)
Proceeds from maturity of held-to-maturity short-term securities	8,275	15,045	11,459	52,021
Investment in available-for-sale short-term securities	(38,375)	(13,700)	(6,025)	(58,100)
Proceeds from sale of available-for-sale short-term securities	6,725	8,675	1,000	16,400
Investment in held-to-maturity long-term securities	(16,677)	(21,270)	—	(37,947)
Proceeds from maturity of held-to-maturity long-term securities	5	185	—	190
Net cash used in investing activities	(51,928)	(13,173)	(10,440)	(90,691)

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 (continued)

(in thousands)

	2006	2005	2004	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)	(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	—	—	31,662	45,795
Proceeds from exercise of options and warrants	1,988	1,610	5,034	8,849
Purchase of treasury stock	—	—	—	(89)
Net cash provided by financing activities	84,685	77,400	30,374	267,379
Cash acquired in acquisition	5	—	94	99
Effect of exchange rate on cash	—	—	3	(94)
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(19,439)	38,476	8,027	48,736
Cash and cash equivalents at beginning of year	68,175	29,699	21,672	—
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 48,736	$ 68,175	$ 29,699	$ 48,736
NON - CASH TRANSACTIONS				
Issuance of common stock in connection with acquisition	$ 3,310	$ —	$ 6,325	$ 9,635
Contingent equity rights in connection with acquisition	—	—	4,004	4,004
Assumption of liabilities in connection with acquisition	345	—	8,723	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	$ —$	—$	1,026	$ 1,166
Cash paid for income taxes	$ —$	—$	1	$ 432

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

Keryx Biopharmaceuticals, Inc. (A Development Stage Company)
Notes to 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 2006 and 2005 were conducted in the United States of America.

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

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

The 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.

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, 2006 and 2005 consist of short-term and long-term government, auction notes and corporate debt 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 costs is not yet in production and is not amortized or depreciated until it is ready for its intended use.

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

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.

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.

STOCK - BASED COMPENSATION

In December 2004, the Financial Accounting Standards Board (“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.

The Company adopted SFAS No. 123R on January 1, 2006 using the modified prospective transition method. Under this method, compensation cost recognized for the year ended December 31, 2006 includes: a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of Statement of Financial Accounting Standards No. 123 “Accounting for Stock-Based Compensation,” (“SFAS 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 7 - Stockholders' Equity.

The Company accounts for equity instruments issued to third party service providers (non-employees) in accordance with the fair value method prescribed by the provisions of Emerging Issues Task Force Issue No. 96-18, "Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling Goods or Services" ("EITF 96-18").

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. SFAS No. 123 established accounting and disclosure requirements using a fair-value-based method of accounting for stock-based employee compensation plans. As permitted by SFAS No. 123, the Company elected to continue to apply the intrinsic-value-based method of APB 25 described above, and adopted only the disclosure requirements of SFAS No. 123, as amended by SFAS No. 148, "Accounting For Stock-Based Compensation - Transition and Disclosure."

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, 2006, 2005 and 2004, which are not included in the computation of net loss per share amounts, were 11,071,689, 8,346,628 and 8,193,174, 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.

The acquisition of ACCESS Oncology (see Note 6 - ACCESS Oncology Acquisition) 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 that long-lived assets subject to amortization be reviewed for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized by the amount by which the carrying amount of the asset exceeds the fair value of the asset. Assets to be disposed of are separately presented in the balance sheet and reported at the lower of the carrying amount or fair value less costs to sell, and are no longer depreciated.

The Company accounts for impairment of goodwill using the provisions SFAS No. 142, “Goodwill and Other Intangible Assets” (“SFAS No. 142”). This statement requires periodic tests of goodwill for impairment. 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, 2006, 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.

RECENTLY ISSUED ACCOUNTING STANDARDS

In September 2006, the SEC staff issued Staff Accounting Bulletin Topic 1N, “Financial Statements — Considering the Effects of Prior Year Misstatements when Quantifying Misstatements in Current Year Financial Statements,” (“SAB 108”) which is effective for calendar-year companies as of December 31, 2006. SAB 108 provides guidance on how prior year misstatements should be taken into consideration when quantifying misstatements in current year financial statements for purposes of determining whether the financial statements are materially misstated. SAB 108 requires that public companies utilize a “dual-approach” to assessing the quantitative effects of financial misstatements, whereby companies should take into account both the effect of a misstatement on the current year balance sheet as well as the impact upon the current year income statement in assessing the materiality of a current year misstatement. Once a current year misstatement has been quantified, the guidance in SAB Topic 1M, “Financial Statements — Materiality,” (“SAB 99”) should be applied to determine whether the misstatement is material. The adoption of SAB 108 did not have a material impact on the Company’s financial condition, results of operations or cash flows.

