KERYX BIOPHARMACEUTICALS INC
Form 10-K
March 31, 2009

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, 2008.

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	NASDAQ Capital Market
(Title of Class)	(Name of Each Exchange on Which Registered)

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

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes £ No 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 £
Non-accelerated filer £	Smaller reporting company x

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 $22,080,654 as of June 30, 2008, based on the closing sale price of such stock as reported on the NASDAQ Capital Market.

There were 47,832,004 shares of the registrant's common stock outstanding as of March 9, 2009.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2009 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, 2008

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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. All other trademarks, service marks, or tradenames referenced in this Annual Report on Form

10-K are the property of their respective owners.

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 ZerenexTM (ferric citrate), KRX-0401 (perifosine), and our additional product candidates or any other products we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our business strategy, including expectations regarding the value and liquidity of our investments, including auction rate securities;
- ability to continue as a going concern;
- expected losses; and
- expectations for future capital requirements.

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

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

PART I

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

ITEM 1. BUSINESS.

OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important, novel pharmaceutical products for the treatment of life-threatening diseases, including renal disease and cancer. We are developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 2 clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. We are also developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth. KRX-0401 also modulates a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase 2 clinical development for multiple tumor types. We also actively engage in business development activities that include evaluating compounds and companies for in-licensing or acquisition, as well as seeking strategic relationships for our product candidates and for our company. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates. We have generated, and expect to continue to generate, revenue from the licensing of rights to Zerenex in Japan to our Japanese partner, Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii").

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

Product candidate	Target indication	Development status
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	Phase 2
KRX-0401 (perifosine)	Multiple forms of cancer	Phase 2

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 renal disease 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;
- identify and explore licensing and partnership opportunities for our current drug candidates; and
- commercialize our drug candidates, either alone or in partnership, which we believe is important to provide maximum shareholder value.

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

Zerenex™ (ferric citrate)

Overview

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

Market Opportunity

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

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

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

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

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

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

Clinical Data

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

and Taiwan.

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

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

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

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

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

In December 2008, we completed our Phase 2 high-dose tolerance and safety study. The goal of this study was to assess tolerability and safety in end-stage renal disease patients with doses of Zerenex ranging from approximately 3.0 grams per day to 12.0 grams per day. The open-label study was conducted in two parts by the Collaborative Study Group utilizing seven sites in the U.S. Part 1 of the study enrolled 34 patients. Patients taking approximately 6 to 15 capsules or tablets per day of their current phosphate binder were immediately switched to a starting dose of 4.5 grams per day of Zerenex, and were treated for 28 days. Part 2 of the study enrolled 21 patients. In this part, patients taking approximately 12 or more capsules or tablets per day of their current phosphate binder were immediately switched to a starting dose of 6.0 grams per day of Zerenex, and were treated for 28 days. In January 2009, we presented preliminary results of part 1 of the study at the J.P. Morgan Annual Healthcare Conference. In March 2009, we provided updated preliminary results for the entire study on our fourth quarter and year-end financial results conference call. The preliminary results for the entire study are found in the table below.

	Serum Phosphorous (Mean +/- standard deviation)
Visit 0 (Baseline)	5.8 +/- 1.5
Visit 4 (Treatment for 28 days)	5.4 +/- 1.3

The average dose of Zerenex administered in this trial was 7.5 grams per day. There were no observed changes in the following iron parameters: serum iron, ferritin, transferrin, and total iron binding capacity, or intact parathyroid hormone. Four serious adverse events were reported, all of which were deemed by the investigators to be unrelated to Zerenex. The most commonly reported adverse event was change in stool color, which is an expected side effect of Zerenex, about which all of the patients were notified in advance, and no patients withdrew from the study as a result. In addition, although not designed as an efficacy clinical trial, Zerenex appeared to manage and control serum phosphorus levels in patients who were switched from their current phosphorus binders without washout to Zerenex.

Development Status

In July 2006, we met with the FDA to discuss the further development of Zerenex, including Phase 3 study design and requirements prior to moving into Phase 3. To support higher doses and longer duration of treatment in Phase 3, we agreed with the FDA to conduct additional studies. The FDA suggested additional animal toxicity studies and a high dose Phase 2 study.

In August 2007, we provided the FDA with our 28-day toxicology package for rats and canines.

In 2008, we completed the dosing in the 90-day toxicology study in rats and 16-week toxicology study in canines. The final reports for these studies were submitted to the FDA in the first quarter of 2009. These studies will assist the Company in designing the chronic toxicity studies, which we are planning, with our Japanese partner, to initiate in 2009.

In 2008, we completed our Phase 2 high-dose tolerance and safety study. Preliminary results are presented above. We plan to meet with the FDA for an end of Phase 2 meeting in 2009 to discuss a Phase 3 program.

In addition, in March 2009, our Japanese partner, JT and Torii, informed us that they had initiated a Phase 2 clinical study of Zerenex in Japan, which triggered a $3 million non-refundable milestone payment which was received by us in March 2009.

KRX-0401 (perifosine)

Overview

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

To date, over 1,800 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. KRX-0401 does not appear to cause flu-like symptoms, thrombocytopenia (decrease in platelets that may result in bleeding) or alopecia (hair loss); all of these toxicities occur frequently with many of the currently available treatments for cancer. The main side effects of KRX-0401 are nausea, vomiting, diarrhea and fatigue, but these are generally well-managed particularly at lower daily doses (50 mg or 100 mg) that have induced tumor regression. Responses have been seen with both daily and weekly regimens. At the doses studied, the daily regimens were better tolerated.

Pre-Clinical and Clinical Data Overview

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

Seven Phase 1 single agent studies of KRX-0401 have been completed; three in Europe by Zentaris and four in the United States by the NCI, a department of the National Institutes of Health, or NIH, as part of a Cooperative Research and Development Agreement, or CRADA, and by us. These trials demonstrated that KRX-0401 can be safely given to humans with a manageable toxicity profile. The dose limiting toxicity in the Phase 1 studies was gastrointestinal: nausea, vomiting and diarrhea.

Thirteen Phase 1/2 studies of KRX-0401 in combination with other drugs have been conducted by Keryx. Agents that have been included in these combinations include gemcitabine, paclitaxel, docetaxel, prednisone, doxorubicin, capecitabine, pemetrexed, irinotecan, Doxil® (doxorubicin HCl liposome injection), trastuzumab, various endocrine therapies, imatinib, bortezomib, lenalidomide, sorafenib, and sunitinib. KRX-0401 has generally been well tolerated when used as a low daily dose (50 mg or 100 mg) in combination with these approved agents. KRX-0401 has also been studied in combination with radiotherapy without evidence of increased toxicity.

The NCI has completed a number of Phase 2 clinical trials studying KRX-0401 as a single agent, including studies in prostate, breast, head and neck and pancreatic cancers, as well as melanoma and sarcomas. In total, nine NCI clinical trials have been conducted across these six tumor types.

KRX-0401 has also been evaluated in ten Phase 2 clinical studies conducted by Keryx evaluating the single agent activity in various tumor types where patients have progressed on standard treatments. Clinical trials where responses have been reported have been conducted in patients with renal cell carcinoma, advanced brain tumors, soft-tissue sarcomas, hepatocellular carcinoma, as well as in hematologic malignancies including multiple myeloma and Waldenstrom's macroglobulinemia. As illustrated in the previous NCI trials, the lower daily doses (50 mg or 100 mg) have been better tolerated than the intermittent higher doses.

Multiple Myeloma Clinical Data

In December 2008, at the American Society of Hematology annual meeting, in an oral presentation by Dr. Paul Richardson, Clinical Director of the Multiple Myeloma Center at Dana-Farber Cancer Institute in Boston, we announced data on the clinical activity of KRX-0401 in combination with bortezomib (with or without dexamethasone) in patients with relapsed/refractory multiple myeloma. Updated data was presented in a poster at the February 2009 International Multiple Myeloma Workshop. This trial was designed as a Phase 1/2 study. The Phase 1 portion enrolled 18 patients and the Phase 2 portion enrolled 66 patients (total of 84 patients), all with advanced multiple myeloma (83% relapsed and refractory). Patients had a median of five lines of prior therapy and all patients were previously treated with at least one course of therapy on bortezomib (median number of prior bortezomib treatments was two). The percent of patients who received other prior treatments included dexamethasone (98%), lenalidomide (75%), thalidomide (74%) and stem cell transplant (57%). In the Phase 1 portion, KRX-0401 was escalated from 50 to 100 mg once daily while bortezomib was escalated from 1.0 to 1.3 mg/m2. No dose-limiting toxicity and no grade 3 peripheral neuropathy were reported. Toxicities were generally well managed and tolerated. Dexamethasone, dosed at 20 mg the day of and day after each bortezomib dose, was added in patients with progressive disease on the combination of KRX-0401 and bortezomib. The Phase 2 dose was selected at 50 mg of KRX-0401 once daily with 1.3 mg/m2 of bortezomib at the FDA approved schedule. Seventy-three patients in the Phase 1/2 study were evaluable for response, assessed by modified EBMT/Blade criteria. As in the Phase 1, adverse events were generally well managed. Overall response rate (ORR), defined as complete responses (CR), partial responses (PR) and minor responses (MR), as well as stable disease (SD) was reported in all evaluable patients and is presented in the table below. Additionally, data for the subsets of patients who were previously refractory to bortezomib (progressed on or within 60 days) and patients who relapsed (responded, then progressed after 60 days off-treatment) from prior bortezomib treatment are presented in the table below.

Evaluable Patients (≥ 2 cycles)	CR		PR		MR		ORR		SD > 3 months	
Bortezomib Relapsed (n=20)	2	10%	6	30%	3	15%	11	55%	9	45%
Bortezomib Refractory (n=53)	1	2%	6	11%	10	19%	17	32%	24	45%
All Evaluable Patients (n=73)	3	4%	12	16%	13	18%	28	38%	33	45%

Patients who had previously relapsed on a bortezomib-based treatment had a median time to progression of 8.5 months at the time of data presentation. The median time to progression for all 73 evaluable study patients (both bortezomib relapsed and refractory) was 6.4 months at the time of data presentation. The investigators concluded that the combination of KRX-0401 and bortezomib (with or without dexamethasone) was well tolerated and is active in heavily pre-treated and relapsed/refractory multiple myeloma patients, including bortezomib-refractory patients. The trial remains open with 16 patients continuing on study treatment as of February 2009.

Development Status

In March 2008, we implemented a strategic restructuring plan to reduce our cash burn rate and re-focus our development efforts on programs and opportunities that we believed were most likely to provide long-term shareholder value. As such, during 2008, we closed enrollment to several clinical trials for KRX-0401 to better focus on tumor types showing promise, such as multiple myeloma, renal cell carcinoma, colorectal cancer and brain cancer.

We believe that the data compiled to date, both with KRX-0401 used as single agent and in combination with novel agents, continues to support the development of KRX-0401 in Phase 2/3 trials for patients with advanced cancer. We are currently exploring the design of a randomized Phase 3 placebo controlled clinical trial in multiple myeloma.

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 key pipeline products. We also direct your attention to the risk factors which could significantly affect our ability to meet these cost and time estimates found in this report in Item 1A under the heading “Risks Associated with Our Product Development Efforts.”

Product candidate	Target indication	Development status	Completion of phase	Estimated cost to complete phase
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	Phase 2	Mid-2009	Approximately $1 million
KRX-0401 (perifosine)	Multiple forms of cancer	Phase 2	Mid-2009	Approximately $1 million

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

INTELLECTUAL PROPERTY AND PATENTS

General

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

Generally, patent applications in the United States are maintained in secrecy for a period of 18 months or more. Since publication of discoveries in the scientific or patent literature often lag behind actual discoveries, we are not certain that we were the first to make the inventions covered by each of our pending patent applications or that we were the first to file those patent applications. The patent positions of biotechnology and pharmaceutical companies are highly uncertain and involve complex legal and factual questions. Therefore, we cannot predict the breadth of claims allowed in biotechnology and pharmaceutical patents, or their enforceability. To date, there has been no consistent policy regarding the breadth of claims allowed in biotechnology patents. Third parties or competitors may challenge or circumvent our patents or patent applications, if issued. If our competitors prepare and file patent applications in the United States that claim technology also claimed by us, we may have to participate in interference proceedings declared by the United States Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent.

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

Pursuant to our license for Zerenex (ferric citrate) with Panion & BF Biotech, Inc., or Panion, we have the exclusive commercial rights to a series of patent applications worldwide, excluding certain Asian-Pacific countries. These patents and patent applications cover a method of treatment of hyperphosphatemia in patients with ESRD, as well as a method for the manufacture of ferric citrate. Panion holds one use patent expiring 2017 (with extensions expected through 2020) and two manufacturing process patents (expiring 2023).

Pursuant to our license for KRX-0401 (perifosine) with Aeterna Zentaris, Inc., we have the exclusive commercial rights to a series of patents and patent applications in the United States, Canada, and Mexico. These patents and patent

applications include a composition of matter patent expiring in 2013 (with extension possible through 2018), as well as method of use patent application, in combination with various other anticancer agents, which would expire in 2022.

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market these product candidates. In particular:

Our composition of matter patent covering KRX-0401 (perifosine) expires in 2013 and we cannot assure that we can obtain an extension to 2018. We do not hold a composition of matter patent covering Zerenex. Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are important. Upon expiration of our composition of matter patent for KRX-0401, or for Zerenex, where we do not have a composition of matter patent, competitors who obtain the requisite regulatory approval can offer products with the same composition as our products so long as the competitors do not infringe any method of use patents that we may hold.

For our product candidates, the principal patent protection that covers or those we expect will cover, our product candidate is a method of use patent. This type of patent only protects the product when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical to our product that is labeled for an indication that is outside of the patented method, or for which there is a substantial use in commerce outside the patented method.

Moreover, physicians may prescribe such a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such off-label prescriptions may infringe or induce infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

In addition, the limited patent protection described above may adversely affect the value of our product candidates and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

Other Intellectual Property Rights

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

In addition to patent protection, we may utilize orphan drug regulations or other provisions of the Food, Drug and Cosmetic Act to provide market exclusivity for certain of our drug candidates. Orphan drug regulations provide incentives to pharmaceutical and biotechnology companies to develop and manufacture drugs for the treatment of rare diseases, currently defined as diseases that exist in fewer than 200,000 individuals in the United States, or, diseases that affect more than 200,000 individuals in the United States but that the sponsor does not realistically anticipate will generate a net profit. Under these provisions, a manufacturer of a designated orphan drug can seek tax benefits, and the holder of the first FDA approval of a designated orphan product will be granted a seven-year period of marketing exclusivity for such FDA-approved orphan product. We believe that KRX-0401 (perifosine) will be eligible for orphan drug designation; however, we cannot assure that KRX-0401, or any other drug candidates we may acquire or in-license, 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.

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.

AEterna Zentaris Inc.

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

Panion & BF Biotech, Inc.

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

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

In September 2007, we entered into a sublicense agreement with Japan Tobacco Inc. (“JT”) and Torii Pharmaceutical Co., Ltd. (“Torii”), JT's pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive rights for the development and commercialization of Zerenex (ferric citrate) in Japan. The licensing arrangement calls for JT and Torii to pay us up to $100 million in up-front license fees and payments upon the achievement of pre-specified milestones, including up to $20 million in up-front payments and near-term milestones, of which Keryx received $12 million in October 2007 and $8 million in April 2008. In March 2009, JT and Torii informed us that they had initiated a Phase 2 clinical study of Zerenex in Japan, which triggered a $3 million non-refundable milestone payment which was received by us in March 2009. In addition, upon commercialization, JT and Torii will make royalty payments to Keryx on net sales of ferric citrate in Japan. JT and Torii will be responsible for the future development and commercialization costs in Japan.

COMPETITION

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

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. Other companies have products or drug candidates in various stages of 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. Additional information can be found under “Risk Factors” within this report.

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SUPPLY AND MANUFACTURING

We have limited experience in manufacturing products for clinical or commercial purposes.

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.

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

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

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

If we need to change manufacturers after commercialization, 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.

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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 new drug application, or 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.

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. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

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

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

- Phase 1: The drug is administered to a small group of humans, either healthy volunteers or patients, to test for safety, dosage tolerance, absorption, metabolism, excretion, and clinical pharmacology.

- Phase 2: Studies are conducted on a larger number of patients to assess the efficacy of the product, to ascertain dose tolerance and the optimal dose range, and to gather additional data relating to safety and potential adverse events.

- Phase 3: Studies establish safety and efficacy in an expanded patient population.

- Phase 4: The FDA may require Phase 4 post-marketing studies to find out more about the drug's long-term risks, benefits, and optimal use, or to test the drug in different populations.

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

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

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

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

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

If the FDA grants approval, the approval will be limited to those disease states, conditions and patient populations for which the product is safe and effective, as demonstrated through clinical studies. Further, a product may be marketed only in those dosage forms and for those indications approved in the NDA. Certain changes to an approved NDA, including, with certain exceptions, any changes to labeling, require approval of a supplemental application before the drug may be marketed as changed. Any products that we manufacture or distribute pursuant to FDA approvals are subject to continuing regulation by the FDA, including compliance with cGMP and the reporting of adverse experiences with the drugs. The nature of marketing claims that the FDA will permit us to make in the labeling and

advertising of our products will be limited to those specified in an FDA approval, and the advertising of our products will be subject to comprehensive regulation by the FDA. Drugs approved under Subpart H carry additional restrictions on marketing activities, including the requirement that all promotional materials to be used in support of the product are pre-submitted to FDA. Claims exceeding those that are approved will constitute a violation of the Federal Food, Drug, and Cosmetic Act. Violations of the Federal Food, Drug, and Cosmetic Act or regulatory requirements at any time during the product development process, approval process, or after approval may result in agency enforcement actions, including withdrawal of approval, recall, seizure of products, injunctions, fines and/or civil or criminal penalties. Any agency enforcement action could have a material adverse effect on our business.

