

KERYX BIOPHARMACEUTICALS INC  
Form 10-K  
March 25, 2010

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

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FORM 10-K

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

For the fiscal year ended December 31, 2009.

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

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KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware  
(State or other jurisdiction of  
incorporation or organization)

13-4087132  
(I.R.S. Employer  
Identification No.)

750 Lexington Avenue  
New York, New York  
(Address of principal executive offices)

10022  
(Zip Code)

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

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

Common Stock, Par Value \$0.001 Per Share  
(Title of Class)

NASDAQ Capital Market  
(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

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Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes  No

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes  No

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

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

Large accelerated filer

Accelerated filer

Non-accelerated filer

Smaller reporting company

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act).

Yes  No

The aggregate market value of voting common stock held by non-affiliates of the registrant (assuming, for purposes of this calculation, without conceding, that all executive officers and directors are "affiliates") was \$40,208,840 as of June 30, 2009, based on the closing sale price of such stock as reported on the NASDAQ Capital Market.

There were 56,861,030 shares of the registrant's common stock outstanding as of March 15, 2010.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for the 2010 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, 2009

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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 trade names referenced in this Annual Report on Form 10-K are the property of their respective owners.

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## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

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

- expectations for increases or decreases in expenses;
- expectations for the clinical and pre-clinical development, manufacturing, regulatory approval, and commercialization of KRX-0401 (perifosine), Zerenex™ (ferric citrate), 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 our investment in an auction rate security;
  - 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. and our respective subsidiaries.

## ITEM 1. BUSINESS.

## OVERVIEW

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. We are developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, all of which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. KRX-0401 is currently in a Phase 3 trial, under Special Protocol Assessment, or SPA, in multiple myeloma, with a Phase 3 trial in refractory metastatic colorectal cancer, under SPA, pending commencement, and in Phase 2 clinical development for several other tumor types.

We are also developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex has completed five Phase 2 clinical studies as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD. Our Phase 3 program for Zerenex, under an SPA, is pending commencement. Zerenex is also in Phase 2 development in Japan by our Japanese partner, Japan Tobacco Inc. (“JT”) and Torii Pharmaceutical Co., Ltd. (“Torii”).

We also actively engage in business development activities that include seeking strategic relationships for our product candidates, as well as evaluating compounds and companies for in-licensing or acquisition. 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, JT and Torii.

The table below summarizes the status of our product pipeline.

Product candidate	Target indication	Development status
KRX-0401 (perifosine)	Multiple myeloma	Phase 3 trial ongoing, under SPA
	Colorectal Cancer	Phase 3 pending, under SPA
	Multiple other forms of cancer	Phase 2 trials ongoing
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	U.S. Phase 3 program pending, under SPA Japan Phase 2 ongoing by sublicensee (JT and Torii)

## OUR STRATEGY

Our mission is to create long-term shareholder value by acquiring, developing and commercializing medically important, pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease.

Our strategy to achieve this mission is to:

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;

seek to acquire medically important drug candidates in late pre-clinical or early clinical development; 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](http://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. You may read and copy any materials we file at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC's website address is <http://www.sec.gov>.

## PRODUCTS UNDER DEVELOPMENT

### KRX-0401 (perifosine)

#### Overview

KRX-0401 (perifosine) is a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, 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 2,000 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 AEterna Zentaris Inc. 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. Additionally, we are conducting a Phase 1 study in the US which evaluates the safety of perifosine in pediatric patients.

Fourteen 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 capecitabine (Xeloda®), gemcitabine, paclitaxel, docetaxel, prednisone, doxorubicin, 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 eleven 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 2009, at the American Society of Hematology annual meeting, in a poster presentation by Dr. Paul Richardson, Clinical Director of the Multiple Myeloma Center at Dana-Farber Cancer Institute in Boston, we announced updated data on the clinical activity of KRX-0401 (perifosine) in combination with bortezomib (with or without dexamethasone) in patients with relapsed/refractory multiple myeloma. 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 (for a total of 84 patients), all with advanced multiple myeloma.

The patients enrolled were heavily pre-treated with a median of 5 prior lines of therapy (range 1 - 13), including;

- 100% of patients had been treated with bortezomib (55% of the patients were previously treated with at least two bortezomib-based therapies (range 1 - 4) and 81% were previously treated with bortezomib plus dexamethasone);
  - 98% of patients were previously treated with dexamethasone;
- 94% of patients were previously treated with lenalidomide (Revlimid®) and/or thalidomide (Thalomid®); and
  - 58% of patients had prior stem cell transplant.

Overall Response Rate (ORR), defined as the percentage of patients achieving a complete, partial or minor response (CR, PR or MR), was the primary endpoint, with Time to Progression (TTP), Progression-Free Survival (PFS), Overall Survival (OS) and Safety as secondary endpoints.