The FASB issued Statement of Financial Accounting Standards No. 157, “Fair Value Measurements” (“SFAS No. 157”), in September 2006. The new standard provides guidance on the definition of and how to measure fair value and what sources of information are to be used in such measurements. It also prescribes expanded disclosures about fair value measurements contained in the financial statements. The pronouncement, including the new disclosures, is effective for the Company as of the first quarter of 2008. The Company is evaluating the potential impact of the new standard on its consolidated financial statements; however, the Company does not expect the adoption of this standard will have a material effect on its consolidated financial statements.

NOTE 2 - CASH AND CASH EQUIVALENTS

(in thousands)	December 31, 2006	December 31, 2005
Money market funds	$ 14,733	$ 13,383
Checking and bank deposits	34,003	54,792
Total	$ 48,736	$ 68,175

NOTE 3 - INVESTMENT SECURITIES

The following tables summarize the Company's investment securities at December 31, 2006 and December 31, 2005 (regarding assumptions used for estimating fair value, see "Note 8 - Fair Value of Financial Instruments."):

	December 31, 2006			
(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 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

(in thousands)	December 31, 2005 Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (mature between July and October 2006) (Held-to-maturity)	$ 7,150	$ —	$ (49)	$ 7,101
Auction notes (Available-for-sale) *	10,050	—	—	10,050
US corporate debt securities (mature between March and May 2006) (Held-to-maturity)	1,072	—	(4)	1,068
	$ 18,272	$ —	$ (53)	$ 18,219
Long-term investments:				
Obligations of domestic governmental agencies (mature between January and July 2007) (Held-to-maturity)	$ 13,950	$ —	$ (90)	$ 13,860
US corporate debt securities (Held-to-maturity)	—	—	—	—
	$ 13,950	$ —	$ (90)	$ 13,860

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

NOTE 4 - PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2006	December 31, 2005
Manufacturing suite and equipment	$ 8,162	$ 663
Lab equipment	38	—
Leasehold improvements	16	16
Office furniture and equipment	311	308
Computers, software and related equipment	318	234
	8,845	1,221
Accumulated depreciation and amortization	(356)	(217)
Net book value	$ 8,489	$ 1,004

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, 2006, 2005 and 2004 was approximately $139,000, $102,000 and $67,000, respectively. The following table summarizes depreciation expense for the years ended December 31, 2006, 2005 and 2004.

(in thousands)	For the year ended December 31 2006	2005	2004
Depreciation expense:			
Cost of services	$ 2	$ 4	$ 7
Research and development	90	72	44
General and administrative	47	26	16
Total	$ 139	$ 102	$ 67

NOTE 5 - OTHER ASSETS

(in thousands)	December 31, 2006	December 31, 2005
Patents and other intangible assets	$ 1,007	$ 352
Long-term deposits	322	67
Deferred registration fees	22	49
	1,351	468
Accumulated amortization	(393)	(308)
	$ 958	$ 160

Amortization expense for the years ended December 31, 2006, 2005 and 2004 was approximately $84,000, $88,000 and $88,000, respectively. The Company expects amortization expense for the years ended December 31, 2007 and 2008 to be approximately $55,000 each year.

NOTE 6 - ACQUISITIONS

ACCUMIN TRANSACTION

On April 6, 2006, Accumin Diagnostics, Inc. (“ADI”), a wholly-owned subsidiary of the Company, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. (“AusAm”). The Company believes that the acquisition of Accumin may help increase the Company’s exposure to physicians that treat diabetes, the target market for Sulonex, by emphasizing the importance of early detection of microalbuminuria.

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 accrued 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 FDA marketing approval. Keryx filed a registration statement on Form S-3 with the Securities and Exchange Commission, or SEC, on April 6, 2006 with respect to the shares issued to AusAm which was declared effective on June 23, 2006 (the “Effective Date”). At closing, 300,000 shares were issued to AusAm by Keryx, but were held in escrow until the Effective Date. On the Effective Date, 245,024 shares were released from escrow to AusAm. As of December 31, 2006, 15,646 shares were issued and outstanding and still held in escrow, pending resolution of a

dispute over purchase consideration (see Note 14).

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 accrued cash settlement costs			341
Total purchase price			$ 3,996

The excess of the purchase price over the net assets acquired represented goodwill of approximately $3,208,000, which has been allocated to our Products segment, which is expected to benefit from the synergies of the Accumin acquisition.