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

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

RESEARCH AND DEVELOPMENT

Company-sponsored research and development expenses (excluding non-cash compensation and discontinued operations) totaled $55,751,000 in 2006, $74,883,000 in 2007 and $38,075,000 in 2008. “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, manufacture, testing, and enhancement of our drug 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 30, 2009, we had 17 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 substantial 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, 2008, we had an accumulated deficit of approximately $331.9 million and a deficiency in equity of $1.5 million. As we continue our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates.

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

Risks Associated with Our Product Development Efforts

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

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients, and the rate we collect, clean, lock and analyze the clinical trial database. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases as we are studying. Certain clinical trials are 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. Moreover, negative or inconclusive results from the clinical trials we conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

Additionally, we have never filed a new drug application, or NDA, or similar application for approval in the United States or in any country, which may result in a delay in, or the rejection of, our filing of an NDA or similar application. During the drug development process, regulatory agencies will typically ask questions of drug sponsors. While we endeavor to answer all such questions in a timely fashion, or in the NDA filing, some questions may not be answered by the time we file our NDA. Unless the FDA waives the requirement to answer any such unanswered questions, submission of an NDA may be delayed or rejected.

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

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

Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies. Safety signals detected during clinical studies and pre-clinical animal studies, such as the gastrointestinal bleeding that has been seen in some high-dose, ferric citrate canine studies, may require us to do additional studies, which could delay the development of the drug or lead to a decision to discontinue development of the drug. 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. Results from earlier studies may not be indicative of results from future clinical trials and the risk remains that a pivotal program 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 pre-clinical and clinical safety and efficacy data of our drug candidates may be flawed and there can be no assurance that safety and/or efficacy concerns from the prior data were overlooked or misinterpreted, which in subsequent, larger studies appear and prevent approval of such drug candidates. We will need to re-input our safety information on KRX-0401 into a Good Clinical Practice-compliant database and can provide no assurance that safety concerns will not subsequently arise.

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

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

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

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

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

Contract manufacturers often encounter difficulties in scaling up production, including problems involving raw material supplies, 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. These risks become more acute as we scale up for commercial quantities, where a reliable source of raw material supplies becomes critical to commercial success. For example, given the large quantity of materials required for ferric citrate production, as we approach commercialization for Zerenex we will need to ensure an adequate supply of starting materials that meet quality, quantity and cost standards. Failure to achieve this level of supply can jeopardize the successful commercialization of the product.

Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidates. In addition, our contract manufacturers will be subject to ongoing periodic and unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with current Good Manufacturing Practices, as well as other governmental regulations and corresponding foreign standards. The same issues apply to contract analytical services which we use for testing of our products. We will not have control over, other than by contract and periodic oversight, third-party manufacturers' compliance with these regulations and standards. We are currently developing analytical tools for ferric citrate active pharmaceutical ingredient testing. Failure to develop effective analytical tools could result in regulatory or technical delay or could jeopardize our ability to begin Phase 3 clinical trials and/or obtain FDA approval. Switching or engaging multiple third-party contractors to produce our products may be difficult because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance must be identical at each manufacturing facility. It may be difficult for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Zerenex, we currently rely on a sole source of ferric citrate active pharmaceutical ingredient. The loss of this sole source of supply would result in significant additional costs and delays in our development program. Moreover, if we need to change manufacturers after commercialization, 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 we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties, we may be unable to commercialize our products.

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

manufacture our product candidates;

assist us in developing, testing and obtaining regulatory approval for and commercializing some of our compounds and technologies; and

market and distribute our drug products.

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

Given the current market conditions for raising capital, and given our limited resources, we may be forced to further restructure our workforce, and thus rely predominantly or entirely on our ability to contract with third parties for our manufacturing, drug development and marketing. If we are unable to contract with such third parties, we may be forced to limit or suspend or terminate the development of some or all of our product candidates, including, without limitation, suspending development of KRX-0401 (perifosine) and/or Zerenex (ferric citrate).

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

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

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

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

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

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

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

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

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

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

the effectiveness of our sales, marketing and distribution efforts.

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

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

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

The drugs that we are attempting to develop will have to compete with existing therapies. For example, Zerenex, if approved in the United States, would compete with other FDA approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Genzyme Corporation, PhosLo® (calcium acetate), marketed by Fresenius Medical Care, and Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, as well as over-the-counter calcium carbonate products such as TUMS® and metal-based options such as aluminum and magnesium. A generic formulation of PhosLo® manufactured by Roxane Laboratories, Inc. was launched in the United States in October 2008. KRX-0401 (perifosine), if approved in the United States would compete with other anti-cancer agents, such as mTOR inhibitors. Wyeth Corp., Novartis AG and Ariad Pharmaceuticals are developing mTOR inhibitors for use in cancer and Wyeth's mTOR inhibitor, temsirolimus, has been approved to treat patients with advanced kidney disease. Biotechnology companies such as Amgen Inc., Biogen-Idec, Inc., ImClone Systems, Inc. (a wholly-owned subsidiary of Eli Lilly and Company), Millennium Pharmaceuticals, Inc., Onyx Pharmaceuticals, Inc., OSI Pharmaceuticals, Inc. and Vertex Pharmaceuticals, Inc. are developing and, in some cases, marketing drugs to treat various diseases, including cancer, by inhibiting cell-signaling pathways. In addition, we are aware of a number of small and large companies developing competitive products that target the Akt pathway.

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 30, 2009, we had 17 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. Our limited resources may hinder our efforts 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.

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 our sale of Accumin prior to its discontinuation, 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 prior to its discontinuation. 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 in 2004, 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 17 full and part-time employees as of March 30, 2009. We also have significantly fewer employees than many other companies that have a product candidate in clinical development, and we rely heavily on third parties to conduct many important functions. While we believe that our corporate compliance program is sufficient to ensure compliance with applicable regulations, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

Risks Related to Our Financial Condition

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

We currently anticipate that our cash, cash equivalents and investment securities as of December 31, 2008, exclusive of our holdings in auction rate securities and inclusive of a $3 million milestone payment received by us in March 2009 under our sublicense agreement for Zerenex in Japan, are sufficient to meet our anticipated working capital needs and fund our business plan through the end of 2009. However, if we are not able to receive proceeds from some portion of our auction rate securities by the first quarter of 2010, we may not have the ability to continue as a going concern for any significant period beyond that point. We are evaluating market conditions to determine the appropriate timing and extent to which we will seek to obtain additional debt, equity or other type of financing. If we determine that it is necessary to seek additional funding, there can be no assurance that we will be able to obtain any such funding on terms that are acceptable to us, if at all.

In addition, the report of our independent registered public accounting firm covering our 2008 Consolidated Financial Statements, included in this Annual Report, contains an explanatory paragraph that makes reference to uncertainty about our ability to continue as a going concern. Future reports may continue to contain this explanatory paragraph. Our forecast of the period of time through which our cash, cash equivalents 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, design and conduct of, and results from, clinical trials for our drug candidates;

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;

the value and liquidity of our investment securities, including our investments in auction rate securities; and

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

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, if at all.

With respect to our auction rate securities, we will continue to attempt to sell these securities until the auctions are successful. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any credit rating downgrades on the auction rate securities in our portfolio, we may incur additional

impairment charges with respect to our auction rate securities portfolio, which could negatively affect our financial condition, cash flow and reported earnings. We continue to monitor the fair value of our auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges. In addition, the lack of liquidity of our auction rate securities could have a material impact on our ability to fund our operations.

Risks Related to Our Intellectual Property and Third-Party Contracts

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.

The intellectual property that we own or have licensed relating to our product candidates are limited, which could adversely affect our ability to compete in the market and adversely affect the value of our product candidates.

The patent rights that we own or have licensed relating to our product candidates are limited in ways that may affect our ability to exclude third parties from competing against us if we obtain regulatory approval to market these product candidates. In particular:

- Our composition of matter patent covering KRX-0401 (perifosine) expires in 2013 and we cannot assure you that we can obtain an extension to 2018. We do not hold a composition of matter patent covering Zerenex. Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are important. Upon expiration of our composition of matter patent for KRX-0401, or for Zerenex, where we do not have a composition of matter patent, competitors who obtain the requisite regulatory approval can offer products with the same composition as our products so long as the competitors do not infringe any method of use patents that we may hold.

- For our product candidates, the principal patent protection that covers or those we expect will cover, our product candidate is a method of use patent. This type of patent only protects the product when used or sold for the specified method. However, this type of patent does not limit a competitor from making and marketing a product that is identical to our product that is labeled for an indication that is outside of the patented method, or for which there is a substantial use in commerce outside the patented method.

Moreover, physicians may prescribe such a competitive identical product for indications other than the one for which the product has been approved, or off-label indications, that are covered by the applicable patents. Although such

off-label prescriptions may infringe or induce infringement of method of use patents, the practice is common and such infringement is difficult to prevent or prosecute.

In addition, the limited patent protection described above may adversely affect the value of our product candidates and may inhibit our ability to obtain a corporate partner at terms acceptable to us, if at all.

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

We may be forced to initiate litigation to enforce our contractual and intellectual property rights, or we may be sued by third parties asserting claims based on contract, tort or intellectual property infringement. In addition, third parties may have or may obtain patents in the future and claim that our drug products or technologies infringe their patents. If we are required to defend against suits brought by third parties, or if we sue third parties to protect our 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.

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

In addition, we may be required to issue up to 3,372,422 shares of our common stock to former stockholders of ACCESS Oncology upon the achievement of certain milestones, of which 500,000 shares may be payable in the next 12 months if we reach the first milestone, or we may conclude, under certain circumstances, that it is in our best interest to settle this contingent share obligation for all or substantially all of such shares in advance of reaching any milestones. A substantial portion of the contingent shares would be payable to related parties.

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 and liquidity;

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 the approval of our stockholders. 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.

We are currently not in compliance with NASDAQ rules for continued listing on the NASDAQ Capital Market and are at risk of being delisted, which may subject us to the SEC’s penny stock rules and decrease the liquidity of our common stock.

On April 22, 2008, we received notice from The NASDAQ Stock Market that we were not in compliance with the $1.00 minimum bid price requirement for continued inclusion on the applicable NASDAQ market. This notification is a standard communication when the bid price of a NASDAQ-listed company closes below the minimum $1.00 per share requirement for 30 consecutive business days. In accordance with NASDAQ rules, we were provided 180 calendar days to regain compliance by having the bid price of our common stock close at $1.00 per share or more for a minimum of 10 consecutive business days. On October 21, 2008, we received notice from The NASDAQ Stock Market that the bid price and market value of publicly traded securities requirements for continued listing on a NASDAQ market had been temporarily suspended. Due to this action, we believe that we have until July 20, 2009, to achieve compliance with the $1.00 minimum closing bid price requirement.

On November 17, 2008, we received notice from The NASDAQ Stock Market that we were no longer in compliance with Marketplace Rule 4310(c)(3), which requires us to have a minimum of $2,500,000 in stockholders' equity, or $35,000,000 market value of listed securities, or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years, for continued listing on the NASDAQ Capital Market. On December 2, 2008, we submitted to The NASDAQ Stock Market a plan to achieve and sustain compliance with all of the NASDAQ Capital Market listing requirements.

On March 3, 2009, we received notice from The NASDAQ Stock Market indicating that we had failed to regain compliance with NASDAQ Marketplace Rule 4310(c)(3). Therefore, The NASDAQ Stock Market determined to delist our common stock from the NASDAQ Capital Market unless we appealed the delisting determination to a hearing. On March 9, 2009, we requested a hearing to appeal the determination of The NASDAQ Stock Market to delist our common stock to a NASDAQ Listings Qualification Panel (“Panel”), which automatically stayed the delisting of our common stock pending issuance of the Panel's decision. The hearing is scheduled for April 30, 2009. At the Panel hearing, we plan to ask the Panel to provide us with additional time to regain compliance with NASDAQ Marketplace Rule 4310(c)(3). There can be no assurance that such a request will be granted or that the Panel will permit us to continue to list our common stock on the NASDAQ Capital Market, or that in the future we will meet the listing requirements of the NASDAQ Capital Market, including, without limitation, bid price, stockholders’ equity and/or market value of listed securities minimum requirements. Additionally, our efforts to continue to meet the listing requirements may be limited by current market conditions, including volatility in the market.

If we are delisted from the NASDAQ Capital Market, our common stock may be traded over-the-counter on the OTC Bulletin Board or in the “pink sheets.” These alternative markets, however, are generally considered to be less efficient than the NASDAQ Capital Market. Many over-the-counter stocks trade less frequently and in smaller volumes than securities traded on the NASDAQ markets, which would likely have a material adverse effect on the liquidity of our common stock.

If our common stock is delisted from the NASDAQ Capital Market, there may be a limited market for our stock, trading in our stock may become more difficult and our share price could decrease even further. In addition, if our common stock is delisted, our ability to raise additional capital may be impaired.

In addition, our common stock may become subject to penny stock rules. The SEC generally defines “penny stock” as an equity security that has a market price of less than $5.00 per share, subject to certain exceptions. We are not currently subject to the penny stock rules because our common stock qualifies for an exception to the SEC’s penny stock rules for companies that have an equity security that is quoted on The NASDAQ Stock Market. However, if we were delisted, our common stock would become subject to the penny stock rules, which impose additional sales practice requirements on broker-dealers who sell our common stock. If our common stock were considered penny stock, the ability of broker-dealers to sell our common stock and the ability of our stockholders to sell their shares in the secondary market would be limited and, as a result, the market liquidity for our common stock would be adversely affected. We cannot assure you that trading in our securities will not be subject to these or other regulations in the future.

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 have entered into an office sharing agreement with a third-party for a portion of our leased space with an initial term through April 2009 and, thereafter, on a month-to-month basis.

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. On March 3, 2009, we entered into a settlement agreement with R.M.P.A. Properties Ltd., with respect to the dispute. In accordance with the settlement agreement, in March 2009, we paid the landlord a total sum of $260,000 for a full release of all claims and obligations under the lease agreement.

We prevailed in an arbitration proceeding with Alfa Wasserman concerning certain terms of the 1998 License Agreement between Alfa Wasserman and the Company related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. An arbitration hearing was held in October 2007 and the arbitrator issued his decision on March 25, 2008, rejecting Alfa Wasserman’s claims that we were in material breach of the License Agreement. The arbitrator determined that each party would bear its own costs for the arbitration.

In April 2008, we notified Alfa Wasserman of our intention to terminate the License Agreement. We offered to transfer to Alfa Wasserman all regulatory applications as provided in the License Agreement and demanded payment by Alfa Wasserman of 25% of our development costs associated with sulodexide, as provided in the License Agreement. Alfa Wasserman itself served a notice of termination of the License Agreement on the alleged grounds that we are in material breach of the agreement for failing to diligently develop sulodexide by terminating the Phase 4 clinical trial. By seeking to terminate the License Agreement, Alfa Wasserman is thereby seeking to avoid reimbursing us our development costs. We intend to submit our claim for development costs and Alfa Wasserman’s claim of material breach to arbitration for resolution.

In April 2008, we commenced an action in the U.S. District Court for the Southern District of New York against Panion & BF Biotech, Inc. ("Panion") for breaching the manufacturing provisions of the March 14, 2008 Amended and Restated License Agreement between the Company and Panion, and the implied covenant of good faith and fair dealing contained therein. We sought declaratory and injunctive relief and damages against Panion. Panion asserted counterclaims against us for alleged breach of the agreement and the implied covenant of good faith and fair dealing contained therein and for alleged breach of fiduciary duties, and sought declaratory and injunctive relief and damages in the amount of "at least one million dollars." We replied, denying Panion's counterclaims. In November 2008, the parties agreed to settle their dispute. The parties entered into a first amendment to the Amended and Restated License Agreement by which Panion granted us additional manufacturing and development rights, and we paid Panion $200,000 in November 2008. Following execution of the settlement agreement and first amendment to the Amended and Restated License Agreement, the parties entered a voluntary dismissal of the action, including Panion's asserted counterclaims.

We in-licensed KRX-0501 from Krenitsky Pharmaceuticals, Inc. (“Krenitsky”) in 2005. In October 2008, Krenitsky commenced an action in the United States District Court, Middle District of North Carolina, Durham Division, against the Company, requesting a declaratory judgment from the court determining that (i) we breached the 2005 License Agreement between Krenitsky and the Company, (ii) Krenitsky was within its legal rights to terminate the License Agreement for cause, (iii) we have no further rights or interests in the licensed patents, and (iv) Krenitsky has no further obligations to us under the License Agreement. In December 2008, the parties agreed to settle their dispute and as a result have entered into a License Termination, Technology Transfer and Settlement Agreement, whereby the license agreement was terminated and certain know-how was transferred to Krenitsky in exchange for a portion of any future license and milestone payments received by Krenitsky related to KRX-0501 and a royalty on sales of the drug, if any. Following execution of the Termination, Technology Transfer and Settlement Agreement, the parties entered a voluntary dismissal of the action.

We are presently engaged in an arbitration proceeding with ICON Central Laboratories (“ICON”), the central laboratory we used for the clinical development of Sulonex, concerning certain fees related mainly to the provision of storage services pursuant to a series of service agreements. In March 2008, we terminated the agreements. ICON is claiming that the we owe it $816,647 in unpaid invoices, much of which is made up of charges for annual storage fees. It is our position that we should not have to pay for storage fees incurred after the effective date of the termination of the agreements, and we intend to vigorously defend this proceeding on this basis, and to assert a counterclaim for a refund of the unused portions of the annual storage fees already paid to ICON.