Seventy-three patients were evaluable for efficacy. Evaluable patients are defined as those patients who had received at least two cycles of therapy on the combination of perifosine with bortezomib. Of the 73 evaluable patients, 53 patients (73%) were previously refractory to bortezomib (defined as progression on or within 60 days of treatment with a bortezomib-based regimen), including 44 patients who were refractory to the combination of bortezomib + dexamethasone. Twenty evaluable patients (27%) were relapsed to a prior bortezomib-based regimen. Best response for all 73 evaluable patients was as follows:

Evaluable Patients	CR /nCR*		PR		MR		ORR		SD**	
All Evaluable Patients (n=73)	3	4%	13	18%	14	19%	30	41%	30	41%

Bortezomib Relapsed (n=20)	2	10%	7	35%	4	20%	13	65%	7	35%
Bortezomib Refractory (n=53)	1	2%	6	11%	10	19%	17	32%	23	43%

\* nCR = Near Complete Response is defined as meeting the criteria for CR (non-detectable monoclonal protein by serum and urine), except with detectable monoclonal protein by immunofixation.

\*\* SD = Stable Disease for a minimum of 3 months.

Approximately 60% (45 / 73) of patients demonstrated progression (or SD for 4 cycles) at some point in their treatment and received 20 mg dexamethasone, four times per week, in addition to perifosine plus bortezomib. Responses occurred both with patients taking perifosine in combination with bortezomib and with patients receiving the combination plus dexamethasone. Best response for each group was as follows:

Best Response	CR /nCR	PR	MR	ORR*	SD*
Perifosine + Bortezomib (n=73)	2 3%	10 14%	6 8%	18 25%	19 26%
Dexamethasone added (n=45)	1 2%	6 13%	10 22%	17 38%	14 31%

\*5 patients achieved an initial response on Perifosine + Bortezomib alone, and subsequently responded again with the addition of Dexamethasone. 3 additional patients achieved stable disease on Perifosine + Bortezomib alone, and subsequently achieved stable disease again with the addition of Dexamethasone.

Median Progression-Free Survival (PFS) and Overall Survival (OS) data for all evaluable patients was as follows:

Evaluable Patients	Median PFS	Median OS
All Evaluable Patients (n=73)	6.4 months 95% CI (5.3, 7.1)	25 months 95% CI (15.5, NR)

NR = Not Reached

NOTE Median PFS and median TTP were identical, as no patient deaths occurred prior to progression. Kaplan Meier methodology was used to determine progression-free and overall survival figures.

Median PFS and OS for bortezomib relapsed vs. refractory were as follows:

Bortezomib Relapsed vs. Refractory	Median PFS	Median OS
Bortezomib Relapsed (n=20)	8.8 months 95% CI (6.3, 11.2)	Not Reached at 38+ months 95% CI (25, NR)
Bortezomib Refractory (n=53)	5.7 months 95% CI (4.3, 6.4)	22.5 months 95% CI (12.3, NR)

NR = Not Reached

NOTE Median PFS and median TTP were identical, as no patient deaths occurred prior to progression. Kaplan Meier methodology was used to determine progression-free and overall survival figures.

No unexpected adverse events have been observed. Toxicities were manageable with supportive care.

#### Multiple Myeloma Phase 3 Registration Clinical Trial

In December 2009, we initiated a Phase 3 registration clinical trial for KRX-0401 (perifosine) in relapsed / refractory multiple myeloma patients. The trial, entitled, "A Phase 3 Randomized Study to Assess the Efficacy and Safety of Perifosine Added to the Combination of Bortezomib (Velcade®) and Dexamethasone in Multiple Myeloma Patients Previously Treated with Bortezomib" is a randomized (1:1), double-blind, placebo-controlled trial comparing the efficacy and safety of perifosine vs. placebo when combined with bortezomib (Velcade®) and dexamethasone. The trial will enroll approximately 400 patients with relapsed or relapsed / refractory multiple myeloma. Patients will be randomized to bortezomib at 1.3 mg/m<sup>2</sup> days 1, 4, 8 and 11 every 21 days in combination with dexamethasone 20 mg

on the day of and day after bortezomib treatment, and either perifosine 50 mg daily or placebo. Patients eligible for the Phase 3 trial must have been previously treated with both bortezomib (Velcade®) and an immunomodulatory agent (Revlimid® and/or Thalomid®), and been previously treated with one to four prior lines of therapy. The primary endpoint is progression-free survival and secondary endpoints include overall response rate, overall survival and safety. Patients can be relapsed from and refractory to all non-bortezomib based therapies, however, patients can only be relapsed (progressed > 60 days after discontinuing therapy) from prior bortezomib-based therapies. The study is powered at 90% to demonstrate the required difference in progression-free survival between the two arms. Approximately 265 events (defined as disease progression or death) will trigger the un-blinding of the data. This trial is being conducted pursuant to an SPA with the Food and Drug Administration (FDA). Additionally, the FDA has granted perifosine Orphan Drug and Fast Track designations in this indication.

The Phase 3 trial is being led by the Principal Investigator, Dr. Paul Richardson, Clinical Director of the Jerome Lipper Multiple Myeloma Center, at Dana-Farber Cancer Institute (DFCI) in Boston, MA and Dr. Kenneth C, Anderson, Chief, Division of Hematologic Neoplasia at DFCI. An estimated 40 to 50 centers throughout the United States and select centers outside of the United States will be participating in this Phase 3 trial.

## Multiple Myeloma Market Opportunity

Multiple myeloma, a cancer of the plasma cell, is an incurable but treatable disease. Multiple myeloma is the second most-common hematologic cancer, representing 1% of all cancer diagnoses and 2% of all cancer deaths. According to the American Cancer Society, in 2009 there will have been an estimated 20,580 new cases of multiple myeloma and an estimated 10,500 deaths from multiple myeloma in the United States. To date, several FDA approved therapies exist for the treatment of multiple myeloma. Despite this progress, patients continue to relapse, become refractory to prior treatments and eventually die from their disease. Thus, new therapies are needed to treat these patients and extend their survival.