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

(in thousands)

Allocation of purchase price:		
Tangible assets acquired	$	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.

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

ACCESS ONCOLOGY ACQUSITION

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 III (or other pivotal) clinical trial for any of the acquired ACCESS Oncology drug candidates;

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

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

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

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

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

The following represents the purchase price for ACCESS Oncology:

(in thousands, except share and per share amounts)

Assumed liabilities			$ 8,723
Number of shares of Keryx common stock issued		623,145	
	$	10.15	6,325

Multiplied by Keryx's volume-adjusted weighted average closing price per share measured over the last seven trading days immediately preceding the closing		
Contingent equity rights		4,004
Other transaction costs		450
Total purchase price	$	19,502

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).

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:		
Net assets acquired	$	725
Adjusted for write-off of existing intangible assets		23
Net tangible assets acquired		702
Acquired in-process research and development charge		18,800
Purchase price	$	19,502

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

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

(in thousands, except per share amounts)		**2004**
Revenue	$	911
Net loss	$	(14,086)
Basic and diluted loss per common share	$	(0.47)

The unaudited pro forma financial information above reflects the elimination of balances and transactions between the Company and ACCESS Oncology, which upon completion of the merger would be considered intercompany balances and transactions. The entries include the elimination of certain interest income and expense and the elimination of the reimbursement of salaries and related facility costs of two employees of ACCESS Oncology, both of which net to zero. In addition, the unaudited pro forma financial information above excludes the non-recurring, non-cash charge of $18,800,000 related to acquired in-process research and development in the year ended December 31, 2004.

NOTE 7 - 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 March 29, 2006, the Company completed a registered direct offering of 4,500,000 shares of its common stock to two institutional investors at $18.40 per share. Total proceeds to the Company from this public offering were approximately $82.7 million, net of offering expenses of approximately $0.1 million. The shares were sold under a shelf registration statement on Form S-3 (File No. 333-130809) filed with the Securities and Exchange Commission, or SEC, on December 30, 2005, and declared effective by the SEC on January 13, 2006, covering shares of the Company's Common Stock having a value not to exceed $150 million.

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

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

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. Keryx filed a registration statement on Form S-3 with the SEC on April 6, 2006 with respect to the shares issued to AusAm which was declared effective on June 23, 2006 (the "Effective Date"). At closing, 300,000 shares were issued to AusAm by Keryx, but were held in escrow until the Effective Date. On the Effective Date, 245,024 shares were released from escrow to AusAm. As of December 31, 2006, 15,646 shares were still held in escrow (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 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 6 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.

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.

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.

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

STOCK OPTIONS, RESTRICTED STOCK AND WARRANTS

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

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

b. The 2000 Stock Option Plan was adopted in June 2000. Under the 2000 Stock Option Plan the compensation committee of the Company's board of directors 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, 2006, up to 13,131 additional shares may be issued under the 2000 Stock Option Plan.

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

d. The 2002 CEO Incentive Stock Option Plan was adopted in December 2002. Under the 2002 CEO Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed Chief Executive Officer of the Company to purchase up to 2,002,657 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Executive Officer was part of a total grant of options issued pursuant to the 1999 Stock Option Plan, the 2000 Stock Option Plan and the 2002 CEO Incentive Stock Option Plan, to purchase a total of 4,050,000 shares of the Company's common stock. As of December 31, 2006, 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.

e. The 2004 President Incentive Stock Option Plan was adopted in February 2004. Under the 2004 President Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed President of the Company to purchase up to 1,000,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed President was made pursuant to an employment agreement following the acquisition of ACCESS Oncology in February 2004. Of 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, 2006, 486,111 options have vested under this plan. In addition, in the event of a merger, acquisition or other change of control or in the event that the Company terminates the President's employment, either without cause or as a result of his death or disability, or he terminates his employment for good reason, the exercisability of any of the options described in this paragraph that are unexercisable at the time of such event or termination shall accelerate and the time period during which he shall be allowed to exercise such options shall be extended to the shorter of two years from the date of the termination of his employment or February 5, 2014. Additionally, the Company's board of directors shall have the discretion to accelerate all or a portion of these options at any time. No additional shares of our common stock may be issued under the 2004 President Incentive Stock Option Plan.

f. The 2004 Long-Term Incentive Plan was adopted in June 2004 by our stockholders. Under the 2004 Long-Term Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants and employees. The 2004 plan authorizes grants to purchase up to 4,000,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 10 years from the date of their grant. As of December 31, 2006, up to an additional 139,027 shares may be issued under the 2004 Long-Term Incentive Plan.