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 2008.

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 Capital 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.

On April 22, 2008, we received notice from The NASDAQ Stock Market that we were not in compliance with the $1.00 minimum bid price requirement for continued inclusion on the applicable NASDAQ market. This notification is a standard communication when the bid price of a NASDAQ-listed company closes below the minimum $1.00 per share requirement for 30 consecutive business days. In accordance with NASDAQ rules, we were provided 180 calendar days to regain compliance by having the bid price of our common stock close at $1.00 per share or more for a minimum of 10 consecutive business days. On October 21, 2008, we received notice from The NASDAQ Stock Market that the bid price and market value of publicly traded securities requirements for continued listing on a NASDAQ market had been temporarily suspended. Due to this action, we believe that we have until July 20, 2009, to achieve compliance with the $1.00 minimum closing bid price requirement.

On November 17, 2008, we received notice from The NASDAQ Stock Market that we were no longer in compliance with Marketplace Rule 4310(c)(3), which requires us to have a minimum of $2,500,000 in stockholders' equity, or $35,000,000 market value of listed securities, or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years, for continued listing on the

NASDAQ Capital Market. On December 2, 2008, we submitted to The NASDAQ Stock Market a plan to achieve and sustain compliance with all of the NASDAQ Capital Market listing requirements.

On March 3, 2009, we received notice from The NASDAQ Stock Market indicating that we had failed to regain compliance with NASDAQ Marketplace Rule 4310(c)(3). Therefore, The NASDAQ Stock Market determined to delist our common stock from the NASDAQ Capital Market unless we appealed the delisting determination to a hearing. On March 9, 2009, we requested a hearing to appeal the determination of The NASDAQ Stock Market to delist our common stock to a NASDAQ Listings Qualification Panel ("Panel"), which automatically stayed the delisting of our common stock pending issuance of the Panel's decision. The hearing is scheduled for April 30, 2009. At the Panel hearing, we plan to ask the Panel to provide us with additional time to regain compliance with NASDAQ Marketplace Rule 4310(c)(3). There can be no assurance that such a request will be granted or that the Panel will permit us to continue to list our common stock on the NASDAQ Capital Market, or that in the future we will meet the listing requirements of the NASDAQ Capital Market, including, without limitation, bid price, stockholders' equity and/or market value of listed securities minimum requirements. Additionally, our efforts to continue to meet the listing requirements may be limited by current market conditions, including volatility in the market.

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, 2008	High	Low
Fourth Quarter	$ 0.36	$ 0.12
Third Quarter	$ 0.54	$ 0.32
Second Quarter	$ 0.67	$ 0.46
First Quarter	$ 8.71	$ 0.52

Fiscal Year Ended December 31, 2007	High	Low
Fourth Quarter	$ 11.14	$ 8.40
Third Quarter	$ 11.05	$ 8.27
Second Quarter	$ 11.64	$ 9.77
First Quarter	$ 13.27	$ 10.19

Holders

The number of record holders of our common stock as of March 9, 2009 was 69.

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, 2008, regarding the securities authorized for issuance under our equity compensation plans, consisting of the 1999 Stock Option Plan, as amended, the 2000 Stock Option Plan, as amended, the 2002 CEO Incentive Stock Option Plan, the 2004 President Incentive Plan, the 2004 Long-Term Incentive Plan and the 2007 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	6,611,802	$ 8.81	2,533,928
Equity compensation plans not approved by security holders	2,502,657	$ 2.89	—
Total	9,114,459	$ 7.19	2,533,928

For information about all of our equity compensation plans, see Note 11 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, 2003 through December 31, 2008, 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, 2003, 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, 2008, 2007, 2006, 2005 and 2004, and Balance Sheet Data as of December 31, 2008, 2007, 2006, 2005 and 2004, 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,				
	2008	2007	2006	2005	2004
	(in thousands, except per share data)				
Statement of Operations Data:					
Revenue:					
License revenue	$ 1,180	$ 204	$ —	$ —	$ —
Service revenue	103	52	431	574	809
Other revenue	—	727	—	—	—
Total revenue	1,283	983	431	574	809
Operating expenses:					
Cost of services	27	124	390	819	835
Research and development:					
Non-cash compensation	(67)	3,574	6,504	594	413
Non-cash acquired in-process research and development	—	—	—	—	18,800
Other research and development	38,075	74,883	55,751	24,182	9,805
Total research and development	38,008	78,457	62,255	24,776	29,018
Selling, general and administrative:					
Non-cash compensation	6,815	7,086	8,408	775	1,087
Other selling, general and administrative	7,474	9,141	8,519	3,416	3,581
Total selling, general and administrative	14,289	16,227	16,927	4,191	4,668
Total operating expenses	52,324	94,808	79,572	29,786	34,521
Operating loss	(51,041)	(93,825)	(79,141)	(29,212)	(33,712)
Other income (expense):					
Interest and other (expense) income, net	(1,665)	4,555	6,393	2,317	770
Income taxes	—	(36)	—	—	(1)
Loss from continuing operations	(52,706)	(89,306)	(72,748)	(26,895)	(32,943)
Loss from discontinued operations	(175)	(756)	(1,016)	—	—
Net loss	$ (52,881)	$ (90,062)	$ (73,764)	$ (26,895)	$ (32,943)
Basic and diluted loss per common share:					
Continuing operations	$ (1.17)	$ (2.05)	$ (1.74)	$ (0.78)	$ (1.10)
Discontinued operations	(0.01)	(0.02)	(0.02)	—	—
Basic and diluted loss per common share	$ (1.18)	$ (2.07)	$ (1.76)	$ (0.78)	$ (1.10)

	As of December 31,				
	2008	2007	2006	2005	2004
	(in thousands)				
Balance Sheet Data:					
Cash, cash equivalents, interest receivable and short-term investment securities	$ 15,467	$ 62,386	$ 112,920	$ 86,783	$ 49,878
Working capital	9,282	42,319	102,774	83,890	46,538
Long-term investment securities	7,185	2,296	12,690	13,950	—
Total assets	26,634	81,061	140,313	105,097	50,862
Deferred revenue, net of current portion	17,308	11,022	—	—	—
Other liabilities	118	202	294	322	92
Contingent equity rights	4,004	4,004	4,004	4,004	4,004
Total stockholders' (deficiency) equity	(1,489)	44,422	123,821	94,678	42,804

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 renal disease and cancer. We are developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex is currently in Phase 2 clinical development for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. We are also developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that modulates Akt, a protein in the body associated with tumor survival and growth. KRX-0401 also modulates a number of other key signal transduction pathways, including the JNK and MAPK pathways, which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 is currently in Phase 2 clinical development for multiple tumor types. We also actively engage in business development activities that include evaluating compounds and companies for in-licensing or acquisition, as well as seeking strategic relationships for our product candidates and for our company. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates. We have generated, and expect to continue to generate, revenue from the licensing of rights to Zerenex in Japan to our Japanese partner, Japan Tobacco Inc. ("JT") and Torii Pharmaceutical Co., Ltd. ("Torii").

Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises, public offerings of our common stock, interest income, and, beginning in 2007, from the upfront and milestone payments from our Sublicense Agreement with JT and Torii and miscellaneous payments from our other prior licensing activities. We have devoted substantially all of our efforts to the identification, in-licensing, development and partnering 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, partnership and licensing activities.

Our license revenues currently consist of license fees arising from our agreement with JT and Torii. We recognize these revenues ratably over the estimated period which we will have certain ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue.

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.

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

Our cost of services consists 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. Costs of services are recognized as services are performed.

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for clinical and laboratory development, facilities-related and other expenses relating to the design, development, manufacture, 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 discontinued operations, for the years ended December 31, 2008, 2007 and 2006 were $38,075,000, $74,883,000 and 55,751,000, respectively.

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

	Years ended December 31,		
	2008	2007	2006
Zerenex	$ 3,423,000	$ 4,825,000	$ 1,531,000
KRX-0401	7,045,000	15,210,000	8,508,000
Other	677,000	2,088,000	658,000
Terminated programs (including Sulonex)	26,930,000	52,760,000	45,054,000
Total	$ 38,075,000	$ 74,883,000	$ 55,751,000

Amounts in the above table excludes discontinued operations.

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, legal activities and facilities-related expenses.

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

Our ongoing clinical trials will be lengthy and expensive. Even if these trials show that our drug candidates are effective in treating certain indications, there is no guarantee that we will be able to record commercial sales of any of our drug candidates in the near future. In addition, we expect losses to continue as we continue to fund in-licensing and development of new drug candidates. As we continue our development efforts, we may enter into additional third-party collaborative agreements and may incur additional expenses, such as licensing fees and milestone payments. In addition, we may 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, 2008 and 2007

License Revenue. License revenue increased by $976,000 to $1,180,000 for the year ended December 31, 2008, as compared to $204,000 for the year ended December 31, 2007. License revenue is related to the amortization of a portion of the license fees of $12.0 million and milestone payment of $8.0 million associated with our sublicense agreement with JT and Torii. Such amounts were recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last-to-expire patent covered by the agreement in 2023, and represents the estimated period over which we will have certain ongoing responsibilities under the sublicense agreement. The increase in license revenue was due to a full year of amortization in 2008, as compared to a partial period of amortization in 2007.

Service Revenue. Service revenue increased by $51,000 to $103,000 for the year ended December 31, 2008, as compared to service revenue of $52,000 for the year ended December 31, 2007. The increase in service revenue was primarily due to the timing and extent of services performed in accordance with our service contracts. We do not expect our service revenue to have a material impact on our financial results during the next fiscal year.

Other Revenue. There was no other revenue for the year ended December 31, 2008. Other revenue was $727,000 for the year ended December 31, 2007, and was related to a payment from Yissum under an October 2004 termination agreement whereby we received a portion of cash consideration earned by Yissum from the terminated license rights. Payments from Yissum are recognized as earned since we have no responsibilities under the terminated license agreement or the termination agreement.

Cost of Services. Cost of services decreased by $97,000 to $27,000 for the year ended December 31, 2008, as compared to an expense of $124,000 for the year ended December 31, 2007. 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 (research and development) related to equity incentive grants decreased by $3,641,000 to a credit of $67,000 for the year ended December 31, 2008, as compared to an expense of $3,574,000 for the year ended December 31, 2007. The decrease was primarily attributable to $3,486,000 decrease in compensation expense related to stock options and restricted stock issued to our President, who was terminated as part of our restructuring of our business in March 2008, as well as due to a reduction in research and development personnel following the restructuring.

Other Research and Development Expenses. Other research and development expenses decreased by $36,808,000 to $38,075,000 for the year ended December 31, 2008, as compared to $74,883,000 for the year ended December 31, 2007. The decrease in other research and development expenses was due primarily to a $22,872,000 decrease in research and development expenses related the Sulonex program which was terminated in March 2008. Included in the research and development expenses related to Sulonex for the year ended December 31, 2008 are an $11,037,000 impairment charge related to the write-down of the assets of the Sulonex manufacturing suite to their fair value following the cessation of our development of Sulonex, and a $2,063,000 expense for costs relating to the required restoration of the leased manufacturing facility to its original condition. For more information regarding these expenses please see “Note 18 - Restructuring” to our consolidated financial statements. Including the impairment charge and restoration expense discussed above, other research and development expenses related to Sulonex were $26,500,000 and $49,372,000 during the years ended December 31, 2008 and 2007, respectively. In addition to the $22,872,000 decrease in other research and development expenses related to Sulonex discussed above, there were decreases of $8,165,000, $1,402,000 and $1,411,000 in expenses related to KRX-0401, Zerenex and our other research and development programs, respectively, primarily due to reductions in headcount and other expenses related to these development programs. We expect other research and development expenses to decline in 2009, as compared to 2008, due to the absence of expenses associated with Sulonex and due to a full year impact of the restructuring that occurred in March 2008.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense (selling, general and administrative) related to equity incentive grants decreased by $271,000 to $6,815,000 for the year ended December 31, 2008, as compared to an expense of $7,086,000 for the year ended December 31, 2007. The decrease was primarily due to a reduction in selling, general and administrative personnel following our March 2008 restructuring.

Other Selling General and Administrative Expenses. Other selling, general and administrative expenses decreased by $1,667,000 to $7,474,000 for the year ended December 31, 2008, as compared to an expense of $9,141,000 for the year ended December 31, 2007. The decrease was primarily related to a reduction of expenses as a result of the March

2008 restructuring, partially offset by a one-time premium payment for insurance of $1,151,000. We expect other selling general and administrative expenses to decline in 2009, as compared to 2008, due to a full year impact of the March 2008 restructuring.

Interest and Other (Expense), Net. Interest and other (expense) income, net, decreased by $6,220,000 to an expense of $1,665,000 for the year ended December 31, 2008, as compared to income of $4,555,000 for the year ended December 31, 2007. The decrease was primarily due to $3,196,000 of impairment charges recorded during the year ended December 31, 2008, related to our investments in auction rate securities. The decrease also resulted from a lower level of invested funds and lower interest rates on our investments as compared to the comparable period last year, resulting in reduced interest income.

Income Taxes. We did not record income tax expense for the year ended December 31, 2008. We recorded $36,000 in income tax expense for the year ended December 31, 2007, as a result of Israeli income tax withheld associated with the Yissum revenue as described above.

Loss from Discontinued Operations. Represents results from discontinued operations relating to our Diagnostic business that was terminated in September 2008. See Note 8 – Discontinued Operations. We do not expect our discontinued operations to have an impact on our financial results in 2009.

Years Ended December 31, 2007 and 2006

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

Service Revenue. Service revenue decreased by $379,000 to $52,000 for the year ended December 31, 2007, as compared to service revenue of $431,000 for the year ended December 31, 2006. The decrease in service revenue was primarily due to the timing and extent of services performed in accordance with our service contracts.

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

Cost of Services. Cost of services decreased by $266,000 to $124,000 for the year ended December 31, 2007, as compared to an expense of $390,000 for the year ended December 31, 2006. The decrease in cost of services was primarily due to the timing and extent of services performed in accordance with our service contracts.

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

Other Research and Development Expenses. Other research and development expenses increased by $19,132,000 to $74,883,000 for the year ended December 31, 2007, as compared to $55,751,000 for the year ended December 31, 2006. The increase in other research and development expenses was due primarily to a $7,839,000 increase in expenses related to our Sulonex pivotal Phase 3 and Phase 4 clinical programs. The comparative period last year included one-half, or $1,000,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment

agreement for the achievement of a corporate milestone. In addition, the increase was due to a $6,702,000 increase in expenses related to KRX-0401 (including a $1,250,000 milestone), a $3,294,000 increase in expenses related to Zerenex (including a $2,500,000 license-related accrual for a contingent liability) and a $1,580,000 increase in expenses related to our other clinical compounds (including $997,000 of expenses relating to the in-licensing and purchase of related inventory for KRX-0701).

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense (selling general and administrative) related to stock option and restricted stock grants decreased by $1,322,000 to $7,086,000 for the year ended December 31, 2007, as compared to an expense of $8,408,000 for the year ended December 31, 2006. This difference was primarily attributable to, during the year ended December 31, 2006, approximately $1,636,000 of expense for the accelerated vesting of options due to the achievement of a financial milestone, and approximately $1,697,000 of expense for modifications made by the Board of Directors of the vesting and exercisability of certain grants during the second quarter of 2006. In the year ended December 31, 2006, based on his activities in this area, a portion of the compensation expense relating to our chief executive officer included an allocation to non-cash compensation expense (research and development). Beginning in 2007, based on his current activities, this expense is being charged to non-cash compensation expense (selling, general and administrative), accounting for approximately $2,458,000 of increased expense, which offsets the decrease discussed above. In addition, during the year ended December 31, 2007, we recorded a reduction of expense of approximately $780,000 associated with stock options and restricted stock issued to our former chief financial officer in 2006, who resigned in the second quarter of 2007.

Other Selling, General and Administrative Expenses. Other selling, general and administrative expenses increased by $622,000 to $9,141,000 for the year ended December 31, 2007, as compared to an expense of $8,519,000 for the year ended December 31, 2006. The increase was due to an increase in legal fees of approximately $1,243,000 associated primarily with the Alfa Wasserman arbitration (see Legal Proceedings) and general maintenance of our products. The comparative period in 2006 included one-half, or $1,000,000, of a one-time bonus paid to our Chief Executive Officer pursuant to his employment agreement for the achievement of a corporate milestone. In addition, during the year ended December 31, 2007, we incurred additional expenses associated with the scale-up of our operations and infrastructure to prepare for possible commercialization of our drug candidates.

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

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

Loss from Discontinued Operations. Represents results from discontinued operations relating to our Diagnostic business that was terminated in September 2008. See Note 8 – Discontinued Operations.

LIQUIDITY AND CAPITAL RESOURCES

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

As of December 31, 2008, we had $15.5 million in cash, cash equivalents, interest receivable, and short-term investment securities, a decrease of $46.9 million from December 31, 2007. In addition, at December 31, 2008, we had $7.2 million in non-current auction rate securities, as discussed below. Cash used in operating activities in continuing operations for the year ended December 31, 2008 was $38.6 million, as compared to $57.3 million for the year ended December 31, 2007. This decrease was due primarily to the cessation of the Sulonex program in March 2008 and the 2008 Restructuring.

For the year ended December 31, 2008, net cash provided by investing activities from continuing operations of $32.6 million was primarily the result of the maturity and sale of short-term securities in our investment portfolio, net of purchases. For the year ended December 31, 2008, net cash provided by financing activities from continuing operations of $0.2 million was the result of proceeds from the exercise of stock options.