## Colorectal Cancer Clinical Data

In January 2010, we announced updated data from a randomized, multi-center, double-blind, placebo-controlled, Phase 2 study of KRX-0401 (perifosine) in combination with capecitabine (Xeloda(R)) versus capecitabine plus placebo in patients with second- or third-line metastatic colon cancer. The data was presented at the 2010 American Society of Clinical Oncology (ASCO) Gastrointestinal Cancers Symposium, held in Orlando, Florida in a poster entitled, "Randomized phase II study of perifosine in combination with capecitabine (P-CAP) versus capecitabine plus placebo (CAP) in patients with second- or third-line metastatic colon cancer (mCRC): Updated results." The data was initially presented at the ASCO 45th Annual Meeting in June 2009.

In this randomized, double-blind, placebo controlled study conducted at 11 centers across the United States, heavily pre-treated patients with second- or third-line metastatic colon cancer were randomized to receive capecitabine (a chemotherapy used in advanced metastatic colon cancer which is marketed by Roche as Xeloda®) at 825 mg/m<sup>2</sup> BID (total daily dose of 1650 mg/m<sup>2</sup>) on days 1 – 14 every 21 days plus either placebo or perifosine at 50 mg daily. The study enrolled a total of 38 patients, 34 of which were third-line or greater. Of the 38 patients enrolled, 35 patients were evaluable for response (20 patients on the perifosine + capecitabine arm and 15 patients on the placebo + capecitabine arm). Three patients on the placebo + capecitabine arm were not evaluable for response (2 patients were non-evaluable due to toxicity (days 14, 46) and 1 was non-evaluable due to a new malignancy on day 6). All patients in the perifosine + capecitabine arm were evaluable for response. The median number of prior treatment regimens for all 38 patients was two, with prior treatment regimens for the P-CAP arm versus CAP arm shown in the table below.

Prior Treatments	P-CAP (n=20)	CAP (n=18)	All Patients (n=38)
FOLFIRI	18 (90%)	16 (89%)	34 (89%)
FOLFOX	15 (75%)	13 (72%)	28 (74%)
FOLFIRI & FOLFOX	13 (65%)	12 (67%)	25 (66%)
Avastin®	15 (75%)	15 (83%)	30 (79%)
EGFR Antibody (1)	9 (45%)	10 (56%)	19 (50%)
5-FU Refractory Status	14 (70%)	13 (72%)	27 (71%)
Third Line or >	18 (90%)	16 (89%)	34 (89%)

(1) Prior treatment with Erbitux® and/or Vectibix®

The primary endpoint of this study was to measure Time to Progression (TTP). Overall Response Rate (ORR), defined as Complete Responses (CR) + Partial Responses (PR) by RECIST, Overall Survival (OS) and safety were measured as secondary endpoints.

The reported efficacy results for all evaluable patients were as follows:

Group	n	ORR %	> SD (min 12 wks)	Median TTP	Median OS*
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		CR / PR (Duration of Response)	n (%)	Weeks	Months
P-CAP	20	20% 1 CR (34 mos - ongoing) 3 PR (21, 19, 11 mos)	15 (75%)	28 [95% CI (12-48)]	18 [95% CI (10.8-25.7)]
CAP	15	7% 1 PR (7 mos)	6 (40%)	11 [95% CI (9-15.9)]	11 [95% CI (5.3-16.9)]
p-value			p=0.036	p=0.0012	p=0.0136

\*Survival is calculated from date of randomization until the date of death from any cause, whether or not additional therapies were received after removal from treatment.

NOTE: Kaplan-Meier method used to calculate both TTP and OS. In addition, TTP and Progression Free Survival (PFS) are identical for all patients in the study.



Results for the subset of patients who were refractory to a 5-FU (Fluorouracil) chemotherapy-based treatment regimen are shown in the table below. 5-FU is a core component of the standard of care FOLFIRI and FOLFOX regimens, and capecitabine is a 5-FU pro-drug.

Group	5-FU Ref n (%)	> SD (min 12 wks) n (%)	Median TTP Weeks	Median OS Months
P-CAP	14 (70%)	1 PR / 8 SD (64%)	18 [95% CI (12-36)]	15.3 [95% CI (8.4-26)]
CAP	11 (73%)	0 PR / 3 SD (27%)	10 [95% CI (6.6-11)]	6.8 [95% CI (4.8-11.7)]
p-value		p=0.066	p=0.0004	p=0.0088

All 38 patients were evaluable for safety. The P-CAP combination was well-tolerated with Grade 3 and 4 adverse events of > 10% incidence for the P-CAP arm versus CAP arm as follows: anemia (15% vs. 0%), fatigue (0% vs. 11%), abdominal pain (5% vs. 11%), and hand-foot syndrome (30% vs. 0%). Of note, incidence of Grade 1 and 2 hand-foot syndrome was similar in both the P-CAP and CAP arms (25% vs. 22%, respectively). Hand-foot syndrome is a reported adverse event with capecitabine monotherapy. Patients who remained on treatment longer in the Phase 2 study had a greater chance to develop hand-foot syndrome as illustrated by a median time to onset of Grade 3 and 4 hand-foot syndrome in the P-CAP arm of 19 weeks.