g. The 2006 CFO Incentive Plan was adopted in February 2006. Under the 2006 CFO Incentive Plan the Company's board of directors granted an option to the newly-appointed Chief Financial Officer of the Company to purchase up to 500,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Financial Officer was made pursuant to an employment agreement. Of these options, 55,556 vest on the one-year anniversary of employment and 13,889 vest every three months following the one-year anniversary of employment until the 36th month of employment; and 333,333 vest after seven years, provided that the newly appointed Chief Financial Officer remains employed by the Company on such date. The 333,333 options may vest earlier upon the achievement of certain milestones, of which 111,111 have vested as of December 31, 2006. No additional shares of our common stock may be issued under the 2006 CFO Incentive Plan.

The following table summarizes equity awards authorized by the Company as of December 31, 2006.

Plan	Exercise price	Authorized	Outstanding	Exercised	Exercisable	Available for grant
1999 Stock Option Plan	$ 0.10 - 1.30	4,230,000	619,195	3,505,305	619,195	—
2000 Stock Option Plan	1.10 - 14.64	4,455,000	2,937,925	1,503,944	2,033,456	13,131
Non Plan	0.33	240,000	60,000	157,500	60,000	—
2002 CEO Incentive Stock Option Plan	1.30	2,002,657	2,002,657	—	2,002,657	—
2004 President Incentive Plan	9.25	1,000,000	1,000,000	—	486,111	—
2004 Long-Term Incentive Plan	7.13 - 18.06*	4,000,000	3,729,936	131,037	866,464	139,027
2006 CFO Incentive Plan	15.30	500,000	500,000	—	111,111	—

16,427,657	10,849,713	5,297,786	6,178,994	152,158

* Exercise price range excludes restricted stock.

A summary of the status of the Company's equity awards as of December 31, 2006, 2005, 2004, and changes during the years then ended is presented in the tables below.

		Outstanding equity awards	
	Shares available	Number of shares	Weighted-average exercise price
Balance, December 31, 2003	1,110,072	8,004,309	1.42
Authorized	5,000,000		
Granted	(1,870,000)	1,870,000	8.86
Exercised	—	(2,184,438)	1.35
Forfeited and expired	15,250	(15,250)	8.15
Balance, December 31, 2004	4,255,322	7,674,621	3.24
Authorized	—		
Granted	(952,500)	952,500	11.50
Exercised	—	(520,969)	1.27
Forfeited and expired	81,500	(81,500)	11.96
Balance, December 31, 2005	3,384,322	8,024,652	4.26
Authorized	500,000		
Granted	(3,799,660)	3,799,660	14.11
Exercised	—	(824,103)	2.41
Canceled	(83,000)		
Forfeited and expired	150,496	(150,496)	6.09
Balance, December 31, 2006	152,158	10,849,713	7.82
Exercisable at December 31, 2004		3,807,576	1.75
Exercisable at December 31, 2005		4,360,135	2.37
Exercisable at December 31, 2006		6,178,994	3.92

As discussed above, as of December 31, 2006, there were 100,000 shares of restricted stock outstanding under the 2004 Long-Term Incentive Plan (included in the tables above).

A summary of share-based compensation activity for the year ended December 31, 2006 is presented below:

Stock Options

	Number of Options	Exercise price per share	Weighted-average exercise price	Weighted-average remaining contractual term (years)	Aggregate intrinsic value
Outstanding at January 1, 2006	8,024,652	$ 0.10 - $16.67	$ 4.26	7.2	$ 83,296,000
Granted	3,699,660	10.51 - 18.06	14.49		
Exercised	(824,103)		2.41		

		0.10 - 12.19			
Forfeited and expired	(150,496)	0.10 - 17.16	6.09		
Outstanding at December 31, 2006	10,749,713	0.10 - 18.06	7.90	7.6	58,048,000
Vested and expected to vest at December 31, 2006	10,706,853	0.10 - 18.06	7.88	7.6	58,031,000
Exercisable at December 31, 2006	6,178,994	0.10 - 16.67	3.92	6.7	57,959,000

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

	For the year ended December 31		
	2006	2005	2004
Weighted-average fair value of options granted during the period at an exercise price equal to market price at issue date	$ 7.79	$ 7.84	$ 5.87
Weighted-average exercise price of options granted during the period at an exercise price equal to market price at issue date	14.49	11.50	8.91
Weighted-average fair value of options granted during the period at an exercise price greater than market price at issue date	N/A	N/A	N/A
Weighted-average exercise price of options granted during the period at an exercise price greater than market price at issue date	N/A	N/A	N/A