As of December 31, 2008, $7.2 million of our investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. Auction rate securities are structured to provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally every 28 days. This mechanism has historically allowed existing investors either to rollover their holdings, whereby they would continue to own their respective securities, or liquidate their holdings by selling such securities at par. This auction process has historically provided a liquid market for these securities; however, the uncertainties in the credit markets have affected all of our holdings in auction rate securities. Since February 2008, the auctions for our auction rate securities have not had sufficient buyers to cover investors' sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at December 31, 2008, we are

uncertain as to when, or if, the liquidity issues relating to these investments will improve. We assessed the fair value of our auction rate securities portfolio. As a result of this valuation process, we recorded impairment charges totaling $3.2 million during the year ended December 31, 2008, for other-than-temporary declines in the value of our auction rate securities. These other-than-temporary impairment charges were included in interest and other (expense) income, net. In addition, in the first quarter of 2008, we reclassified the entire auction rate securities portfolio from short-term to long-term investments due to the uncertainty of when we will be able to sell these securities. In November 2008, we sold one of our auction rate security investments in the secondary market. The security had a par value of $2.0 million and an adjusted book value of $1.6 million. Proceeds from the sale of this security were $1.7 million, representing a gain of $0.1 million over the adjusted book value. The estimated fair value of our remaining auction rate securities is $7.2 million at December 31, 2008.

We will continue to attempt to sell our auction rate securities until the auctions are successful; however, there is no assurance as to when, or if, the market for auction rate securities will stabilize. The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue or if these securities experience credit rating downgrades, we may incur additional impairment charges with respect to our auction rate securities portfolio, which could negatively affect our financial condition, cash flow and reported earnings, and the lack of liquidity of our auction rate securities could have a material impact on our ability to fund our operations.

We have incurred substantial 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, 2008, we have an accumulated deficit of $331.9 million and a deficiency in equity of $1.5 million. We are dependent upon significant financing to provide the working capital necessary to execute our business plan. We have not yet commercialized any of our drug candidates and cannot be sure if 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 obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates alone or in partnership. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates, if approved. We currently anticipate that our cash, cash equivalents and investment securities as of December 31, 2008, exclusive of our holdings in auction rate securities and inclusive of a $3 million milestone payment received by us in March 2009 under our sublicense agreement for Zerenex in Japan, are sufficient to meet our anticipated working capital needs and fund our business plan through the end of 2009. However, if we are not able to receive proceeds from some portion of our auction rate securities by the first quarter of 2010, we may not have the ability to continue as a going concern for any significant period beyond that point. The actual amount of funds that we will need to operate is subject to many factors, including the timing, design and conduct of clinical trials for our drug candidates. We are evaluating market conditions to determine the appropriate timing and extent to which we will seek to obtain additional debt, equity or other type of financing. If we determine that it is necessary to seek additional funding, there can be no assurance that we will be able to obtain any such funding on terms that are acceptable to us, if at all.

In addition, the report of our independent registered public accounting firm covering our 2008 Consolidated Financial Statements, included in this Annual Report, contains an explanatory paragraph that makes reference to uncertainty about our ability to continue as a going concern.

The accompanying financial statements have been prepared assuming that we will continue as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The factors discussed above, taken together with our limited cash, cash equivalents, and short-term investment securities, and illiquid investments in auction rate securities raise substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary should we be unable to continue as a going concern.

OFF-BALANCE SHEET ARRANGEMENTS

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

OBLIGATIONS AND COMMITMENTS

As of December 31, 2008, we have known contractual obligations, commitments and contingencies of $1,469,000. Of this amount, $413,000 relates to research and development agreements (relating to our KRX-0401 and Zerenex clinical programs), all of which is due within the next year. Certain of these commitments are contingent upon our continuing development of our drug candidates. The additional $1,056,000 relates to our operating lease obligations, of which $597,000 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	$ 413,000	$ 413,000	$ —	$ —	$ —
Operating leases	1,056,000	597,000	459,000	—	—
Total	$ 1,469,000	$ 1,010,000	$ 459,000	$ —	$ —

We have undertaken to make contingent milestone payments to certain of our licensors of up to approximately $40.8 million over the life of the licenses, of which approximately $36.4 million will be due upon or following regulatory approval of the licensed drugs. 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 KRX-0401 meets certain development milestones. Of the 3,372,422 shares, 500,000 of these shares would be payable upon achieving the first development milestone. A substantial portion of the contingent shares would be payable to related parties. The contingent equity rights have been recognized as a non-current liability on the consolidated balance sheet. The uncertainty relating to the timing of the commitments described in this paragraph prevents us from including them in the table above.

CRITICAL ACCOUNTING POLICIES

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

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

Stock Compensation. We have granted stock options and restricted stock to employees, directors and consultants, as well as warrants to other third parties. In applying SFAS No. 123R to employee and director grants, 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, these estimates are 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 equity awards expected to vest. As a result,

if other assumptions had been used, our recorded stock-based compensation expense could have been materially different from that reported. In addition, because some of the options and warrants issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, the total expense is uncertain.

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

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

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

Prior to discontinuing the sale of our diagnostic product, we had recognized diagnostic revenue when persuasive evidence of an arrangement existed, the product had been shipped, title and risk of loss had passed to the customer and collection from the customer was reasonably assured. Diagnostic revenue is included in discontinued operations.

We recognize service revenues 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.

Accounting Related to Goodwill. As of December 31, 2008, there was approximately $3.2 million of goodwill on our consolidated balance sheet. SFAS No. 142, "Goodwill and Other Intangible Assets," or SFAS No. 142, addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. This statement also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. SFAS No. 142 requires goodwill be tested using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value.

We are required to perform impairment tests under SFAS No. 142 annually, at December 31, 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. In future years, the possibility exists that changes in forecasts and estimates from those used at the acquisition date could result in

impairment indicators.

Impairment of Long-Lived Assets. In accordance with the guidance in SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets," or SFAS No. 144, we recognize an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, we make certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized for the excess of the carrying value of the asset above its fair value.

We had entered into a relationship with SPL, a U.S.-based contract manufacturer, for Sulonex to build a larger scale manufacturing suite within their current facility, which they would operate on our behalf. We spent approximately $11.3 million in capital expenditures building the suite. In accordance with the guidance in SFAS No. 144, with the cessation of our development of Sulonex in March 2008, we recognized an impairment charge of $11.0 million, which is included in other research and development expenses in the year ended December 31, 2008, to write the assets down to their fair value of $300,000, the amount for which the assets were sold during the three months ended June 30, 2008.

Impairment of Investment Securities. As of December 31, 2008, $7.2 million of our investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. The uncertainties in the credit markets have affected all of our holdings in auction rate securities. Since February 2008, the auctions for our auction rate securities have not had sufficient buyers to cover investors' sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at December 31, 2008, we are uncertain as to when, or if, the liquidity issues relating to these investments will improve. We assessed the fair value of our auction rate securities portfolio. As a result of this valuation process, as described below, we recorded impairment charges totaling $3.2 million during the year ended December 31, 2008, for other-than-temporary declines in the value of our auction rate securities. These other-than-temporary impairment charges were included in interest and other (expense) income, net. In addition, in the first quarter of 2008, we reclassified the entire auction rate securities portfolio from short-term to long-term investments due to the uncertainty of when we will be able to sell these securities.

The valuation methods used to estimate the auction rate securities' fair value were (1) a discounted cash flow model, where the expected cash flows of the auction rate securities are discounted to the present using a yield that incorporates compensation for illiquidity, and (2) a market comparables method, where the auction rate securities are valued based on indications, from the secondary market, of what discounts buyers demand when purchasing similar auction rate securities. The valuation also included assessments of the underlying structure of each security, expected cash flows, discount rates, credit ratings, workout periods, and overall capital market liquidity. These assumptions, assessments and the interpretations of relevant market data are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value of our auction rate securities. In addition, the estimated fair value of the auction rates securities may differ from the values that would have been used had a ready market existed, and the differences could be material to the consolidated financial statements.

The fair value of our auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue or if these securities experience credit rating downgrades, we may incur additional impairment charges with respect to our auction rate securities portfolio. We continue to monitor the fair value of our auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges.

We review investment securities for impairment in accordance with the guidance in FSP SFAS 115-1 and 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," to determine the classification of the impairment as temporary or other-than-temporary. Losses are recognized in our consolidated statement of operations when a decline in fair value is determined to be other-than-temporary. We review our investments on an ongoing basis for indications of possible impairment. Once identified, the determination of whether the impairment is temporary or other-than-temporary requires significant judgment. The primary factors we consider in classifying an impairment include the extent and time the fair value of each investment has been below cost and our

ability to hold such investment to maturity.

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 consolidated 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 deferred tax assets with a valuation allowance at December 31, 2008 and 2007. 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 maintaining the valuation allowance.

RECENTLY ISSUED ACCOUNTING STANDARDS

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

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

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

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

In September 2006, the FASB issued SFAS No. 157, “Fair Value Measurements,” to clarify the definition of fair value, establish a framework for measuring fair value and expand the disclosures on fair value measurements. SFAS No. 157 defines fair value as the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants at the measurement date. SFAS No. 157 also stipulates that, as a market-based measurement, fair value measurement should be determined based on the assumptions that market participants would use in pricing the asset or liability, and establishes a fair value hierarchy that distinguishes between: (a) market participant assumptions developed based on market data obtained from sources independent of the reporting entity, or observable inputs; and (b) the reporting entity’s own assumptions about market participant assumptions developed based on the best information available in the circumstances, or unobservable inputs. Except for the deferral for the implementation of SFAS No. 157 for specified other non-financial assets and liabilities, SFAS No. 157 is effective for our fiscal year ended December 31, 2008. As a result of the adoption of SFAS No. 157, we measured our financial assets and liabilities at fair value and provided the required disclosures in our consolidated financial statements.

In February 2008, the FASB issued FASB Staff Position ("FSP") 157-2, "Effective Date of FASB Statement No. 157" ("FSP 157-2"), which delays the effective date of SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157") for non-financial assets and non-financial liabilities. The delay is intended to allow the FASB and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS No. 157. For items within the scope of FSP 157-2, this FSP defers the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. We currently do not believe that the adoption of the deferred portion of SFAS No. 157 will have a material impact on our financial condition or results of operations.

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 rate securities in accordance with our investment policy. Some of the securities in which we invest have market risk. This means that a change in prevailing interest rates, and/or credit risk, may cause the fair value 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 fair value of our investment will probably decline. As of December 31, 2008, our portfolio of financial instruments consists of cash equivalents and short-term and long-term interest bearing securities, including money market funds, government debt and auction rate securities. The average duration to maturity of all of our held-to-maturity investments held as of December 31, 2008, was less than 12 months. Due to the short-term nature of our money market funds and held-to-maturity investments, we believe we have no material exposure to interest rate risk, and/or credit risk, arising from our money market funds and held-to-maturity investments.

As of December 31, 2008, $7.2 million of our investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. The uncertainties in the credit markets have affected all of our holdings in auction rate securities. Since February 2008, the auctions for our auction rate securities have not had sufficient buyers to cover investors' sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at December 31, 2008, we are uncertain as to when, or if, the liquidity issues relating to these investments will improve. We will continue to attempt to sell our auction rate securities until the auctions are successful. If uncertainties in the credit and capital markets continue, these markets deteriorate further or we experience any credit rating downgrades on the auction rate securities in our portfolio, we may incur additional impairment charges with respect to our auction rate securities portfolio, which could negatively affect our financial condition, cash flow and reported earnings. We continue to monitor the fair value of our auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges.

The valuation methods used to estimate the auction rate securities' fair value were (1) a discounted cash flow model, where the expected cash flows of the auction rate securities are discounted to the present using a yield that incorporates compensation for illiquidity, and (2) a market comparables method, where the auction rate securities are valued based on indications, from the secondary market, of what discounts buyers demand when purchasing similar auction rate securities. The valuation also included assessments of the underlying structure of each security, expected cash flows, discount rates, credit ratings, workout periods, and overall capital market liquidity. These assumptions, assessments and the interpretations of relevant market data are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value. Assuming a 10% adverse change in the fair value of these securities overall, the fair value of our auction rate

securities would decline approximately $700,000. However, each of our auction rate security investments have different features and are subject to different risks and therefore, any market decline would impact these securities to a different degree. In addition, the estimated fair value of the auction rates securities may differ from the values that would have been used had a ready market existed, and the differences could be material to the consolidated financial statements.

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(T). CONTROLS AND PROCEDURES.

Evaluation of Disclosure Controls and Procedures. As of December 31, 2008, management carried out, under the supervision and with the participation of our Chief Executive Officer and Principal Financial and Accounting Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Principal Financial and Accounting Officer concluded that, as of December 31, 2008, 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, 2008. 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, 2008, our internal control over financial reporting was effective based on these criteria. This annual report does not include an attestation report of the Company’s independent registered public accounting firm regarding internal control over financial reporting. Management’s report was not subject to attestation by the Company’s independent registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permits the Company to provide only management’s report in this annual 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, 2008, 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 Principal Financial and Accounting Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all errors and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within our company have been detected.

ITEM 9B. OTHER INFORMATION

Not Applicable.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2009 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 2009 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 2009 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 2009 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 2009 Annual Meeting of Stockholders.

PART IV

ITEM 15. EXHIBITS and FINANCIAL STATEMENT SCHEDULES

(a) 1. Consolidated Financial Statements

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

2. Consolidated Financial Statement Schedules

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

3. Exhibits

Exhibit Number	Exhibit Description
2.1	Agreement and Plan of Merger by and among Keryx Biopharmaceuticals, Inc., AXO Acquisition Corp., and ACCESS Oncology, Inc. dated as of January 7, 2004, filed as Exhibit 2.1 to the Registrant's Current Report on Form 8-K dated January 8, 2004, filed on January 15, 2004 (File No. 000-30929), and incorporated herein by reference.
2.2	First Amendment to the Agreement and Plan of Merger by and among Keryx Biopharmaceuticals, Inc., AXO Acquisition Corp., and ACCESS Oncology, Inc. dated as of February 5, 2004, filed as Exhibit 2.2 to the Registrant's Current Report on Form 8-K dated February 5, 2004, filed on February 20, 2004 (File No. 000-30929), and incorporated herein by reference.
3.1	Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference.
3.2	Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant's Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.

3.3	Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007, filed as Exhibit 3.3 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 and incorporated herein by reference.
4.1	Specimen Common Stock Certificate, filed as Exhibit 4.1 to the Registrant’s First Amendment to the Registration Statement on Form S-1 filed on June 30, 2000 (File No. 333-37402), and incorporated herein by reference.

4.2 Form of Warrant for the Purchase of Shares of Common Stock between certain holders of Series A Preferred Stock and Keryx Biopharmaceuticals, Inc., dated as of December 14, 1999, filed as Exhibit 4.9 to the Registrant's Registration Statement on Form S-1 filed on May 19, 2000 (File No. 333-37402), and incorporated herein by reference.

4.3 Form of Common Stock Purchase Warrant dated November 20, 2003, issued to the purchasers under the Securities Purchase Agreement, filed as Exhibit 10.3 to the Registrant's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.

4.4 Securities Purchase Agreement dated November 12, 2003 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.

4.5 Registration Rights Agreement dated November 17, 2003 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on December 12, 2003 (File No. 333-111143), and incorporated herein by reference.

4.6 Securities Purchase Agreement dated February 12, 2004 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.1 to the Company's Registration Statement on Form S-3 filed on March 16, 2004 (File No. 333-113654), and incorporated herein by reference.

4.7 Registration Rights Agreement dated February 17, 2004 among Keryx Biopharmaceuticals, Inc. and the Purchasers identified on the signature pages thereof, filed as Exhibit 10.2 to the Registrant's Registration Statement on Form S-3 filed on March 16, 2004 (File No. 333-113654), and incorporated herein by reference.

10.1! License Agreement between Alfa Wassermann S.p.A. and Partec Ltd., dated as of November 12, 1998, filed as Exhibit 10.7 to the Registrant's Second Amendment to the Registration Statement on Form S-1 filed on July 24, 2000 (File No. 333-37402), and incorporated by reference.

10.2! License Agreement between Opocrin S.p.A. and Keryx Biopharmaceuticals, Inc., dated September 25, 2002, filed as Exhibit 10.9 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2002 filed on November 12, 2002 (File No. 000-30929), and incorporated herein by reference.

10.3† 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.

10.4† 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.

10.5† 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.

10.6†	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.
10.7!	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.
10.8!	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.
10.9	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.

10.10†	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.
10.11!	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, 2006, and incorporated herein by reference.
10.12†	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.
10.13!	Sub-license Agreement by and among Keryx Biopharmaceuticals, Inc., Japan Tobacco Inc., and Torii Pharmaceutical Co., Ltd. dated September 26, 2007, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended September 30, 2007, filed on November 9, 2007, and incorporated herein by reference.
10.14†	Employment Agreement between Dr. I. Craig Henderson and Keryx Biopharmaceuticals, Inc. dated April 25, 2007, filed as Exhibit 10.3 to the Registrant's Annual Report on Form 10-Q for the quarter ended March 31, 2007, filed on May 7, 2007, and incorporated herein by reference.
10.15!	Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008, filed as Exhibit 10.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended March 31, 2008, filed on May 12, 2008, and incorporated herein by reference.
10.16*	First Amendment to Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008.
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 31, 2009.
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 31, 2009.
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 31, 2009.
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 31, 2009.

!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.
Consolidated Financial Statements as of December 31, 2008

Contents

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"), as of December 31, 2008 and 2007, and the related consolidated statements of operations, stockholders' (deficiency) equity, and cash flows for each of the years in the three-year period ended December 31, 2008. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2008 and 2007, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2008, in conformity with U.S. generally accepted accounting principles.