#### Metastatic Colorectal Cancer Phase 3 Registration Clinical Trial

In February 2010, we announced that we reached agreement with the FDA regarding an SPA on the design of a Phase 3 trial KRX-0401 (perifosine) in patients with refractory metastatic colorectal cancer. The Phase 3 X-PECT (Xeloda® + Perifosine Evaluation in Colorectal cancer Treatment) trial will be a randomized (1:1), double-blind trial comparing the efficacy and safety of perifosine + capecitabine vs. placebo + capecitabine in approximately 430 patients with refractory metastatic colorectal cancer. Patients must have failed available therapies including 5-fluorouracil (5-FU), oxaliplatin (Eloxatin®), irinotecan, bevacizumab (Avastin®) and, if K-Ras wild-type (WT), failed therapy with prior cetuximab (Erbix®) or panitumumab (Vectibix®). For oxaliplatin-based therapy, failure of therapy will also include patients who discontinued due to toxicity. The primary endpoint is overall survival (OS), with secondary endpoints including overall response rate (ORR: complete responses + partial responses), progression-free survival (PFS) and safety. The median OS for the X-PECT study's targeted patient population, that has failed prior therapies as described above, is expected to be approximately 5 months. The X-PECT study will be powered at 90% to detect a statistically significant difference in OS, with an assumed median OS for the control arm of 5-6 months and 7-8 months for the perifosine arm. Approximately 360 events of death will trigger the un-blinding of the study. Approximately 40 to 50 U.S. sites will participate in the study. The study is expected to begin in the second quarter of 2010.

#### Colorectal Cancer Market Opportunity

According to the American Cancer Society, colorectal cancer is the third most common form of cancer diagnosed in the United States. It is estimated that over 146,000 people were diagnosed with some form of colorectal cancer with over 49,000 patients dying from colorectal cancer in 2009. Surgery is often the main treatment for early stage colorectal cancer. When colorectal cancer metastasizes (spreads to other parts of the body such as the liver) chemotherapy is commonly used. Treatment of patients with recurrent or advanced colorectal cancer depends on the location of the disease. Chemotherapy regimens (i.e. FOLFOX or FOLFIRI either with or without bevacizumab) have been shown to increase survival rates in patients with metastatic/advanced colorectal cancer. Currently, there are seven approved drugs for patients with metastatic colorectal cancer: 5-fluorouracil (5-FU), capecitabine (Xeloda®), irinotecan (Camptosar®), oxaliplatin (Eloxatin®), bevacizumab (Avastin®), cetuximab (Erbix®), and panitumumab (Vectibix®). Depending on the stage of the cancer, two or more of these types of treatment may be combined at the same time or used after one another. For example, FOLFOX combines 5-FU, leucovorin and oxaliplatin, whereas FOLFIRI combines 5-FU, leucovorin and irinotecan. Bevacizumab, a VEGF monoclonal antibody, is commonly

administered with chemotherapy. Typically, patients who fail 5-FU, oxaliplatin, irinotecan, and bevacizumab-containing therapies, and who have wild-type KRAS status receive EGFR monoclonal antibody therapy with either cetuximab or panitumumab. Once patients progress on these agents, there are no further standard treatment options.

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## Renal Cell Carcinoma Clinical Data

On September 26, 2009, Dr. Thomas E. Hutson, Director of the Genitourinary Oncology Program at Baylor-Sammons Cancer Center in Dallas, TX, presented updated Phase 2 results demonstrating KRX-0401 (perifosine) single agent efficacy in patients with metastatic renal cell carcinoma, in a presentation entitled, "Phase 2 study of perifosine in patients with metastatic renal cell carcinoma progressing after prior therapy with both a VEGF Receptor Inhibitor and an mTOR inhibitor." Data from this study was first presented at the American Society of Clinical Oncology (ASCO) annual meeting in May 2009. The presentation included results from a subgroup of patients who failed both a VEGF receptor inhibitor (sunitinib or sorafenib) and an mTOR inhibitor (temsirolimus or everolimus). Evaluable patients (n=16) were defined as those who had greater than 7 days of treatment (2 additional patients withdrew consent within 7 days). Patients received 100 mg of perifosine daily until progression or unacceptable toxicity. The primary endpoint of this study was clinical benefit, defined as response rate (CR / PR by RECIST) or percent of patients progression-free for at least 3 months. Median progression-free survival (PFS) and overall survival were also analyzed for efficacy. Safety was a secondary endpoint. Perifosine was well-tolerated with the most common adverse events being gastrointestinal discomfort and fatigue. Best response to single agent perifosine was as follows:

N	PR N (%)	SD > 12 wks N (%)	PD < 12 wks N (%)	Median PFS	Overall Survival Not Reached (14/16 alive) at 22+ months
16	1 (6%)	7 (44%)	8 (50%)	16 wks [95% CI (11.7, 28)]	