The following table summarizes information about stock options outstanding at December 31, 2006:

	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	271,852	17.9	$ 0.10	271,852	$ 0.10
0.11 - 0.50	60,000	3.1	$ 0.33	60,000	$ 0.33
0.51 - 3.00	4,014,735	5.9	$ 1.30	4,014,735	$ 1.30
3.01 - 5.75	329,190	6.8	$ 4.55	248,721	$ 4.54
5.76 - 10.00	1,146,000	7.1	$ 9.15	581,799	$ 9.12
10.01 - 19.00	4,927,936	8.6	$ 13.73	1,001,887	$ 12.52
	10,749,713			6,178,994	

At December 31, 2006, 4,696,829 options issued to directors and employees and 600,957 options issued to consultants have been exercised. The terms of the outstanding options at December 31, 2006 are as follows:

To Directors and Employees

	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	261,852	17.9	$ 0.10	261,852	$ 0.10
0.11 - 0.50	60,000	3.1	0.33	60,000	0.33
0.51 - 3.00	3,823,735	5.9	1.30	3,832,485	1.30
3.01 - 5.75	213,936	7.1	4.70	153,571	4.44
5.76 - 10.00	1,116,000	7.0	9.20	558,924	9.20
10.01 - 19.00	4,507,436	8.6	13.86	858,137	12.70
	9,982,959			5,724,969	

As of December 31, 2006, 4,377,166 options issued to directors and employees are milestone-based, of which 3,379,944 options are vested and exercisable.

To Consultants

	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	10,000	17.9	$ 0.10	10,000	$ 0.10
0.11 - 0.50	—	—	—	—	—
0.51 - 3.00	191,000	6.2	1.14	182,250	1.14
3.01 - 5.75	115,254	6.1	4.28	95,150	4.70
5.76 - 10.00	30,000	7.6	7.13	22,875	7.32
10.01 - 19.00	420,500	7.7	12.30	143,750	11.42
	766,754			454,025	

As of December 31, 2006, 93,000 options issued to consultants are milestone-based, of which 43,000 options are vested and exercisable.

Restricted Stock

	Number of Shares	Average Grant Date Fair Value
Nonvested, January 1, 2006	—	—
Granted	100,000	$ 15.30
Vested	—	—
Forfeited	—	—
Nonvested, December 31, 2006	100,000	$ 15.30

There have been no restricted stock issuances prior to January 1, 2006.

Warrants

	Warrants	Weighted-average exercise price
Balance, December 31, 2003	1,242,377	3.71
Issued	—	—
Exercised	(348,824)	6.00
Canceled	(375,000)	0.01
Balance, December 31, 2004	518,553	$ 4.86
Issued	—	—
Exercised	(157,647)	6.00
Canceled	(38,930)	1.94
Balance, December 31, 2005	321,976	$ 4.65
Issued	—	—

Exercised	—		—
Canceled	—		—
Balance, December 31, 2006	321,976	$	4.65

As of December 31, 2006, 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, 2006 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	3.0	$ 0.01	72,564	$ 0.01
6.00	249,412	1.9	6.00	249,412	6.00
	321,976	2.1	$ 4.65	321,976	$ 4.65

Stock-based Compensation

The application of SFAS No. 123R had the following effect on reported amounts, for the year ended December 31, 2006, relative to amounts that would have been reported using the intrinsic value method under previous accounting:

(in thousands, except per share amounts)	Year ended December 31, 2006
Net loss, using previous accounting method	$ (62,097)
Basic and diluted loss per ordinary share, using previous method	(1.48)
Impact of the adoption of SFAS No. 123R	(11,667)
Net loss, as reported	(73,764)
Basic and diluted loss per ordinary share, as reported	$ (1.76)

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

The weighted average fair market value of options and restricted stock granted during the year ended December 31, 2006, as of the date of the grant, was $7.79 and $15.30, respectively. The assumptions used in the calculation of the fair value of options granted during the year ended December 31, 2006 were a weighted average expected term of 3.1 years, a weighted average expected volatility rate of 78.31% and a weighted average risk-free interest rate of 4.74%. The Company used historical information to estimate forfeitures within the valuation model. As of December 31, 2006, there was $21.8 million of total unrecognized compensation cost, related to nonvested stock options and restricted stock, which is expected to be recognized over a weighted-average period of 2.5 years. That amount does not include, as of December 31, 2006, 1,047,222 options and 50,000 shares of restricted stock outstanding, which are milestone-based and vest upon certain corporate milestones, such as FDA approval of our drug candidates, market capitalization targets and a qualified change in control. 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 outstanding at December 31, 2006:

(in thousands)	Year ended December 31, 2006
Stock-based compensation expenses associated with restricted stock	$ 189
Stock-based compensation expense associated with option grants to employee and directors+	12,536
Stock-based compensation expense associated with option grants to consultants	2,187
Stock-based compensation expense associated with warrants	—
	14,912

+ Includes additional non-cash compensation expense during the year ended December 31, 2006 of $106,000, relating to a previous grant made to a former director. The Company also incurred additional non-cash compensation expense during the year ended December 31, 2006, of $1,697,000, relating to previous grants made to a former officer and two additional former directors. The Board of Directors agreed to modify their option agreements such that their vesting and exercisability has been extended beyond the terms of their original agreements.

Prior to January 1, 2006, the Company applied the intrinsic value-based method of accounting prescribed by the Accounting Principles Board Opinion No. 25, “Accounting for Stock Issued to Employees” (“APB 25”), and related interpretations, including Financial Accounting Standards Board (“FASB”) Interpretation 44, “Accounting for Certain Transactions involving Stock Compensation, an Interpretation of APB Opinion No. 25,” to account for its fixed-plan stock options for employees and non-employee directors. Under this method, compensation expense was recorded on the date of grant only if the current market price of the underlying stock exceeded the exercise price. Prior to January 1, 2006, the Company provided pro forma disclosure amounts in accordance with SFAS No. 123, as amended by Statement of Financial Accounting Standards 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	2004	Amounts accumulated during the development stage
Net loss, as reported	$ (26,895)	$ (32,943)	$ (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	667	10,179
Deduct: Stock-based compensation expense to employees and directors determined under fair value based method	(3,797)	(3,770)	(20,216)
Pro forma net loss	$ (30,247)	$ (36,046)	$ (124,485)
Basic and diluted loss per common share:			

As reported	$ (0.78)	$ (1.10)	$ (6.34)
Pro forma	$ (0.88)	$ (1.20)	$ (6.89)

The value of these options has been estimated using the Black-Scholes model. The weighted average fair market value of options granted during the year ended December 31, 2005 as of the date of the grant, was $7.84. The assumptions used in the calculation of the fair value of options granted during the year ended December 31, 2005 were a weighted average expected term of 4.9 years, a weighted average expected volatility rate of 84.88% and a weighted average risk-free interest rate of 3.72%. The weighted average fair market value of options granted during the year ended December 31, 2004, as of the date of the grant, was $4.38. The assumptions used in the calculation of the fair value of options granted during the year ended December 31, 2004 were a weighted average expected term of 4.8 years, a weighted average expected volatility rate of 84.24% and a weighted average risk-free interest rate of 2.85%.

The Company applies EITF 96-18 “Accounting for Equity Instruments that are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services,” in accounting for its options granted to consultants. For the years ended December 31, 2005 and 2004, the Company recorded non-cash compensation expense of approximately $924,000 and $833,000, respectively. Unvested options are revalued at every reporting period and amortized over the vesting period in order to determine the compensation expense. The value of these options has been estimated using the Black-Scholes model under the assumptions stated above.

The Company applies EITF 96-18 in accounting for its warrants granted to non-employees and non-directors. For the years ended December 31, 2005 and 2004, the Company did not record any non cash compensation expense, as all warrants were vested. 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 were issued in 2005 and 2004.

Review of Stock Option Grant Procedures

At the direction of the Company’s Board of Directors, the Company commenced an internal review into the Company’s historical stock option practices from the date of its initial public offering through the second quarter of 2006 under the Company’s stock option plans in effect during this period, including a review of the underlying option grant documentation and procedures. This internal review was completed during the third quarter of 2006 and is discussed below.

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

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

NOTE 8 - FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company’s financial instruments at December 31, 2006 and 2005 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 9 - INCOME TAXES

As of December 31, 2006, the Company has U.S. net operating loss carryforwards of approximately $172 million which expire from 2019 through 2026. 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 $95 million and $57.9 million as of December 31, 2006 and 2005, respectively. If the entire deferred tax asset were realized, $15.3 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 is subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision.