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has incurred substantial recurring losses from operations, a deficiency in equity, limited cash, cash equivalents, and short-term investment securities, and illiquid investments in auction rate securities that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

As discussed in Note 4 to the consolidated financial statements, the Company has changed its method of accounting for the fair value of financial assets and liabilities in 2008 due to the adoption of Statement of Financial Accounting Standards No. 157, "Fair Value Measurements." Also, as discussed in Note 1 to the consolidated financial statements, the Company has changed its method of accounting for share-based payments in 2006 due to the adoption of Statement of Financial Accounting Standards No. 123 (revised 2004), "Share-Based Payment."

/s/ KPMG LLP

New York, New York
March 31, 2009

Keryx Biopharmaceuticals, Inc.
Consolidated Balance Sheets as of December 31

(in thousands, except share and per share amounts)

	2008	2007
Assets		
Current assets:		
Cash and cash equivalents	$ 13,143	$ 19,065
Short-term investment securities	2,299	43,038
Interest receivable	25	283
Assets of discontinued operations	—	87
Other current assets	508	1,257
Total current assets	15,975	63,730
Long-term investment securities	7,185	2,296
Property, plant and equipment, net	182	11,483
Goodwill	3,208	3,208
Other assets, net	84	344
Total assets	$ 26,634	$ 81,061
Liabilities and stockholders' (deficiency) equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 4,613	$ 18,971
Accrued compensation and related liabilities	496	1,254
Current portion of deferred revenue	1,464	1,023
Liabilities of discontinued operations	120	163
Total current liabilities	6,693	21,411
Deferred revenue, net of current portion	17,308	11,022
Contingent equity rights	4,004	4,004
Other liabilities	118	202
Total liabilities	28,123	36,639
Commitments and contingencies (Notes 14 and 17)		
Stockholders' (deficiency) equity:		
Preferred stock, $0.001 par value per share (5,000,000 shares authorized, no shares issued and outstanding)	—	—
Common stock, $0.001 par value per share (95,000,000 shares authorized, 47,729,507 and 43,751,101 shares issued, 47,649,559 and 43,671,153 shares outstanding at December 31, 2008 and 2007, respectively)	48	44
Additional paid-in capital	330,738	323,772
Treasury stock, at cost, 79,948 shares at December 31, 2008 and 2007, respectively	(357)	(357)
Accumulated deficit	(331,918)	(279,037)
Total stockholders' (deficiency) equity	(1,489)	44,422
Total liabilities and stockholders' (deficiency) equity	$ 26,634	$ 81,061

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Operations for the Year Ended December 31

(in thousands, except share and per share amounts)

	2008	2007	2006
Revenue:			
License revenue	$ 1,180	$ 204	$ —
Service revenue	103	52	431
Other revenue	—	727	—
Total revenue	1,283	983	431
Operating expenses:			
Cost of services	27	124	390
Research and development:			
Non-cash compensation	(67)	3,574	6,504
Other research and development	38,075	74,883	55,751
Total research and development	38,008	78,457	62,255
Selling, general and administrative:			
Non-cash compensation	6,815	7,086	8,408
Other selling, general and administrative	7,474	9,141	8,519
Total selling, general and administrative	14,289	16,227	16,927
Total operating expenses	52,324	94,808	79,572
Operating loss	(51,041)	(93,825)	(79,141)
Interest and other (expense) income, net	(1,665)	4,555	6,393
Loss from continuing operations before income taxes	(52,706)	(89,270)	(72,748)
Income taxes	—	36	—
Loss from continuing operations	(52,706)	(89,306)	(72,748)
Loss from discontinued operations	(175)	(756)	(1,016)
Net loss	$ (52,881)	$ (90,062)	$ (73,764)
Basic and diluted loss per common share:			
Continuing operations	(1.17)	(2.05)	(1.74)
Discontinued operations	(0.01)	(0.02)	(0.02)
Basic and diluted loss per common share	$ (1.18)	$ (2.07)	$ (1.76)
Weighted average shares used in computing basic and diluted net loss per common share	44,902,398	43,583,950	41,919,741

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' (Deficiency) Equity
for the Years Ended December 31, 2008, 2007 and 2006

(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	$ 211,521
Changes during the year:					
Issuance of common stock in public offering (net of issuance expenses of $104)	—	—	4,500,000	5	82,692
Issuance of common stock in connection with acquisition	—	—	245,024	—*	3,310
Issuance of common stock held in escrow	—	—	15,646	—*	—
Issuance of restricted stock	—	—	100,000	—*	—
Exercise of options	—	—	824,103	1	1,987
Reclassification of unearned compensation upon adoption of SFAS No. 123R	—	—	—	—	(1,581)
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	14,912
Net loss	—	—	—	—	—
Balance at December 31, 2006	—	$ —	43,516,669	$ 44	$ 312,841

	Treasury stock		Unearned compensation	Accumulated deficit	Total
	Shares	Amount			
Balance at December 31, 2005	56,100	$ (89)	$ (1,581)	$ (115,211)	$ 94,678
Changes during the year:					
Issuance of common stock in public offering (net of issuance expenses of $104)	—	—	—	—	82,697
Issuance of common stock in connection with acquisition	—	—	—	—	3,310
Issuance of common stock held in escrow	—	—	—	—	—*
Issuance of restricted stock	—	—	—	—	—*
Exercise of options	—	—	—	—	1,988
Reclassification of unearned compensation upon adoption of SFAS No. 123R	—	—	1,581	—	—
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	14,912
Net loss	—	—	—	(73,764)	(73,764)
Balance at December 31, 2006	56,100	$ (89)	$ —	$ (188,975)	$ 123,821

* Amount less than one thousand dollars.

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' (Deficiency) Equity
for the Years Ended December 31, 2008, 2007 and 2006 (continued)

(in thousands, except share amounts)

	Series A convertible preferred stock		Common stock		Additional paid-in
	Shares	Amount	Shares	Amount	capital
Balance at December 31, 2006	—	$ —	43,516,669	$ 44	$ 312,841
Changes during the year:					
Cancellation of common stock held in escrow	—	—	(15,646)	(—)*	—
Issuance of restricted stock	—	—	195,000	—*	—
Forfeiture of restricted stock	—	—	(83,334)	(—)*	—
Surrender of common stock for tax withholding	—	—	—	—	—
Exercise of options	—	—	138,412	—	271
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—*	10,660
Net loss	—	—	—	—	—
Balance at December 31, 2007	—	$ —	43,751,101	$ 44	$ 323,772

	Treasury stock		Unearned	Accumulated	
	Shares	Amount	compensation	deficit	Total
Balance at December 31, 2006	56,100	$ (89)	$ —	$ (188,975)	$ 123,821
Changes during the year:					
Cancellation of common stock held in escrow	—	—	—	—	(—)*
Issuance of restricted stock	—	—	—	—	—*
Forfeiture of restricted stock	—	—	—	—	(—)*
Surrender of common stock for tax withholding	23,848	(268)	—	—	(268)
Exercise of options	—	—	—	—	271
Compensation in respect of options, restricted stock and warrants granted to employees, directors and third-parties	—	—	—	—	10,660
Net loss	—	—	—	(90,062)	(90,062)
Balance at December 31, 2007	79,948	$ (357)	$ —	$ (279,037)	$ 44,422

* Amount less than one thousand dollars.

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Changes in Stockholders' (Deficiency) Equity
for the Years Ended December 31, 2008, 2007 and 2006 (continued)

(in thousands, except share amounts)

	Series A convertible preferred stock		Common stock		Additional paid-in
	Shares	Amount	Shares	Amount	capital
Balance at December 31, 2007	—	$ —	43,751,101	$ 44	$ 323,772
Changes during the year:					
Issuance of restricted stock	—	—	3,976,906	4	—
Forfeiture of restricted stock	—	—	(73,500)	(—)*	—
Exercise of options	—	—	75,000	—*	222
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	—	—	6,744
Net loss	—	—	—	—	—
Balance at December 31, 2008	—	$ —	47,729,507	$ 48	$ 330,738

	Treasury stock		Unearned	Accumulated	
	Shares	Amount	compensation	deficit	Total
Balance at December 31, 2007	79,948	$ (357)	$ —	$ (279,037)	$ 44,422
Changes during the year:					
Issuance of restricted stock	—	—	—	—	4
Forfeiture of restricted stock	—	—	—	—	(—)*
Exercise of options	—	—	—	—	222
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	—	—	—	—	6,744
Net loss	—	—	—	(52,881)	(52,881)
Balance at December 31, 2008	79,948	$ (357)	$ —	$ (331,918)	$ (1,489)

* Amount less than one thousand dollars.

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows for the Year Ended December 31

(in thousands)

	2008	2007	2006
CASH FLOWS FROM OPERATING ACTIVITIES			
Net loss	$ (52,881)	$ (90,062)	$ (73,764)
Loss from discontinued operations	(175)	(756)	(1,016)
Loss from continuing operations	(52,706)	(89,306)	(72,748)
Adjustments to reconcile loss from continuing operations to cash flows used in operating activities of continuing operations:			
Stock compensation expense	6,748	10,660	14,912
Depreciation and amortization	111	130	176
Impairment of investment securities	3,196	—	—
Other impairment charges	11,037	—	—
Gain on sale of investment securities	(81)	—	—
Changes in assets and liabilities, net of effects of acquisitions:			
Decrease (increase) in other current assets	749	706	1,236
Decrease (increase) in accrued interest receivable	258	242	(189)
Decrease (increase) in security deposits	260	—	(255)
(Decrease) increase in accounts payable and accrued expenses	(14,059)	8,790	5,359
(Decrease) increase in accrued compensation and related liabilities	(758)	(281)	598
(Decrease) in other liabilities	(84)	(92)	(28)
Increase in deferred revenue	6,727	11,845	97
Net cash used in operating activities of continuing operations	(38,602)	(57,306)	(50,841)
Net cash used in operating activities of discontinued operations	(131)	(239)	(1,359)
Net cash used in operating activities	(38,733)	(57,545)	(52,201)
CASH FLOWS FROM INVESTING ACTIVITIES			
Purchases of property, plant and equipment	(146)	(3,159)	(7,582)
Payments of transaction costs	—	—	(231)
Decrease (increase) in other assets	—	—	27
Investment in held-to-maturity short-term securities	(33)	(6,136)	(4,080)
Proceeds from maturity of held-to-maturity short-term securities	20,869	24,020	8,275
Investment in available-for-sale short-term securities	(12,000)	(56,700)	(38,375)
Proceeds from sale of available-for-sale short-term securities	22,200	76,200	6,725
Proceeds from sale of available-for-sale long-term securities	1,700	—	—
Investment in held-to-maturity long-term securities	(1)	(6,372)	(16,677)
Proceeds from maturity of held-to-maturity long-term securities	—	3	5
Net cash provided by (used in) investing activities of continuing operations	32,589	27,856	(51,913)
Net cash provided by (used in) investing activities of discontinued operations	—	15	(15)
Net cash provided by (used in) investing activities	32,589	27,871	(51,928)

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

Keryx Biopharmaceuticals, Inc.
Consolidated Statements of Cash Flows for the Year Ended December 31 (continued)

(in thousands)

	2008	2007	2006
CASH FLOWS FROM FINANCING ACTIVITIES			
Proceeds from public offerings, net	$ —	$ —	$ 82,697
Proceeds from exercise of options and warrants	222	271	1,988
Purchase of treasury stock	—	(268)	—
Net cash provided by financing activities of continuing operations	222	3	84,685
Cash acquired in acquisition	—	—	5
Effect of exchange rate on cash	—	—	—
NET DECREASE IN CASH AND CASH EQUIVALENTS	(5,922)	(29,671)	(19,439)
Cash and cash equivalents at beginning of year	19,065	48,736	68,175
CASH AND CASH EQUIVALENTS AT END OF YEAR	$ 13,143	$ 19,065	$ 48,736
NON - CASH TRANSACTIONS			
Sale of manufacturing facility assets in settlement of liability	$ 300	$ —	$ —
Issuance of common stock in connection with acquisition	—	—	3,310
Assumption of liabilities in connection with acquisition	—	—	345
SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION			
Cash paid for income taxes	$ —	$ 36	$ —

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

Keryx Biopharmaceuticals, Inc.
Notes to the Consolidated Financial Statements

NOTE 1 - ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

DESCRIPTION OF BUSINESS

Keryx Biopharmaceuticals, Inc. and subsidiaries ("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 renal disease and cancer. 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 2008, 2007 and 2006 were conducted in the United States of America.

The Company was in the development stage at December 31, 2007. During the year ended December 31, 2008, the Company completed its development activities and commenced its planned principal operations.

LIQUIDITY

The Company has incurred substantial operating losses since its inception and expects to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2008, the Company has an accumulated deficit of $331.9 million and a deficiency in equity of $1.5 million. The Company is dependent upon significant financing to provide the working capital necessary to execute its business plan. The Company has not yet commercialized any of its drug candidates and cannot be sure if it will ever be able to do so. Even if the Company commercializes one or more of its drug candidates, the Company may not become profitable. The Company's ability to achieve profitability depends on a number of factors, including its ability to obtain regulatory approval for its drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its drug candidates alone or in partnership. The Company may continue to incur substantial operating losses even if it begins to generate revenues from its drug candidates, if approved. The Company currently anticipates that its cash, cash equivalents and investment securities as of December 31, 2008, exclusive of its holdings in auction rate securities and inclusive of a $3 million milestone payment received by the Company in March 2009 under its sublicense agreement for Zerenex in Japan, are sufficient to meet the Company's anticipated working capital needs and fund its business plan through the end of 2009. However, if the Company is not able to receive proceeds from some portion of its auction rate securities by the first quarter of 2010, the Company may not have the ability to continue as a going concern for any significant period beyond that point. The actual amount of funds that the Company will need to operate is subject to many factors, including the timing, design and conduct of clinical trials for the Company's drug candidates. The Company is evaluating market conditions to determine the appropriate timing and extent to which it will seek to obtain additional debt, equity or other type of financing. If the Company determines that it is necessary to seek additional funding, there can be no assurance that it will be able to obtain any such funding on terms that are acceptable to the Company, if at all.

The accompanying financial statements have been prepared assuming that the Company continues as a going concern, which contemplates the realization of assets and satisfaction of liabilities in the normal course of business. The factors discussed above, taken together with the Company's limited cash, cash equivalents, and short-term investment securities, and illiquid investments in auction rate securities raise substantial doubt about the Company's ability to continue as a going concern. The financial statements do not include any adjustments that might be necessary should the Company be unable to continue as a going concern.

The Company's common stock is listed on the NASDAQ Capital Market and trades under the symbol "KERX." On April 22, 2008, the Company received notice from The NASDAQ Stock Market that it was not in compliance with the $1.00 minimum bid price requirement for continued inclusion on the applicable NASDAQ market. On October 21, 2008, the Company received notice from The NASDAQ Stock Market that the bid price and market value of publicly traded securities requirements for continued listing on a NASDAQ market had been temporarily suspended. Due to this action, the Company believes that it has until July 20, 2009, to achieve compliance with the $1.00 minimum closing bid price requirement.

On November 17, 2008, the Company received notice from The NASDAQ Stock Market that it was no longer in compliance with Marketplace Rule 4310(c)(3), which requires the Company to have a minimum of $2,500,000 in stockholders' equity, or $35,000,000 market value of listed securities, or $500,000 of net income from continuing operations for the most recently completed fiscal year or two of the three most recently completed fiscal years, for continued listing on the NASDAQ Capital Market. On December 2, 2008, the Company submitted to The NASDAQ Stock Market a plan to achieve and sustain compliance with all of the NASDAQ Capital Market listing requirements.

On March 3, 2009, the Company received notice from The NASDAQ Stock Market indicating that it had failed to regain compliance with NASDAQ Marketplace Rule 4310(c)(3). Therefore, The NASDAQ Stock Market determined to delist the Company’s common stock from the NASDAQ Capital Market unless the Company appealed the delisting determination to a hearing. On March 9, 2009, the Company requested a hearing to appeal the determination of The NASDAQ Stock Market to delist the Company’s common stock to a NASDAQ Listings Qualification Panel (“Panel”), which automatically stayed the delisting of the Company’s common stock pending issuance of the Panel's decision. The hearing is scheduled for April 30, 2009. At the Panel hearing, the Company plans to ask the Panel to provide it with additional time to regain compliance with NASDAQ Marketplace Rule 4310(c)(3). There can be no assurance that such a request will be granted or that the Panel will permit the Company to continue to list its common stock on the NASDAQ Capital Market, or that in the future the Company will meet the listing requirements of the NASDAQ Capital Market, including, without limitation, bid price, stockholders’ equity and/or market value of listed securities minimum requirements. Additionally, the Company’s efforts to continue to meet the listing requirements may be limited by current market conditions, including volatility in the market. If the Company’s common stock is delisted from the NASDAQ Capital Market, there may be a limited market for the Company’s stock, trading in the Company’s stock may become more difficult and the Company’s share price could decrease even further. In addition, if the Company’s common stock is delisted, the Company’s ability to raise additional capital may be impaired.

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.

CORRECTION OF IMMATERIAL ERROR

The Company had previously disclosed in its consolidated financial statements as of, and for the quarter and six months ended, June 30, 2006, differences that were identified during fiscal 2006 in connection with the Company’s internal review of its historical stock option practices, including the underlying option grant documentation and procedures, which resulted in the determination of additional compensation expense based on revised measurement dates. At that time, the Company determined that the additional compensation expense resulting from revised measurement dates was immaterial for each period and as a result was not recorded. The Company has continued to assess the impact of this adjustment under the provisions of SEC Staff Accounting Bulletin Nos. 99 and 108 and concluded it would continue to be immaterial in subsequent periods. Due to the Company’s decision to cease development of Sulonex and the related restructurings implemented during 2008, the Company believes this additional compensation expense may become material in future periods. As a result, the Company has recorded an adjustment to increase its accumulated deficit and additional paid-in capital as of January 1, 2006 by $763,000 to account for the recognition of these additional stock-based compensation costs incurred prior to January 1, 2006. The adjustment recorded as of January 1, 2006 has no effect on the total amount of the Company’s stockholders’ (deficiency) equity balances in the consolidated financial statements as of, and for years ended December 31, 2006, 2007 and 2008, and there will be no impact on any future period.