PR: Partial response; SD: Stable disease; PD: Progressive disease

## Waldenstrom's Macroglobulinemia Clinical Data

In an article entitled "Clinical and Translational Studies of a Phase II Trial of the Novel Oral Akt Inhibitor Perifosine in Relapsed or Relapsed/Refractory Waldenstrom's Macroglobulinemia" which appeared in the February 1, 2010 issue of Clinical Cancer Research, we reported Phase 2 data demonstrating the single agent activity of KRX-0401 (Perifosine) for the treatment of advanced Waldenstrom's Macroglobulinemia ("Waldenstrom's"). In the Phase 2 study, 37 patients were treated with KRX-0401 (perifosine) 150 mg daily for 6 cycles. In this study, 41% of the patients had 3 or more lines of prior therapy and 78% had 2 or more prior lines of therapy. Such prior therapies include nucleoside analogues, bortezomib, alkylating agents and rituximab (Rituxan®), which are not approved for, but are often used in the treatment of Waldenstrom's. Stable or responding patients were allowed to continue therapy until progression. Of the 37 patients, 4 achieved a partial response (11%), 9 achieved a minimal response (24%), and 20 showed stable disease (54%). Overall, 89% (33/37) of patients treated with single agent perifosine were reported to have stable disease or better, while 11% (4 patients) demonstrated progression. The median progression-free survival in the study was 12.6 months (90% C.I. (10.2, 22.7)), with a median overall survival of 26 months (90% C.I. (26 – upper limit not reached)). Perifosine was generally well-tolerated with gastrointestinal symptoms and fatigue reported as the most common adverse events related to therapy.

Also described in the article are translational studies using gene expression profiling and immunohistochemistry on pre- versus post-treatment patient samples. Results showed that in the majority of samples tested, there was a significant reduction of phospho-GSK3 $\beta$  (downstream from Akt) using immunohistochemistry. Similarly, results demonstrated that perifosine significantly inhibited the expression of multiple members of the NF- $\kappa$ B family of genes, confirming previous in vitro studies showing activity of perifosine targeting this pathway.

## Other Indications

In July 2009, we announced the initiation of a Phase 1 clinical study to evaluate KRX-0401 (perifosine) as a single agent treatment for recurrent solid tumors in pediatric patients. This is the first clinical study evaluating KRX-0401 in

pediatric patients. The study is nearing completion of enrollment at Memorial Sloan-Kettering Cancer Center in New York City, and is being fully funded by an external grant provided by a private organization.

In October 2009, we announced the initiation of a Phase 2 clinical study to evaluate KRX-0401 (perifosine) as a single agent treatment for relapsed or refractory Chronic Lymphocytic Leukemia (CLL) and Small Lymphocytic Lymphoma (SLL). This Phase 2 study is currently enrolling patients at Duke University and is being externally funded.

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 has completed five Phase 2 clinical studies as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with ESRD, and a Phase 3 program for Zerenex, under an SPA, is pending commencement. Zerenex is also in Phase 2 development in Japan by our Japanese partner, JT and Torii.

#### Market Opportunity

In the U.S., according to data from the U.S. Renal Data System, there are approximately 485,000 patients with 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 between 3.5 and 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)
<b>Placebo Comparison:</b>				
Mean Difference from Placebo		-0.02	-1.1	-1.5
P-value		NS	0.06	0.0119
<b>Baseline Comparison:</b>				
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)
<b>Placebo Comparison:</b>				
Mean Difference from Placebo		-0.9	-7.91	-11.4
P-value		0.8950	0.1375	0.0378
<b>Baseline Comparison:</b>				
Mean Difference from Baseline	-0.3	-1.1	-8.1	-11.7
P-value	NS	NS	NS	<0.01

\*mean (standard deviation)

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

respectively.

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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 ( $p < 0.005$ ), 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 studies were not designed to compare Zerenex to calcium-based products, therefore, no formal assessment can be made of the comparative efficacy.

In June 2009, we announced results of the U.S. Phase 2 study of Zerenex for the treatment of elevated serum phosphorous levels, or hyperphosphatemia, in patients with end-stage renal disease (ESRD) on thrice weekly hemodialysis. The study was a multicenter, open-label clinical trial, which enrolled 55 patients. The primary objective of this study was to assess the tolerability and safety of Zerenex with doses ranging from approximately 1 gram per day to 12 grams per day.

In the first part of the Phase 2 study, 34 ESRD patients who were taking approximately 6 to 15 tablets/capsules per day of calcium acetate, calcium carbonate, lanthanum carbonate or sevelamer hydrochloride or any combination of these agents were eligible for enrollment and immediately switched to a starting dose of 4.5 grams per day of Zerenex. In the second part of the study, 21 ESRD patients who were taking greater than 12 tablets/capsules per day of calcium acetate, calcium carbonate, lanthanum carbonate or sevelamer hydrochloride or any combination of these agents were eligible for enrollment and immediately switched to a starting dose of 6.0 grams per day of Zerenex. Patients were treated with Zerenex for four weeks and were titrated weekly to achieve and maintain normal serum phosphorus levels, between 3.5 to 5.5 mg/dL, the therapeutic goal.

Although designed primarily as a safety study, key efficacy parameters were evaluated, with results as follows:

At baseline:

- Baseline mean +/- standard deviation (SD) serum phosphorus was approximately 5.9 +/- 1.5 mg/dL immediately prior to the switch to Zerenex;
- The average daily dose of PhosLo(R) (calcium acetate) was 6.9 grams per day and for Renagel(R) (sevelamer hydrochloride) was 9.9 grams per day, for patients not on combination therapy prior to the switch to Zerenex.