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

The tax expense reported in prior periods primarily related to the subsidiaries in Israel. Income tax expense attributable to income from continuing operations was $0, $0 and $1,000, for the years ended December 31, 2006, 2005 and 2004, 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)	**2006**	**2005**	**2004**
Losses before taxes on income, as reported in the consolidated statements of operations	$ (73,764)	$ (26,895)	$ (32,943)
Computed "expected" tax benefit	(25,817)	(9,413)	(11,530)
Increase (decrease) in income taxes resulting from:			
Expected benefit from state & local taxes	(8,154)	(3,379)	(2,853)
Change in state and local effective tax rate	(831)	(3,130)	—
Permanent differences, including IPR&D of $6,580 in 2004	1,067	(571)	6,586
Effect of foreign operations	—	—	143
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	33,735	16,493	7,654
	$ —	$ —	$ —

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)	**2006**	**2005**	**2004**
Deferred tax benefit	$ (37,129)	$ (18,931)	$ (19,104)
Federal deferred tax benefit relating to the exercise of stock options	3,394	2,438	5,926
Federal deferred tax benefit relating to ACCESS Oncology	—	—	5,524
Increase in the valuation allowance for deferred tax assets	33,735	16,493	7,654
	$ —	$ —	$ —

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2006 and 2005 are presented below.

(in thousands)	December 31, 2006	December 31, 2005
Deferred tax assets/(liabilities):		
Net operating loss carryforwards	$ 78,235	$ 45,697
Net operating loss carryforwards (ACCESS Oncology)	6,128	6,128
Non-cash compensation	7,843	2,298
Research and development	1,977	2,457
Intangible assets due to different amortization methods	730	870
Accrued compensation	19	357
Other temporary differences	72	68
Net deferred tax asset, excluding valuation allowance	95,004	57,875
Less valuation allowance	(95,004)	(57,875)
Net deferred tax assets	$ —	$ —

NOTE 10 - INTEREST AND OTHER INCOME, NET

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

(in thousands)	For the year ended December 31, 2006	2005	2004
Interest income	$ 6,378	$ 2,317	$ 690
Interest expense and other bank charges	—	—	(27)
Other income	15	—	107
	$ 6,393	$ 2,317	$ 770

In 2006, other income consisted of rental income from a related-party. In 2004, other income consisted of a one-time payment of $107,000 from a related-party service agreement that terminated in 2004.

NOTE 11 - COMMITMENTS AND CONTINGENCIES

Research & Development Agreements

The Company has entered into various research and development agreements (primarily relating to the Company's pivotal Phase III and Phase IV clinical program for Sulonex) under which it is obligated to make payments of approximately $70,530,000 through December 2010. The following table shows future research and development payment obligations by period as of December 31, 2006.

(in thousands)	2007	2008	2009	2010	2011
Research and development agreements	$ 31,205	$ 23,086	$ 16,097	$ 142	—

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 $658,000, $514,000 and $240,000 for the years ended December 31, 2006, 2005, and 2004, respectively.

Future minimum lease commitments as of December 31, 2006, in the aggregate total approximately $2,568,000 through 2010. The following table shows future minimum lease commitments by period as of December 31, 2006.

(in thousands)	2007	2008	2009	2010	2011
Operating leases	$ 788	$ 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 $49,000, $48,000 and $50,000 in 2006, 2005 and 2004, respectively, pursuant to the terms of this arrangement, which amounts have been included in accounts payable and accrued expenses in the accompanying balance sheets as of December 31, 2006 and 2005, respectively. The 2004 and 2005 amounts have been paid, and the 2006 amount 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 commitments described in this paragraph are not reflected in the table above.

The Company has undertaken to make contingent milestone payments to certain of our licensors of up to approximately $77.4 million over the life of the licenses, of which approximately $58.8 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 two licensors $50,000 and $22,500, respectively, annually until the licenses expire. As of December 31, 2006, the Company has recorded a total of $2,922,500 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 6 — Acquisitions —ACCESS Oncology Acquisition). 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 12 - 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 13 - SEGMENT INFORMATION

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

Segment information for the years ended December 31, 2006, 2005 and 2004 were as follows:

	Revenue	**Amounts accumulated during the development**

(in thousands)	2006	2005	2004	Stage
Diagnostics	$ 103	$ —	$ —	$ 103
Services	431	574	809	1,814
Products	—	—	—	—
Total	$ 534	$ 574	$ 809	$ 1,917

(in thousands)	Operating loss 2006	2005	2004	Amounts accumulated during the development Stage
Diagnostics	$ (1,016)	$ —	$ —	$ (1,016)
Services	41	(245)	(26)	(230)
Products	(79,182)	(28,967)	(33,686))	(199,837)
Total	$ (80,157)	$ (29,212)	$ (33,712)	$ (201,083)