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 EQUIVALENTS

The Company treats liquid investments with original maturities of less than three months when purchased as cash equivalents.

INVESTMENT SECURITIES

Investment securities at December 31, 2008 and 2007 consist of short-term and long-term government and auction rate securities. The Company classifies its short-term and long-term debt securities as held-to-maturity, with the exception of auction rate 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. 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. Available-for-sale investment securities (which are comprised of auction rate securities) are recorded at fair value. Changes in fair value are recorded in accumulated other comprehensive income unless realized on sale or recognized as an other-than-temporary impairment. See Note 4 – Fair Value Measurements.

A decline in the market value of any investment 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 operations and a new cost basis for the security is established. Other-than-temporary impairment charges are included in interest and other (expense) income, net. 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.

PATENT COSTS

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

REVENUE RECOGNITION

The Company recognizes license revenue consistent with the provisions of Staff Accounting Bulletin (“SAB”) No. 104 and Emerging Issues Task Force (“EITF”) Issue No. 00-21, “Revenue Arrangements with Multiple Deliverables.” The

Company analyzes each element of its licensing agreement to determine the appropriate revenue recognition. The Company recognizes revenue on upfront payments and milestone payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. The Company may recognize milestone payments in revenue upon the achievement of specified milestones if (1) the milestone is substantive in nature, and the achievement of the milestone was not reasonably assured at the inception of the agreement and (2) the fees are nonrefundable. Any milestone payments received prior to satisfying these revenue recognition criteria are recognized as deferred revenue. Sales milestones and royalties that are deferred will be recognized when earned under the agreements.

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.

Other revenue consists of a payment in 2007 associated with a termination agreement, which was recognized when earned. (See Note 9).

COST OF SERVICES

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 in relation to external clinical research organizations, or CROs, and clinical site costs. The Company analyzes the progress of clinical trials, including levels of patient enrollment, invoices received and contracted costs when evaluating the adequacy of the amount expensed and the related prepaid asset and accrued liability. Additionally, administrative costs related to external CROs are recognized on a straight-line basis over the estimated contractual period. With respect to clinical site costs, the financial terms of these agreements are subject to negotiation and vary from contract to contract. Payments under these contracts may be uneven, and depend on factors such as the achievement of certain events, the successful accrual of patients, the completion of portions of the clinical trial or similar conditions. The objective of the Company’s policy is to match the recording of expenses in its financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical site costs are recognized based on the Company’s estimate of the degree of completion of the event or events specified in the specific clinical study or trial contract.

Effective January 1, 2008, the Company adopted EITF No. 07-3, “Accounting for Nonrefundable Advance Payments for Goods or Services Received for Use in Future Research and Development Activities” (“EITF 07-3”). EITF 07-3 requires that nonrefundable advance payments for goods or services that will be used or rendered for future research and development activities be deferred and amortized over the period that the goods are delivered or the related services are performed, subject to an assessment of recoverability. The adoption of EITF 07-3 did not have an effect on the Company’s results of operations and financial position as no nonrefundable advance payments were made during 2008.

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 operations in the period that includes the enactment date. If the likelihood of realizing the deferred tax assets or liability is less than “more likely than not,” a valuation allowance is then created.

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

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

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

STOCK - BASED COMPENSATION

In December 2004, the FASB issued SFAS No. 123R, “Share-Based Payment” (“SFAS No. 123R”). SFAS No. 123R requires all share-based payments to employees, and 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 beginning January 1, 2006 includes: a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the grant-date fair value estimated in accordance with the original provisions of SFAS No. 123, “Accounting for Stock-Based Compensation” (“SFAS No. 123”), and b) compensation cost for all share-based payments granted subsequent to January 1, 2006, based on the grant-date fair value estimated in accordance with the provisions of SFAS No. 123R. The results for prior periods have not been restated.

Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. SFAS No. 123R requires forfeitures to be estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates. In the Company’s pro forma disclosures required under SFAS No. 123 for periods prior to 2006, the Company accounted for forfeitures as they occurred. Upon adoption of SFAS No. 123R, the Company elected to use the Black-Scholes model to value share-based payments granted to employees subsequent to January 1, 2006 and elected to attribute the value of stock-based compensation expense using the straight-line single option method. These methods were previously used for the Company’s pro forma information required under SFAS No. 123. For additional information, see Note 11 – Stockholders' Equity.

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

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. Shares of restricted stock are included in common stock outstanding unless forfeited. Diluted net loss per share does not reflect the effect of shares of common stock to be issued upon the exercise of stock options and warrants, as their inclusion would be anti-dilutive. The options and warrants outstanding as of December 31, 2008, 2007 and 2006, which are not included in the computation of net loss per share amounts, were 9,187,023, 11,191,149 and, 11,106,689, respectively.

COMPREHENSIVE LOSS

Comprehensive loss is the same as net loss for all years presented.

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. The Company's 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 in February 2004 (see Note 10 – Contingent Equity Rights) resulted in negative goodwill. Since the negative goodwill was a result of not recognizing contingent consideration (i.e., the contingent equity rights), the lesser of the negative goodwill and the maximum value of the contingent equity rights at the date of the acquisition was recorded as if it were a liability, thereby eliminating the negative goodwill.

IMPAIRMENT

The Company accounts for impairment of long-lived assets using the provisions of SFAS No. 144, "Accounting for the Impairment or Disposal of Long-Lived Assets" ("SFAS No. 144"). This statement requires the recognition of an impairment loss when circumstances indicate that the carrying value of long-lived tangible and intangible assets with finite lives may not be recoverable. Management's policy in determining whether an impairment indicator exists, a triggering event, comprises measurable operating performance criteria as well as qualitative measures. If an analysis is necessitated by the occurrence of a triggering event, the Company makes certain assumptions in determining the impairment amount. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future cash flows expected to be generated by the asset or used in its disposal. If the carrying amount of an asset exceeds its estimated future cash flows, an impairment charge is recognized. During the first quarter of 2007, management reviewed both its original and projected revenue estimates associated with the Accumin diagnostic tool. As a result of this analysis, the Company concluded that the asset was impaired and recorded an impairment charge of approximately $600,000 to write-down identifiable intangible long-lived assets associated with Accumin. The charge was recorded in loss from discontinued operations. As further discussed in Note 5, the Company recorded an impairment charge of $11.0 million during the year ended December 31, 2008 related to the write-down of fixed assets following the cessation of its development of Sulonex.

The Company accounts for impairment of goodwill using the provisions of SFAS No. 142, "Goodwill and Other Intangible Assets" ("SFAS No. 142"). This statement addresses how intangible assets that are acquired individually or with a group of other assets (but not those acquired in a business combination) should be accounted for in financial statements upon their acquisition. SFAS No. 142 also addresses how goodwill and other intangible assets should be accounted for after they have been initially recognized in the financial statements. SFAS No. 142 requires goodwill be tested using a two-step process. The first step compares the fair value of the reporting unit with the unit's carrying value, including goodwill. When the carrying value of the reporting unit is greater than fair value, the unit's goodwill may be impaired, and the second step must be completed to measure the amount of the goodwill impairment charge, if any. In the second step, the implied fair value of the reporting unit's goodwill is compared with the carrying amount of the unit's goodwill. If the carrying amount is greater than the implied fair value, the carrying value of the goodwill must be written down to its implied fair value. The negative outcome of the Company's pivotal SUN-MICRO Phase 3 clinical trial of Sulonex™ (sulodexide) for the treatment of diabetic nephropathy, announced on March 7, 2008, and the Company's subsequent decision to terminate the ongoing SUN-MACRO Phase 4 clinical trial triggered an impairment

test. As of March 31, 2008, management concluded that there was no impairment of the Company's goodwill. Additionally, as of December 31, 2008, management conducted its annual assessment of goodwill and concluded that there is no impairment to its goodwill. The Company will continue to perform impairment tests under SFAS No. 142 annually, at December 31, and whenever events or changes in circumstances suggest that the carrying value of an asset may not be recoverable.

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 held-to-maturity investments with multiple financial institutions that invests in investment-grade securities with average maturities of less than twelve months. The Company also maintains long-term investments in auction rate securities. See Note 3 – Investment Securities and Note 4 – Fair Value Measurements.

RECENTLY ISSUED ACCOUNTING STANDARDS

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

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

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

In February 2007, the FASB issued SFAS No. 159, “The Fair Value Option for Financial Assets and Financial Liabilities - including an amendment of FASB Statement No. 115” (“SFAS 159”). SFAS 159 is expected to expand the use of fair value accounting, but does not affect existing standards which require certain assets or liabilities to be carried at fair value. The objective of SFAS 159 is to improve financial reporting by providing companies with the opportunity to mitigate volatility in reported earnings caused by measuring related assets and liabilities differently

without having to apply complex hedge accounting provisions. Under SFAS 159, a company may choose, at its initial application or at other specified election dates, to measure eligible items at fair value and report unrealized gains and losses on items for which the fair value option has been elected in earnings at each subsequent reporting date. SFAS 159 is effective for financial statements issued for fiscal years beginning after November 15, 2007, and interim periods within those fiscal years. The Company has not elected the fair value option for any of its existing assets and liabilities and thus the adoption of SFAS 159 did not have an impact on its results of operations and financial position.

In February 2008, the FASB issued FASB Staff Position ("FSP") 157-2, "Effective Date of FASB Statement No. 157" ("FSP 157-2"), which delays the effective date of SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157") for non-financial assets and non-financial liabilities. The delay is intended to allow the FASB and constituents additional time to consider the effect of various implementation issues that have arisen, or that may arise, from the application of SFAS No. 157. For items within the scope of FSP 157-2, this FSP defers the effective date of SFAS No. 157 to fiscal years beginning after November 15, 2008, and interim periods within those fiscal years. The Company currently does not believe that the adoption of the deferred portion of SFAS No. 157 will have a material impact on the Company's financial condition or results of operations.

NOTE 2 – CASH AND CASH EQUIVALENTS

(in thousands)	December 31, 2008	December 31, 2007
Money market funds	$ 12,159	$ 14,457
Checking and bank deposits	984	4,608
Total	$ 13,143	$ 19,065

NOTE 3 - INVESTMENT SECURITIES

The Company records its investments as either held-to-maturity or available-for-sale. Held-to-maturity investments are recorded at amortized cost. Available-for-sale investment securities (which are comprised of auction rate securities) are recorded at fair value (see Note 4 – Fair Value Measurements). Other-than-temporary impairment charges are included in interest and other (expense) income, net. The following tables summarize the Company's investment securities at December 31, 2008 and December 31, 2007:

	December 31, 2008			
(in thousands)	Amortized cost, as adjusted	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investment securities:				
Obligations of domestic governmental agencies (mature May 2009) (held-to-maturity)	$ 2,299	$ 39	$ —	$ 2,338
Long-term investments:				
Auction rate securities (mature between 2037 and 2047) (available-for-sale)	$ 7,185	$ —	$ —	$ 7,185

	December 31, 2007			
(in thousands)	Amortized cost	Gross unrealized holding gains	Gross unrealized holding losses	Estimated fair value
Short-term investments:				
Obligations of domestic governmental agencies (mature between April and October 2008) (held-to-maturity)	$ 20,838	$ 91	$ —	$ 20,929
Auction rate securities (available-for-sale) *	22,200	—	—	22,200
	$ 43,038	$ 91	$ —	$ 43,129
Long-term investments:				
Obligations of domestic governmental agencies (mature May 2009) (held-to-maturity)	$ 2,296	$ 54	$ —	$ 2,350

* Amortized cost approximates fair value. Unrealized gains and losses are immaterial.

NOTE 4 – FAIR VALUE MEASUREMENTS

As of January 1, 2008, the Company adopted SFAS No. 157, "Fair Value Measurements" ("SFAS No. 157") for its financial assets and liabilities carried at fair value on a recurring basis in the financial statements only. SFAS No. 157 defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurements. The SFAS No. 157 hierarchy ranks the quality and reliability of inputs, or assumptions, used in the determination of fair value and requires financial assets and liabilities carried at fair value to be classified and disclosed in one of the following three categories:

- Level 1 – quoted prices in active markets for identical assets and liabilities;
- Level 2 – inputs other than Level 1 quoted prices that are directly or indirectly observable; and
- Level 3 – unobservable inputs that are not corroborated by market data.

As of December 31, 2008, $7.2 million of the Company's investment securities were auction rate securities and represent interests in student loan-backed securities. The auction rate securities are recorded at their fair value and classified as long-term investments. Auction rate securities are structured to provide liquidity through a Dutch auction process that resets the applicable interest rate at pre-determined calendar intervals, generally every 28 days. This mechanism has historically allowed existing investors either to rollover their holdings, whereby they would continue to own their respective securities, or liquidate their holdings by selling such securities at par. This auction process has historically provided a liquid market for these securities; however, the uncertainties in the credit markets have affected all of the Company's holdings in auction rate securities. Since February 2008, the auctions for the auction rate securities held by the Company have not had sufficient buyers to cover investors' sell orders, resulting in unsuccessful auctions. When an auction is unsuccessful, the interest rate is re-set to a level pre-determined by the loan documents and remains in effect until the next auction date, at which time the process repeats. While all but one of these investments were rated A or higher at December 31, 2008, the Company is uncertain as to when, or if, the liquidity issues relating to these investments will improve. The Company assessed the fair value of its auction rate securities portfolio. As a result of this valuation process, as described below, the Company recorded impairment charges totaling $3.2 million during the year ended December 31, 2008, for other-than-temporary declines in the value of its auction rate securities. These other-than-temporary impairment charges were included in interest and other (expense) income, net. In addition, in the first quarter of 2008, the Company reclassified the entire auction rate securities portfolio from short-term to long-term investments due to the uncertainty of when the Company will be able to sell these securities. In November 2008, the Company sold one of its auction rate security investments in the secondary market. The security had a par value of $2.0 million and an adjusted book value of $1.6 million. Proceeds from the sale of this security were $1.7 million, representing a gain of $0.1 million over the adjusted book value. The estimated fair value of the Company's remaining auction rate securities is $7.2 million at December 31, 2008.

The valuation methods used to estimate the auction rate securities' fair value were (1) a discounted cash flow model, where the expected cash flows of the auction rate securities are discounted to the present using a yield that incorporates compensation for illiquidity, and (2) a market comparables method, where the auction rate securities are valued based on indications, from the secondary market, of what discounts buyers demand when purchasing similar auction rate securities. The valuation also included assessments of the underlying structure of each security, expected cash flows, discount rates, credit ratings, workout periods, and overall capital market liquidity. These assumptions, assessments and the interpretations of relevant market data are subject to uncertainties, are difficult to predict and require significant judgment. The use of different assumptions, applying different judgment to inherently subjective matters and changes in future market conditions could result in significantly different estimates of fair value of the Company's auction rate securities. In addition, the estimated fair value of the auction rates securities may differ from the values that would have been used had a ready market existed, and the differences could be material to the

consolidated financial statements.

The fair value of the Company's auction rate securities could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue or if these securities experience credit rating downgrades, the Company may incur additional impairment charges with respect to its auction rate securities portfolio. The Company continues to monitor the fair value of its auction rate securities and relevant market conditions and will recognize additional impairment charges if future circumstances warrant such charges.

The Company reviews investment securities for impairment in accordance with the guidance in FSP SFAS 115-1 and 124-1, "The Meaning of Other-Than-Temporary Impairment and Its Application to Certain Investments," to determine the classification of the impairment as temporary or other-than-temporary. Losses are recognized in the Company's consolidated statement of operations when a decline in fair value is determined to be other-than-temporary. The Company reviews its investments on an ongoing basis for indications of possible impairment. Once identified, the determination of whether the impairment is temporary or other-than-temporary requires significant judgment. The Company believes that the impairment charges related to its auction rate securities investments are other-than-temporary. The primary factors the Company considers in classifying an impairment include the extent and time the fair value of each investment has been below cost and the Company's ability to hold such investment to maturity.

The following table provides the fair value measurements of applicable Company financial assets according to the fair value levels defined by SFAS No. 157 as of December 31, 2008:

(in thousands)	Financial assets at fair value as of December 31, 2008 Level 1	Level 2	Level 3
Money market funds (1)	$ 12,159	$ —	$ —
Obligations of domestic governmental agencies (held-to-maturity) (2)	2,299	—	—
Auction rate securities (3)	—	—	7,185
Total	$ 14,458	$ —	$ 7,185

(1) Included in cash and cash equivalents on the Company's consolidated balance sheet. The carrying amount of money market funds is a reasonable estimate of fair value.
(2) Amortized cost approximates fair value.
(3) Included in long-term investment securities on the Company's consolidated balance sheet.

The following table summarizes the change in carrying value associated with Level 3 financial assets for the twelve months ended December 31, 2008:

(in thousands)	Available-for-sale long-term investments
Balance at January 1, 2008	$ —
Transfer into Level 3 at original cost (1)	12,000
Sale of security	(1,700)
Realized gain on sale of security	81
Total impairment charges included in net loss	(3,196)
Balance at December 31, 2008	$ 7,185

(1) Based on deteriorated market conditions experienced in the first quarter of 2008, the Company changed the fair value measurement methodology of its auction rate securities portfolio that the Company classifies as available-for-sale from quoted prices in active markets to a model based on discounted cash flows and market comparables. Accordingly, these securities were re-classified from Level 1 to Level 3.