Following the treatment period (four weeks on Zerenex):

- At the end of the treatment period (after four weeks on Zerenex) the mean +/- SD serum phosphorus was approximately 5.4 +/- 1.3 mg/dL;
  - The average daily dose of Zerenex at the end of four weeks of treatment was 6.8 grams per day;

In the subset of 29 patients who had a serum phosphorus above the normal range ( $> 5.5$  mg/dL) at baseline, immediately prior to the switch to Zerenex, the mean (SD) baseline serum phosphorus was 7.0 (1.1) mg/dL, and at the end of treatment with Zerenex the mean (SD) serum phosphorus was 5.6 (1.6) mg/dL;

In the Phase 2 study, there were four serious adverse events which were deemed unrelated to Zerenex. Darkened stool was reported in the study and was associated with the presence of iron in the gastrointestinal tract. With the exception of the reporting of darkened stool as an (asymptomatic) adverse event, the gastrointestinal adverse event profile was similar in incidence to that reported for other currently marketed phosphate binders. There was no increase in serum calcium noted in the study.

Following the results of the U.S. Phase 2 study of Zerenex announced in June 2009, the top line efficacy and safety results from this Phase 2 study were submitted to the FDA, and discussed at a face to face meeting with the Division of Cardiovascular and Renal Drug Products. The FDA also reviewed the final reports for the 90-day rat and 16-week canine toxicology studies. The FDA indicated that the results of the Phase 2 study and the toxicology studies were adequate to support entry into a Phase 3 program. The FDA also reviewed the protocols for the ongoing chronic toxicology studies (6-month rat and 42-week canine), which can be completed after the U.S. Phase 3 program has begun.

On September 23, 2009, we announced results of the Open Label Extension (OLE) trial of Zerenex for the treatment of elevated serum phosphorous levels, or hyperphosphatemia, in patients with ESRD on dialysis. The OLE trial, conducted in Taiwan, enrolled 29 of the 37 Taiwanese patients that had completed the randomized, multi-center, multi-national (United States and Taiwan) dose-ranging Phase 2 study. This OLE represents the first trial to examine the long-term safety and efficacy of Zerenex as a phosphate binder. The treatment period in all previous Zerenex Phase 2 clinical trials did not exceed 28 days.

The OLE trial provided for a daily dose, ranging from 2 to 6 g/day of Zerenex, for a period of up to one year following completion of the 28-day, dose-ranging Phase 2 study. The average duration of the patients' participation in the OLE trial was 306 +/- 85 days.

Data from the OLE trial indicated that the mean serum phosphorus level throughout the trial was 5.22 +/- 0.18 mg/dL, and the mean product of calcium times phosphate (CaxP) was 49.06 +/- 2.15 mg(2)/dL(2), both within the normal range as recommended by the KDOQI guidelines. In addition, during the OLE trial, the administration of IV iron as a supplement was withheld in 8 patients (27.6%) for periods ranging from 3 to 6 months and the administration of EPO was withheld in 8 patients (27.6%) for short periods because the hemoglobin, hematocrit, and iron parameters were within normal clinical ranges as assessed by the investigator. There were no signs of potential iron overload in the study patients, and there were no Zerenex-related serious adverse events as noted by the investigator.

### Phase 3 Registration Clinical Program

In January 2010, we announced that we reached an agreement with the FDA regarding an SPA on the design of a Phase 3 clinical program for Zerenex. In accordance with the SPA agreement with the FDA, the Phase 3 clinical program for Zerenex will consist of two clinical studies, as follows:

- **Short-term efficacy study:** A multicenter, randomized, open-label clinical trial with a planned enrollment of approximately 150 patients on hemodialysis, who will be randomized to fixed doses of Zerenex, ranging from 1 gram per day to 8 grams per day, for a treatment period of 28 days. Patients will undergo a 2-week washout period prior to randomization. The primary endpoint of the study will be to demonstrate a dose response in the change of serum phosphorous from baseline (end of washout period) to end of the treatment period (day 28). This short-term study is pending commencement, with data expected in the second half of 2010.
- **Long-term safety and efficacy study:** A multicenter, randomized, open-label, safety and efficacy clinical trial with a planned enrollment of approximately 300 patients on hemodialysis or peritoneal dialysis. The long term study will consist of a 2-week washout period followed by a 52-week safety assessment in which patients will be randomized 2:1 to receive either Zerenex or the same dose of phosphate binder administered immediately prior to washout. The 52-week safety assessment will be followed by a 4-week efficacy assessment in which only patients randomized to treatment with Zerenex during the safety assessment will be randomized to continue treatment with either Zerenex or placebo for a 4-week period. The long-term study is expected to begin in mid-2010.

### 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	Expected completion of phase	Estimated cost to complete phase
KRX-0401 (perifosine)	Multiple myeloma	Phase 3, under SPA	2H 2011	\$12 million
	Colorectal cancer	Phase 3 pending, under SPA	2H 2011	\$11 million
Zerenex™ (ferric citrate)			1H 2012	\$12 million

Hyperphosphatemia in patients with end-stage renal disease	U.S. Phase 3 program pending under SPA
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Completion dates and costs in the above table are estimates and are subject 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 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, processes of manufacture, 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. However, the life of a patent covering a product that has been subject to regulatory approval may have the ability be extended through the patent restoration program, although any such extension could still be minimal.

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 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 expected through 2018, which is the maximum term of extension under the patent term restoration program), as well as a method of use patent application, directed to the use of perifosine in combination with various other anticancer agents, which would expire in 2022.