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

(in thousands)	Net loss 2006	2005	2004	Amounts accumulated during the development Stage
Operating losses of reportable segments	$ (80,157)	$ (29,212)	$ (33,712)	$ (201,083)
Interest and other income	6,393	2,317	770	13,362
Income taxes	—	—	(1)	(491)
Consolidated net loss	$ (73,764)	$ (26,895)	$ (32,943)	$ (188,212)

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

The excess of the purchase price over the net assets acquired in the Accumin transaction represented goodwill of approximately $3,208,000, which has been allocated to our Products segment, which is expected to benefit from the synergies of the acquisition. The carrying amount of goodwill by reportable segment as of December 31, 2006 and 2005 was as follows:

(in thousands)	Goodwill December 31, 2006	December 31, 2005
Diagnostics	—	—
Services	—	—
Products	$ 3,208	—
Total	$ 3,208	—

NOTE 14 - 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 $1,032,000, 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. In October 2006, the Circuit Court of Jerusalem held that the service of process on Keryx Biopharmaceuticals, Inc. was valid. The Company has appealed this determination and the appeal is currently pending. The Circuit Court of Jerusalem held that the service of process on Michael S. Weiss was invalid. Consequently, the Circuit Court of Jerusalem dismissed the suit against Mr. Weiss. To date, 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.

In April 2006, the Company acquired the assets of the diagnostics business of AusAm Biotechnologies, Inc., a debtor in a pending Chapter 11 proceeding, in a court-approved transaction. Subsequent to the closing, disputes arose between the debtor and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, the debtor filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145. (In re: AusAm Biotechnologies, Inc., Chapter 11 Case No. 06-10214 (RDD) (Bankr. S.D.N.Y.)). Keryx opposed the motion and asserted a counterclaim alleging fraud in connection with the acquisition. The parties have agreed to a settlement in principle of the matter, subject to documentation and Bankruptcy Court approval, pursuant to which Keryx will pay AusAm approximately $110,000.

NOTE 15 - QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	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)

	2005			
	Mar. 31	**June 30**	**Sept. 30**	**Dec. 31**
	(in thousands, except per share data)			
Diagnostic revenue	$ —	$ —	$ —	$ —
Service revenue	157	126	82	209
Total revenue	157	126	82	209
Operating expenses:				
Cost of diagnostics sold	—	—	—	—
Cost of services	181	161	197	280
Research and development:				
Non-cash compensation	176	137	226	55
Other research and development	4,042	5,180	6,501	8,459
Total research and development	4,218	5,317	6,727	8,514
Selling, general and administrative:				
Non-cash compensation	185	168	258	164
Other selling, general and administrative	645	699	671	1,401
Total selling, general and administrative	830	867	929	1,565
Total operating expenses	5,229	6,345	7,853	10,359
Operating loss	(5,072)	(6,219)	(7,771)	(10,150)
Other income (expense)				
Interest and other income, net	240	267	823	987
Net loss	$ (4,832)	$ (5,952)	$ (6,948)	$ (9,163)
Net loss per common share				
Basic and diluted	$ (0.15)	$ (0.19)	$ (0.19)	$ (0.24)

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.

Date: March 16, 2007

KERYX BIOPHARMACEUTICALS, INC.

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 Ronald C. Renaud, Jr., 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 March 16, 2007, and in the capacities indicated:

Signatures	**Title**
/s/ Michael S. Weiss Michael S. Weiss	Chairman and Chief Executive Officer (principal executive officer)
/s/ Ronald C. Renaud, Jr. Ronald C. Renaud, Jr.	Senior Vice President, Chief Financial Officer, Secretary and Treasurer (principal financial and accounting officer)
/s/ I. Craig Henderson, M.D. I. Craig Henderson, M.D.	President and Director
/s/ Senator Wyche Fowler, Jr. Senator Wyche Fowler, Jr.	Director
/s/ Malcolm Hoenlein	Director

Malcolm Hoenlein	
/s/ Jack Kaye, CPA Jack Kaye, CPA	Director
/s/ Eric A. Rose, M.D. Eric A. Rose, M.D.	Director

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.25	CFO Incentive Stock Option Agreement dated February 14, 2006.
10.26	President Incentive Stock Option Agreement dated February 5, 2004.
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 March 16, 2007.
31.2	Certification of Chief Financial Officer pursuant to Rule 13a-14(a)/15d-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002, dated March 16, 2007.
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 16, 2007.
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. §1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, dated March 16, 2007.