NOTE 5 - PROPERTY, PLANT AND EQUIPMENT

(in thousands)	December 31, 2008	December 31, 2007
Manufacturing suite and equipment	$ —	$ 11,224
Leasehold improvements	20	36
Office furniture and equipment	315	315
Computers, software and related equipment	436	386
	771	11,961
Accumulated depreciation and amortization	(589)	(478)
Net book value	$ 182	$ 11,483

The Company spent approximately $11.3 million in capital expenditures building a manufacturing suite for Sulonex. With the cessation of the Company's development of Sulonex in March 2008, the Company took an impairment charge of $11.0 million, which is included in other research and development expenses in year ended December 31, 2008, to write the assets down to their fair value of $300,000, the amount for which the assets were sold during year ended December 31, 2008. The sale of the assets offset a payable and, therefore, cash was not received by the Company. In addition, the Company recognized a $2.1 million expense, which is included in other research and development expenses in the year ended December 31, 2008, for costs related to the required restoration of the leased facility to its original condition. See Note 18 – Restructuring.

Depreciation expense for the years ended December 31, 2008, 2007 and 2006 was approximately $111,000, $130,000 and $132,000, respectively. The following table summarizes depreciation expense for the years ended December 31, 2008, 2007 and 2006.

	For the year ended December 31		
(in thousands)	2008	2007	2006
Depreciation expense:			
Cost of services	$ —	$ —	$ 2
Research and development	84	86	84
General and administrative	27	44	46
Total	$ 111	$ 130	$ 132

NOTE 6 – GOODWILL

On April 6, 2006, Accumin Diagnostics, Inc. ("ADI"), a wholly-owned subsidiary of the Company, completed the acquisition of AccuminTM, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. ("AusAm"). The purchase price of Accumin was $3,996,000, which included the issuance of 245,024 shares of the Company's common stock, the assumption of certain liabilities of AusAm equal to approximately $345,000 and transaction costs and cash settlement costs of approximately $341,000.

Subsequent to the closing, disputes arose between AusAm and Keryx relating to the determination of the purchase consideration under the acquisition agreement. On July 31, 2006, AusAm filed a motion purporting to seek to enforce the terms of the acquisition agreement and alleging damages in the amount of $818,145. The matter has been settled pursuant to a settlement agreement approved by the Bankruptcy Court on April 10, 2007. In April 2007, under the settlement, Keryx paid AusAm $110,075 in full settlement of all claims made by AusAm in the action. Following completion of the settlement, 15,646 shares of the Company's common stock, which were issued and outstanding and held in escrow, were canceled.

The Accumin transaction has been accounted for as a purchase by the Company. 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 the Company's Products segment based on the proposed synergies associated with Sulonex prior to its discontinuation of development by the Company.

In September 2008, the Company terminated its license agreement related to the Accumin product and ceased all operations related to the Diagnostic segment. See Note 8 – Discontinued Operations.

NOTE 7 - OTHER ASSETS

(in thousands)	December 31, 2008	December 31, 2007

Patents and other intangible assets	$	352	$	352
Long-term deposits		62		322
Deferred registration fees		22		22
		436		696
Accumulated amortization		(352)		(352)
	$	84	$	344

Amortization expense for the years ended December 31, 2008, 2007 and 2006 was approximately $0, $14,000 and $84,000, respectively. The Company does not expect to record amortization expenses going forward, as all intangible assets are fully amortized.

NOTE 8 – DISCONTINUED OPERATIONS

In September 2008, the Company terminated its license agreement related to the Accumin product and ceased all operations related to the Diagnostic segment. The results of the Company's Diagnostic segment and the related financial position have been reflected as discontinued operations in the consolidated financial statements in accordance with SFAS No. 144 and EITF Issue No. 03-13, "Applying the Conditions in Paragraph 42 of FASB Statement No. 144 in Determining Whether to Report Discontinued Operations" ("EITF Issue No. 03-13"). The consolidated financial statements have been reclassified to conform to discontinued operations presentation for all historical periods presented.

Summarized selected financial information for discontinued operations are as follows:

(in thousands)	2008	2007	2006
Diagnostic revenue	$ —	$ 66	$ 103
Operating expenses:			
Cost of diagnostics sold	—	38	140
Research and development	4	6	388
Selling, general and administrative	171	778	591
Total operating expenses	175	822	1,119
Loss from discontinued operations	$ (175)	$ (756)	$ (1,016)

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

The assets and liabilities of discontinued operations are stated separately as of December 31, 2008 and 2007 on the accompanying consolidated balance sheets. The major assets and liabilities categories are as follows:

(in thousands)	December 31, 2008	December 31, 2007
Assets		
Other current assets	$ —	$ 73
Property, plant and equipment, net	—	14
Assets of discontinued operations	$ —	$ 87
Liabilities		
Accounts payable and accrued expenses	$ 120	$ 163
Liabilities of discontinued operations	$ 120	$ 163

NOTE 9 - LICENSE AGREEMENTS

In September 2007, the Company entered into a Sublicense Agreement with Japan Tobacco Inc. (“JT”) and Torii Pharmaceutical Co., Ltd. (“Torii”), JT's pharmaceutical business subsidiary, under which JT and Torii obtained the exclusive sublicense rights for the development and commercialization of ferric citrate in Japan, which is being developed in the United States under the trade name Zerenex. JT and Torii are responsible for the future development and commercialization costs in Japan.

An upfront payment of $12.0 million, which was received in October 2007, is being recognized as license revenue on a straight-line basis over the life of the agreement, which is through the expiration of the last-to-expire patent covered by the agreement in 2023, and represents the estimated period over which the Company will have certain ongoing responsibilities under the sublicense agreement. The Company recorded license revenue of approximately $774,000 and $204,000 for the years ended December 31, 2008 and 2007, respectively, and, at December 31, 2008 and 2007, has deferred revenue of approximately $11.0 million and $11.8 million, respectively, associated with this $12.0 million payment (approximately $774,000 of which has been classified as a current liability at December 31, 2008 and 2007).

An additional milestone payment of $8.0 million, for the achievement of certain milestones reached in March 2008, was received in April 2008, and is being recognized as license revenue on a straight-line basis over the life of the agreement (as discussed above). The Company recorded license revenue of approximately $406,000 for the year ended December 31, 2008, and, at December 31, 2008, has deferred revenue of approximately $7.6 million (approximately $533,000 of which has been classified as a current liability) associated with this $8.0 million payment.

The Company may receive up to an additional $80.0 million in payments upon the achievement of pre-specified milestones. In addition, upon commercialization, JT and Torii will make royalty payments to the Company on net sales of ferric citrate in Japan.

In October 2004, the Company entered into a termination agreement with Yissum Research and Development Company of the Hebrew University of Jerusalem (“Yissum”), whereby in consideration for the Company’s agreement to a termination of certain license rights, Yissum agreed to pay the Company 33.3% of any cash consideration received by Yissum relating to the terminated license rights, up to $6.0 million. In December 2007, the Company recognized $726,600 of other revenue, which was received net of $36,330 of income tax withheld, related to this termination agreement. Payments from Yissum are recognized as earned since the Company has no responsibilities under the terminated license agreement or the termination agreement.

NOTE 10 – CONTINGENT EQUITY RIGHTS

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

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

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

- 500,000 shares of the Company's common stock upon enrollment of the first patient in a Keryx-sponsored Phase 3 (or other pivotal) clinical trial for any of the acquired ACCESS Oncology drug candidates;

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

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

- 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.

To date, none of the above milestones have been achieved. 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 former preferred stockholders of ACCESS Oncology do not have a share of the milestone consideration. The Company's stockholders approved the issuance of shares of its common stock payable as contingent milestone consideration at the 2004 annual meeting of stockholders, which took place on June 10, 2004.

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

NOTE 11 - STOCKHOLDERS' EQUITY

Preferred Stock

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

Common Stock

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

On March 29, 2006, the Company completed a registered direct offering of 4,500,000 shares of its common stock to two institutional investors at $18.40 per share. Total proceeds to the Company from this public offering were

approximately $82.7 million, net of offering expenses of approximately $0.1 million.

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

Treasury Stock

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

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

Equity Incentive Plans

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

a. The 1999 Stock Option Plan was adopted in November 1999. Under the 1999 Stock Option Plan, the Company's board of directors could grant stock-based awards to directors, consultants and employees. The plan authorizes grants to purchase up to 4,230,000 shares of authorized but unissued common stock. The plan limits the term of each option, to no more than 25 years from the date of the grant, unless otherwise authorized by the board. The plan permits the board of directors or a committee appointed by the board to administer the plan. The administrator has the authority, in its discretion, to determine the terms and conditions of any option granted to a Company service provider, including the vesting schedule. As of December 31, 2008, no additional shares of the Company's 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, 2008, up to 322,051 additional shares may be issued under the 2000 Stock Option Plan.

c. The 2002 CEO Incentive Stock Option Plan was adopted in December 2002. Under the 2002 CEO Incentive Stock Option Plan the Company's board of directors granted an option to the newly-appointed Chief Executive Officer of the Company to purchase up to 2,002,657 shares of authorized but unissued common stock. The option has a term of 10 years from the date of the grant. The option granted to the newly appointed Chief Executive Officer was part of a total grant of options issued pursuant to the 1999 Stock Option Plan, the 2000 Stock Option Plan and the 2002 CEO Incentive Stock Option Plan, to purchase a total of 4,050,000 shares of the Company's common stock. As of December 31, 2008, 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 the Company's common stock may be issued under the 2002 CEO Incentive Stock Option Plan.

d. The 2004 President Incentive Stock Option Plan was adopted in February 2004. Under the 2004 President Incentive Stock Option Plan the Company's board of directors granted an option to the then 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 then newly appointed President was made pursuant to

an employment agreement following the acquisition of ACCESS Oncology in February 2004. Of this option, 166,667 was to vest over a three-year period and 833,333 was to vest upon the earlier of the achievement of certain performance-based milestones or February 5, 2011. As part of the 2008 Restructuring, on March 26, 2008, the Company notified its President that the Company was terminating his employment, effective April 15, 2008. As a result, 500,000 options were forfeited and, as of December 31, 2008, 500,000 options remain outstanding and vested under this plan, and will remain exercisable until April 15, 2010. No additional shares of the Company's common stock may be issued under the 2004 President Incentive Stock Option Plan.

e. The 2004 Long-Term Incentive Plan was adopted in June 2004 by the Company's 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, 2008, up to an additional 835,408 shares may be issued under the 2004 Long-Term Incentive Plan.

f. The 2007 Incentive Plan was adopted in June 2007 by the Company's stockholders. Under the 2007 Incentive Plan, the compensation committee of the Company's board of directors is authorized to grant stock-based awards to directors, consultants, employees and officers. The 2007 Incentive Plan authorizes grants to purchase up to 6,000,000 shares of authorized but unissued common stock. The plan limits the term of each option to no more than 10 years from the date of their grant. As of December 31, 2008, up to an additional 1,376,469 shares may be issued under the 2007 Incentive Plan.

The following table summarizes stock option activity for the years ended December 31, 2008, 2007 and 2006:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
Outstanding at December 31, 2005	8,024,652	$ 4.26		
Granted	3,699,660	14.49		
Exercised	(824,103)	2.41		
Forfeited & expired	(115,496)	7.91		
Outstanding at December 31, 2006	10,784,713	7.87		
Granted	1,235,769	9.67		
Exercised	(138,412)	1.96		
Forfeited	(544,730)	14.48		
Expired	(468,167)	11.31		
Outstanding at December 31, 2007	10,869,173	7.69		
Granted	243,800	4.28		
Exercised	(75,000)	2.96		$ 259,900
Forfeited	(1,326,214)	10.29		
Expired	(597,300)	8.74		
Outstanding at December 31, 2008	9,114,459	$ 7.19	5.6	$ 36,678
Vested and expected to vest at December 31, 2008	9,084,275	$ 7.18	5.6	$ 36,678
Exercisable at December 31, 2008	7,939,549	$ 6.62	5.3	$ 36,678

The following table summarizes information about stock options outstanding at December 31, 2008:

	Options outstanding			Options exercisable	
Range of exercise prices	Number outstanding	Weighted-average remaining contractual life (years)	Weighed-average exercise price	Number exercisable	Weighed-average exercise price

$ 0.10 - $ 2.14	4,134,319	4.8	$ 1.23	4,104,319	$ 1.24
3.01 - 8.98	660,051	7.9	7.07	249,360	6.47
9.25 - 12.81	1,731,350	4.7	10.62	1,560,774	10.60
13.00 - 18.06	2,588,739	6.9	14.43	2,025,096	14.48
$ 0.10 - $ 18.06	9,114,459	5.6	$ 7.19	7,939,549	$ 6.62

Upon the exercise of stock options, the Company issues new shares. As of December 31, 2008, 3,328,833 options issued to employees and directors, and 93,000 options issued to consultants, are milestone-based, of which 3,203,833 options issued to employees and directors, and 43,000 options issued to consultants, are vested and exercisable.

Certain employees and consultants have been awarded restricted stock under the 2004 Long-Term Incentive Plan and 2007 Incentive Plan. The time-vesting restricted stock grants vest primarily over a period of two to four years. The following table summarizes restricted share activity for the years ended December 31, 2008, 2007 and 2006:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
Outstanding at December 31, 2005	—	—	
Granted	100,000	$ 15.30	
Vested	—	—	
Forfeited	—	—	
Outstanding at December 31, 2006	100,000	15.30	
Granted	195,000	10.28	
Vested	(73,332)	11.77	
Forfeited	(83,334)	15.30	
Outstanding at December 31, 2007	138,334	10.09	
Granted	3,976,906	0.33	
Vested	(59,168)	9.04	$ 27,075
Forfeited	(73,500)	10.19	
Outstanding at December 31, 2008	3,982,572	$ 0.36	$ 876,166

As of December 31, 2008, 1,800,000 shares of restricted stock, which are issued to the Company’s chief executive officer, are milestone-based, of which none have vested.

Shares available for the issuance of stock options or other stock-based awards under the Company’s stock option and incentive plans were 2,533,928 shares at December 31, 2008.

Warrants

The following table summarizes warrant activity for the years ended December 31, 2008, 2007 and 2006:

	Warrants	Weighted-average exercise price	Aggregate Intrinsic Value
Outstanding at December 31, 2005	321,976	$ 4.65	
Issued	—	—	
Exercised	—	—	
Canceled	—	—	
Outstanding at December 31, 2006	321,976	4.65	
Issued	—	—	
Exercised	—	—	
Canceled	—	—	
Outstanding at December 31, 2007	321,976	4.65	
Issued	—	—	

Exercised	—	—	
Expired	(249,412)	6.00	
Outstanding at December 31, 2008	72,564	$ 0.01	$ 15,478

The terms of outstanding warrants as of December 31, 2008 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	1.0	$ 0.01	72,564	$ 0.01

Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes model. The expected term of options granted is derived from historical data and the expected vesting period. Expected volatility is based on the historical volatility of the Company's common stock. 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 paid for the foreseeable future.

Black-Scholes Option Valuation Assumptions	2008	2007	2006
Risk-free interest rates	2.6%	4.1%	4.7%
Dividend yield	—	—	—
Volatility	76.3%	68.4%	78.3%
Weighted-average expected term	4.3 years	4.8 years	3.1 years

The weighted average grant date fair value of options granted was $2.40, $5.69 and $7.79 per option for the years ended December 31, 2008, 2007 and 2006, respectively. The Company used historical information to estimate forfeitures within the valuation model. As of December 31, 2008, there was $3.9 million and $0.8 million of total unrecognized compensation cost related to non-vested stock options and restricted stock, respectively, which is expected to be recognized over a weighted-average period of 2.2 years and 2.4 years, respectively. The amounts do not include, as of December 31, 2008, 175,000 and 1,800,000 options and restricted shares outstanding, respectively, which are milestone-based and vest upon certain corporate milestones, such as FDA approval of the Company's drug candidates, market capitalization targets, and 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 and restricted stock for the years ended December 31, 2008, 2007 and 2006:

	Year ended December 31,		
(in thousands)	2008	2007	2006
Stock-based compensation expense associated with restricted stock (1)	$ (114)	$ 1,028	$ 189
Stock-based compensation expense associated with option grants (2)	6,862	9,632	14,723
	$ 6,748	$ 10,660	$ 14,912

(1) Includes a $290,000 credit to compensation expense related to restricted stock issued the Company's former President, who was terminated as part of the 2008 Restructuring.

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

NOTE 12 – INCOME TAXES

As of December 31, 2008, the Company has U.S. net operating loss carryforwards of approximately $253.4 million which expire from 2019 through 2028. 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.

The Company has established a valuation allowance against its net deferred tax assets due to the Company's history of pre-tax losses and the resulting likelihood that the deferred tax assets are not realizable. The valuation allowance for deferred tax assets was $141.8 million and $118.4 million as of December 31, 2008 and 2007, respectively. At December 31, 2008, deferred tax assets have not been recorded on net operating loss carryforwards for certain stock option deductions of $5.1 million. If the entire deferred tax asset were realized, $15.9 million would be allocated to paid-in-capital related to the tax effect of compensation deductions from the exercise of employee and consultant stock options. Due to the Company's various equity transactions, the utilization of certain tax loss carryforwards could be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision.