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 (expiring 2017, with extensions expected through 2020), as well as a method for the manufacture of ferric citrate (expiring 2023). We have also filed a patent application relating to the formulation of ferric citrate.

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 (the maximum term of extension under the patent term restoration program). 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 other patents that we may hold, such as method of use patents.

Our method of use patents only protect the products 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.

Proof of direct infringement by a competitor for method of use patents can also prove difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, proof that a competitor contributes to or induces infringement of a patented method of use by another can also prove difficult because an off-label use of a product could prohibit a finding of contributory infringement and inducement of infringement requires proof of intent by the competitor.

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 directly infringe or contribute to or induce infringement of method of use patents, 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. KRX-0401 (perifosine) has received Orphan-Drug designation from the FDA for the treatment of multiple myeloma.

We cannot assure that 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. (“Zentaris”), 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. To date, we have paid an aggregate of \$1.8 million to Zentaris and Zentaris is eligible to receive additional payments of up to an aggregate of \$17.0 million upon our successful achievement of certain clinical development, regulatory and sales milestones, in addition to royalty payments on net sales of perifosine. 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 & BF Biotech, Inc. (“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). To date, we have paid an aggregate of \$3.6 million to Panion and Panion is eligible to receive additional payments of up to an aggregate of \$8.0 million upon our successful achievement of certain clinical development and regulatory milestones, in addition to 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 JT and 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. In June 2009, we amended and restated the sublicense agreement with JT and Torii.

## 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.

#### 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 Administration 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 and authorized bodies. We do not have control over third-party manufacturers' compliance with these regulations and standards, other than through contractual obligations. If they are deemed out of compliance with cGMPs, product recalls could result, inventory could be destroyed, production could be stopped and supplies could be delayed or otherwise disrupted.

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 (FDCA). The FDA regulates, among other things, the pre-clinical and clinical testing, safety, efficacy, approval, manufacturing, record keeping, adverse event reporting, packaging, labeling, storage, advertising, promotion, export, sale and distribution of biopharmaceutical products.

The regulatory review and approval process is lengthy, expensive and uncertain. We are required to submit extensive pre-clinical and clinical data and supporting information to the FDA for each indication or use to establish a drug candidate's safety and efficacy before we can secure FDA approval to market or sell a product in the U.S. 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 investigational new drug application, or 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 of a completed application in 6-months or less and also may be permitted to submit portions of a 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 this authority, 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, and, therefore, could not submit the NDA to the FDA or foreign regulatory authorities for marketing approval.

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.

Sponsors of drugs may apply for a Special Protocol Assessment (SPA) from the FDA. The SPA process is a procedure by which the FDA provides official evaluation and written guidance on the design and size of proposed protocols that are intended to form the basis for a new drug application. However, final marketing approval depends on the results of efficacy, the adverse event profile and an evaluation of the benefit/risk of treatment demonstrated in the Phase 3 trial. The SPA agreement may only be changed through a written agreement between the sponsor and the FDA, or if the FDA becomes aware of a substantial scientific issue essential to product safety or efficacy.

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.

It is also becoming more common for the FDA to request a Risk Evaluation and Mitigation Strategy (REMS) as part of a NDA. The REMS plan contains post-market obligations of the sponsor to train prescribing physicians, monitor off-label drug use, and conduct sufficient Phase 4 follow-up studies and registries to ensure the continued safe use of the drug.

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 significant time, money and effort to ensure continued compliance, and the FDA conducts periodic inspections to certify compliance. It may be difficult for our manufacturers or us to comply with the applicable cGMP, as interpreted by the FDA, and other FDA regulatory requirements. If we, or our contract manufacturers, fail to comply, then the FDA may 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 significant 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 monitoring and 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 generally be limited to those specified in FDA approved labeling, and the advertising of our products will be subject to comprehensive monitoring and regulation by the FDA. Drugs whose review was accelerated may carry additional restrictions on marketing activities, including the requirement that all promotional materials are pre-submitted to FDA. Claims exceeding those contained in approved labeling will constitute a violation of the FDCA. Violations of the FDCA or regulatory requirements at any time during the product development process, approval process, or marketing and sale following approval may result in agency enforcement

actions, including withdrawal of approval, recall, seizure of products, warning letters, 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 \$74,883,000 in 2007, \$38,075,000 in 2008 and \$7,372,000 in 2009. “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 15, 2010, we had 15 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, 2009, we had an accumulated deficit of approximately \$321.4 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 we are studying. Certain clinical trials are designed to continue until a pre-determined number of events have occurred in the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates. They may also incur additional 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 in a cost-effective or timely manner. In addition, conducting multi-national studies adds another level of complexity and risk. We are subject to events affecting countries outside the United States. Negative or inconclusive results from the clinical trials we conduct or unanticipated adverse medical events could cause us to have to repeat or terminate the clinical trials. We may also opt to change the delivery method, formulation or dosage which could affect efficacy results for the drug candidate. For example, our new one gram caplet formulation for Zerenex has not been tested in our previous clinical trials, and therefore, there is no assurance that this new formulation will be safe and efficacious in a clinical trial setting. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

In December 2009, we initiated a Phase 3 pivotal clinical trial for KRX-0401 (perifosine) in relapsed / refractory multiple myeloma patients pursuant to a SPA with the FDA. In January 2010, we announced that we had reached an agreement with the FDA regarding a SPA on the design of a Phase 3 clinical program for Zerenex (ferric citrate) in patients with end-stage renal disease. In February 2010, we announced that we had reached an agreement with the FDA regarding a SPA on the design of a Phase 3 trial for KRX-0401 (perifosine) in patients with refractory metastatic colorectal cancer. Many companies which have been granted SPAs and/or the right to utilize fast track or accelerated approvals have ultimately failed to obtain final approval to market their drugs. Since we are seeking approvals under SPAs, based on protocol designs negotiated with the agency, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint is achieved, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision.