The Company recorded $36,000 in income tax expense for the year ended December 31, 2007, as a result of Israeli income tax withheld associated with the Yissum revenue (see Note 9). No income tax expense was attributable to income from continuing operations for the year ended December 31, 2008 and the year ended December 31, 2006. Income tax expense differed from amounts computed by applying the US federal income tax rate of 35% to pretax loss as follows:

(in thousands)	For the year ended December 31, 2008	2007	2006
Losses from continuing operations before income taxes, as reported in the consolidated statements of operations	$ (52,706)	$ (89,270)	$ (72,748)
Computed “expected” tax benefit	(18,447)	(31,245)	(25,462)
Increase (decrease) in income taxes resulting from:			
Expected benefit from state & local taxes	(4,869)	(4,563)	(8,050)
Change in state and local effective tax rate	(4,387)	4,533	(831)
Unrecognized compensation deduction	—	7,053	—
Permanent differences	523	447	1,067
Withholding tax	—	36	—
Other	(60)	159	—
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	27,240	23,616	33,276
	$ —	$ 36	$ —

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

(in thousands)	For the year ended December 31, 2008	2007	2006
Deferred tax benefit	$ (27,154)	$ (23,883)	$ (36,670)
Federal deferred tax benefit relating to the exercise of stock options	(86)	267	3,394
Increase in the valuation allowance for deferred tax assets	27,240	23,616	33,276
	$ —	$ —	$ —

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2008 and 2007 are presented below.

(in thousands)	December 31, 2008	December 31, 2007
Deferred tax assets/(liabilities):		

Net operating loss carryforwards	$ 113,752	$ 93,554
Net operating loss carryforwards (ACCESS Oncology)	6,128	6,128
Non-cash compensation	13,528	10,980
Deferred revenue	4,737	5,069
Unrealized loss on securities	1,292	—
Research and development	939	1,397
Intangible assets due to different amortization methods	1,009	1,203
Accrued compensation	299	30
Other temporary differences	77	67
Deferred tax asset, excluding valuation allowance	141,761	118,428
Less valuation allowance	(141,761)	(118,428)
Net deferred tax assets	$ —	$ —

The Company may be subject to audits by various federal, state and foreign taxing authorities. The Company regularly reevaluates its tax positions and the associated interest and penalties, if applicable, resulting from audits of federal, state and foreign income tax filings, as well as changes in tax law that would reduce the technical merits of the position to below more likely than not. Unrecognized tax benefits arise when the estimated benefit recorded in the financial statements differs from the amounts taken, or expected to be taken, in a tax return because of the uncertainties described above. Audits of the Company's U.S. federal income tax returns for 2004 through 2006 were completed in 2008. As a result, the Company's balance of unrecognized tax benefits was reduced from $7.05 million to $0 at December 31, 2008.

The Company accounts for interest and penalties related to uncertain tax positions, if any, in selling, general and administrative expense. As of December 31, 2008 the Company has not accrued any interest and penalties.

NOTE 13 – INTEREST AND OTHER (EXPENSE) INCOME, NET

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

	For the year ended December 31,		
(in thousands)	2008	2007	2006
Interest income	$ 1,349	$ 4,550	$ 6,378
Other income	101	5	15
Gain on sale of auction rate securities	81	—	—
Impairment expense of auction rate securities	(3,196)	—	—
	$ (1,665)	$ 4,555	$ 6,393

In 2008, the Company recorded impairment charges totaling $3,196,000 for other-than-temporary declines in the fair value of its auction rate securities (see Note 3 – Investment Securities, and Note 4 – Fair Value Measurements). In 2008, other income consisted of rental income, and in 2007 and 2006, other income consisted of rental income from a related-party that terminated in 2007.

NOTE 14 - COMMITMENTS AND CONTINGENCIES

Research & Development Agreements

The Company has entered into various research and development agreements (relating to the Company's development of Zerenex and KRX-0401) under which it is obligated to make payments of approximately $413,000 through December 2009. The following table shows future research and development payment obligations by period as of December 31, 2008.

(in thousands)	2009	2010	2011	2012	2013
Research and development agreements	$ 413	—	—	—	—

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

Leases

The Company leases its office space under a lease agreement that expires in October 2010. Total rental expense was approximately $658,000, $723,000 and $658,000 for the years ended December 31, 2008, 2007, and 2006, respectively. The Company recognized sublet income of $101,000 for the year ended December 31, 2008 related to office sharing agreements.

Future minimum lease commitments as of December 31, 2008, in the aggregate total approximately $1,056,000 through 2010. The following table shows future minimum lease commitments by period as of December 31, 2008.

(in thousands)	2009	2010	2011	2012	2013
Operating leases	$ 597	$ 459	—	—	—

During 2004, the Company entered into a lease arrangement with its former President, Dr. Craig Henderson, for the utilization of part of his residence for office space associated with the Company's former employees in San Francisco, California. The lease was terminated effective April 15, 2008 as part of the 2008 Restructuring. The Company has expensed $16,000, $65,000 and $49,000 in 2008, 2007 and 2006, respectively, pursuant to the terms of this arrangement, which $28,000 was included in accounts payable and accrued expenses in the accompanying balance sheet as of December 31, 2007. All amounts due have been paid prior to December 31, 2008.

Royalty and Contingent Milestone Payments

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

The Company has undertaken to make contingent milestone payments to certain of its licensors of up to approximately $40.8 million over the life of the licenses, of which approximately $36.4 million will be due upon or following regulatory approval of the licensed drugs. 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 KRX-0401 meets certain development milestones. Of the 3,372,422 shares, 500,000 of these shares would be payable upon achieving the first development milestone. A substantial portion of the contingent shares would be payable to related parties of the Company. The contingent equity rights have been recognized as a non-current liability on the consolidated balance sheet. The uncertainty relating to the timing of the commitments described in this paragraph prevents the Company from including them in the table Research and Development Agreements above.

NOTE 15 – 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 16 – SEGMENT INFORMATION

Until September 2008, the Company had three reportable segments, which included the Diagnostics segment. Following the termination of the Accumin diagnostic product, the Company now has two reportable segments: Services and Products. 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 renal disease and cancer, and also includes license revenue, other revenue and associated costs.

Segment information for the years ended December 31, 2008, 2007 and 2006 was as follows:

	Revenue		
(in thousands)	2008	2007	2006
Services	$ 103	$ 52	$ 431
Products	1,180	931	—
Total	$ 1,283	$ 983	$ 431

	Operating loss		
(in thousands)	2008	2007	2006
Services	$ 76	$ (72)	$ 41
Products	(51,117)	(93,753)	(79,182)
Total	$ (51,041)	$ (93,825)	$ (79,141)

A reconciliation of the totals reported for the operating segments to the consolidated loss from continuing operations is as follows:

	Loss from continuing operations		
(in thousands)	2008	2007	2006
Operating losses of reportable segments	$ (51,041)	$ (93,825)	$ (79,141)
Interest and other (expense) income	(1,665)	4,555	6,393
Income taxes	—	(36)	—
Consolidated loss from continuing operations	$ (52,706)	$ (89,306)	$ (72,748)

	Assets (1) As of December 31,	
(in thousands)	2008	2007
Services	—	—
Products	3,982	16,293
Total assets of reportable segments	3,982	16,293
Cash, cash equivalents, interest receivable and investment securities	22,652	64,681
Assets of discontinued operations	—	87
Consolidated total assets	$ 26,634	$ 81,061

(1) Assets for the Company's reportable segments include fixed assets, goodwill, accounts receivable and prepaid expenses.

The carrying amount of goodwill by reportable segment as of December 31, 2008 and 2007 was as follows:

	Goodwill	
(in thousands)	December 31, 2008	December 31, 2007
Services	—	—
Products	$ 3,208	$ 3,208
Total	$ 3,208	$ 3,208

NOTE 17 - 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. On March 3, 2009, the Company entered into a settlement agreement with R.M.P.A. Properties Ltd., with respect to the dispute. In accordance with the settlement agreement, in March 2009, the Company paid the landlord a total sum of $260,000 for a full release of all claims and obligations under the lease agreement. Accordingly, $260,000 was included in accounts payable and accrued expenses at December 31, 2008.

The Company prevailed in an arbitration proceeding with Alfa Wasserman concerning certain terms of the 1998 License Agreement between Alfa Wasserman and the Company related to the provision of data to Alfa Wasserman and consultation regarding management of the licensed patents. An arbitration hearing was held in October 2007 and the arbitrator issued his decision on March 25, 2008, rejecting Alfa Wasserman's claims that the Company was in material breach of the License Agreement. The arbitrator determined that each party would bear its own costs for the arbitration.

In April 2008, the Company notified Alfa Wasserman of its intention to terminate the License Agreement. The Company offered to transfer to Alfa Wasserman all regulatory applications as provided in the License Agreement and demanded payment by Alfa Wasserman of 25% of the Company's development costs associated with sulodexide, as provided in the License Agreement. Alfa Wasserman itself served a notice of termination of the License Agreement on the alleged grounds that the Company is in material breach of the agreement for failing to diligently develop sulodexide by terminating the Phase 4 clinical trial. By seeking to terminate the License Agreement, Alfa Wasserman is thereby seeking to avoid reimbursement to Keryx of development costs. The Company intends to submit its claim for development costs and Alfa Wasserman's claim of material breach to arbitration for resolution.

In April 2008, the Company commenced an action in the U.S. District Court for the Southern District of New York against Panion & BF Biotech, Inc. ("Panion") for breaching the manufacturing provisions of the March 14, 2008 Amended and Restated License Agreement between the Company and Panion, and the implied covenant of good faith and fair dealing contained therein. The Company sought declaratory and injunctive relief and damages against Panion. Panion asserted counterclaims against the Company for alleged breach of the agreement and the implied covenant of good faith and fair dealing contained therein and for alleged breach of fiduciary duties, and sought declaratory and injunctive relief and damages in the amount of "at least one million dollars." The Company replied, denying Panion's counterclaims. In November 2008, the parties agreed to settle their dispute. The parties entered into a first amendment to the Amended and Restated License Agreement by which Panion granted the Company additional manufacturing and development rights, and the Company paid Panion $200,000 in November 2008. Following execution of the settlement agreement and first amendment to the Amended and Restated License Agreement, the parties entered a voluntary dismissal of the action, including Panion's asserted counterclaims.

The Company in-licensed KRX-0501 from Krenitsky Pharmaceuticals, Inc. ("Krenitsky") in 2005. In October 2008, Krenitsky commenced an action in the United States District Court, Middle District of North Carolina, Durham Division, against the Company, requesting a declaratory judgment from the court determining that (i) the Company breached the 2005 License Agreement between Krenitsky and the Company, (ii) Krenitsky was within its legal rights to terminate the License Agreement for cause, (iii) the Company has no further rights or interests in the licensed patents, and (iv) Krenitsky has no further obligations to the Company under the License Agreement. In December 2008, the parties agreed to settle their dispute and as a result have entered into a License Termination, Technology Transfer and Settlement Agreement, whereby the license agreement was terminated and certain know-how was transferred to Krenitsky in exchange for a portion of any future license and milestone payments received by Krenitsky related to KRX-0501 and a royalty on sales of the drug, if any. Following execution of the Termination, Technology

Transfer and Settlement Agreement, the parties entered a voluntary dismissal of the action.

The Company is presently engaged in an arbitration proceeding with ICON Central Laboratories ("ICON"), the central laboratory it used for the clinical development of Sulonex, concerning certain fees related mainly to the provision of storage services pursuant to a series of service agreements. In March 2008, the Company terminated the agreements. ICON is claiming that the Company owes it $816,647 in unpaid invoices, much of which is made up of charges for annual storage fees. It is the Company's position that it should not have to pay for storage fees incurred after the effective date of the termination of the agreements, and the Company intends to vigorously defend this proceeding on this basis, and to assert a counterclaim for a refund of the unused portions of the annual storage fees already paid to ICON.

NOTE 18 – RESTRUCTURING

On March 26, 2008, the Company implemented a strategic restructuring plan to reduce its cash burn rate and re-focus its development efforts (the "2008 Restructuring"). The 2008 Restructuring, which was prompted by the negative outcome of the Company's pivotal SUN-MICRO Phase 3 clinical trial of Sulonex™ (sulodexide) for the treatment of diabetic nephropathy, announced on March 7, 2008, and subsequent decision by the Company to terminate the ongoing SUN-MACRO Phase 4 clinical trial, was intended to conserve the financial resources of the Company and enable it to focus its efforts on programs and opportunities that management believed were most likely to provide long-term shareholder value. The 2008 Restructuring included a workforce reduction of approximately 50% as compared to the Company's workforce at December 31, 2007. Following the workforce reduction, the Company had approximately 25 full and part-time employees.

As part of the 2008 Restructuring, on March 26, 2008, the Company notified its President, I. Craig Henderson, M.D., that the Company was terminating his employment, effective April 15, 2008. Dr. Henderson remained in his position as a member of the Company's Board of Directors until the annual meeting in June 2008. The Company recognized a $1,569,000 credit to expense, in the year ended December 31, 2008, related to the forfeiture of stock options and restricted stock issued to Dr. Henderson. In addition, the Company reached a mutual agreement with its Chief Accounting Officer, Mark Stier, that Mr. Stier resigned effective June 30, 2008. His responsibilities were assumed by James F. Oliviero, Vice President, Finance, who was appointed Principal Financial and Accounting Officer on May 6, 2008.

The following table summarizes restructuring costs that were provided for and/or incurred by the Company during the year ended December 31, 2008:

(in thousands)		2008
Research and development		
Impairment of manufacturing facility	$	11,037
Manufacturing facility restoration		2,063
Severance		624
Non-cash compensation		(1,569)
Total research and development		12,155
Selling, general and administrative		
Severance		99
Total selling, general and administrative		99
Total restructuring costs	$	12,254

During 2008, the Company paid out $2,063,000 for the manufacturing facility restoration and $723,000 for severance obligations. At December 31, 2008, there were no remaining restructuring liabilities.

NOTE 19 – QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	2008			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenue:				
License revenue	$ 199	$ 327	$ 327	$ 327
Service revenue	—	62	41	—
Other revenue	—	—	—	—
Total revenue	199	389	368	327
Operating expenses:				
Cost of services	—	14	13	—
Research and development:				
Non-cash compensation	(980)	251	334	328
Other research and development	30,827	4,242	2,208	798
Total research and development	29,847	4,493	2,542	1,126
Selling, general and administrative:				
Non-cash compensation	1,717	1,767	1,662	1,669
Other selling, general and administrative	1,887	2,078	2,284	1,225
Total selling, general and administrative	3,604	3,845	3,946	2,894
Total operating expenses	33,451	8,352	6,501	4,020
Operating loss	(33,252)	(7,963)	(6,133)	(3,693)
Other income (expense)				
Interest and other (expense) income, net	(1,203)	274	(622)	(114)
Income taxes	—	—	—	—
Loss from continuing operations	(34,455)	(7,689)	(6,755)	(3,807)
Loss from discontinued operations	(81)	(8)	(86)	—
Net loss	$ (34,536)	$ (7,697)	$ (6,841)	$ (3,807)
Net loss per common share				
Continuing operations	(0.79)	(0.17)	(0.15)	(0.08)
Discontinued operations	(—)*	(—)*	(—)*	—
Basic and diluted loss per common share	$ (0.79)	$ (0.17)	$ (0.15)	$ (0.08)

*Amount less than once cent

	2007			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
Revenue:				
License revenue	$ —	$ —	$ 41	$ 163
Service revenue	12	14	11	15
Other revenue	—	—	—	727

Total revenue	12	14	52	905
Operating expenses:				
Cost of services	32	30	28	34
Research and development:				
Non-cash compensation	995	1,178	735	666
Other research and development	17,444	15,684	15,965	25,790
Total research and development	18,439	16,862	16,700	26,456
Selling, general and administrative:				
Non-cash compensation	2,006	1,407	1,780	1,893
Other selling, general and administrative	2,115	2,354	2,062	2,610
Total selling, general and administrative	4,121	3,761	3,842	4,503
Total operating expenses	22,592	20,653	20,570	30,993
Operating loss	(22,580)	(20,639)	(20,518)	(30,088)
Other income (expense)				
Interest and other (expense) income, net	1,441	1,200	1,017	897
Income taxes	—	—	—	(36)
Loss from continuing operations	(21,139)	(19,439)	(19,501)	(29,227)
Loss from discontinued operations	(674)	(21)	(27)	(34)
Net loss	$ (21,813)	$ (19,460)	$ (19,528)	$ (29,261)
Net loss per common share				
Continuing operations	(0.49)	(0.45)	(0.45)	(0.67)
Discontinued operations	(0.01)	(—)*	(—)*	(—)*
Basic and diluted loss per common share	$ (0.50)	$ (0.45)	$ (0.45)	$ (0.67)

*Amount less than once cent

NOTE 20 – SUBSEQUENT EVENT (UNAUDITED)

In March 2009, the Company's Japanese partner, JT and Torii, informed the Company that they had initiated a Phase 2 clinical study in Japan, which triggered a $3 million non-refundable milestone payment which was received by the Company in March 2009.

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 31, 2009

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 James F. Oliviero, 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 31, 2009, and in the capacities indicated:

Signatures	Title
/s/ Michael S. Weiss Michael S. Weiss	Chairman and Chief Executive Officer (principal executive officer)
/s/ James F. Oliviero James F. Oliviero	Vice President, Finance (principal financial and accounting officer)
/s/ Kevin Cameron Kevin Cameron	Director
/s/ Senator Wyche Fowler, Jr. Senator Wyche Fowler, Jr.	Director
/s/ Malcolm Hoenlein Malcolm Hoenlein	Director
/s/ Jack Kaye Jack Kaye	Director
Eric A. Rose, M.D.	Director

/s/ Michael P. Tarnok Michael P. Tarnok	Director

EXHIBIT INDEX

Exhibit Number	Exhibit Description
10.16*	First Amendment to Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008.
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 31, 2009.
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 31, 2009.
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 31, 2009.
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 31, 2009.
*	Confidential treatment has been requested with respect to the omitted portions of this exhibit.