Additionally, we have never filed a 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 remain unanswered by the time we file our NDA. Unless the FDA opts not to pursue these questions, submission of a 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. It 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. The FDA may pose additional questions or request further clinical substantiation. 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 perform additional safety studies or analyses, which could delay the development of the drug or lead to a decision to discontinue development of the drug. The submission of data to the FDA from our long-term rat and canine pre-clinical studies are prerequisites for our initiation of a long-term Phase 3 clinical trial for Zerenex, and any safety signals could potentially delay the start of such clinical trial 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 traits of safety and efficacy despite positive results in initial clinical testing. Results from earlier studies may not be indicative of results from future clinical trials. The risk remains that a pivotal program may generate efficacy data that will be insufficiently persuasive 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. There can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted, which in subsequent, larger studies might appear and prevent approval of such drug candidates. We may not be able to replicate in our planned Phase 3 clinical program for Zerenex, the efficacy and safety results for Zerenex observed in the previous Phase 2 clinical trials and the Open Label Extension (OLE) clinical

trial. The positive effects of Zerenex on IV iron and EPO use observed in the OLE clinical trial may not be reproducible. In addition, we may not be able to replicate in the Phase 3 trials for KRX-0401, the efficacy and safety results for KRX-0401 observed in previous clinical trials. In addition, we will need to re-input our safety information on KRX-0401 into a database compliant with Good Clinical Practice. We 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. Accordingly, we may encounter unforeseen problems and delays in the approval process. Although we may engage a clinical research organization with experience in conducting regulatory trials, errors in the conduct, monitoring and/or auditing could potentially invalidate the results.

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 drug 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. Moreover, issues that may arise in our current transition to a commercial batch manufacturer for Zerenex can lead to delays in our planned clinical trials and development timelines, and could affect our ability to complete our clinical trials on a cost-effective or timely basis, if at all.

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 and drug product 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.

If, in the future, the market conditions for raising capital deteriorate, we may be forced to 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.

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 may 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, KRX-0401 (perifosine), if approved in the United States would compete with other anti-cancer agents, such as mTOR inhibitors. Pfizer Inc., Novartis AG and Ariad Pharmaceuticals are developing mTOR inhibitors for use in cancer and Pfizer's mTOR inhibitor, temsirolimus, and Novartis' mTOR inhibitor, everolimus, have 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), Merck & Co., Inc., Millennium Pharmaceuticals, Inc. (a wholly-owned subsidiary of Takeda Pharmaceutical Company), Novartis AG, Onyx Pharmaceuticals, Inc. and OSI 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 phosphoinositide 3-kinase (PI3K)/Akt pathway. 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.

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 15, 2010, we had 15 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, Ron Bentsur, our 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. Bentsur, such 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 pricing of healthcare products and services in the United States or internationally, the reimportation of drugs into the U.S. from other countries (where they are then sold at a lower price), and the amount of reimbursement available from governmental agencies or other third party payors. Health care reform legislation currently being considered in the U.S. House of Representatives and the Senate could have a substantial impact on the pharmaceutical industry. For example, proposals to impose an annual fee on manufacturers of branded prescription pharmaceuticals could impact our products. 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.

For example, the Centers for Medicare & Medicaid Services has proposed that Medicare payment for phosphate binders be bundled into the packaged composite rate paid by Medicare to dialysis clinics as reimbursement for most of the dialysis-related services provided to Medicare patients. If these product classes are bundled into the composite rate as proposed, separate Medicare reimbursement will no longer be available for phosphate binders. It is too early to project the impact bundling may have on the phosphate binder industry.

On September 27, 2007, the Food and Drug Administration Amendments Act of 2007 was enacted, giving the FDA enhanced post-market authority, including the authority to require post-marketing studies and clinical trials, labeling changes based on new safety information, and compliance with risk evaluations and mitigation strategies approved by the FDA. The FDA's exercise of its new authority could result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, increased costs to assure compliance with new post-approval regulatory requirements, and potential restrictions on the sale or distribution of approved products.

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.

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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. OCOG has not entered into a new third-party service contracts since 2005 and does not plan to enter into any further service contracts. 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 15 full and part-time employees as of March 15, 2010. 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, 2009, exclusive of our auction rate security investment, anticipated milestones to be received, and expected exercises of expiring options and warrants, are sufficient to meet our anticipated working capital needs and fund our business plan for approximately 20 to 24 months from December 31, 2009. 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 investment in an auction rate security; 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 one remaining auction rate security investment, we will continue to attempt to sell this security until the auction is successful. If uncertainties in the credit and capital markets continue, these markets deteriorate further or this security experiences any credit rating downgrades, we may incur additional impairment charges with respect to this auction rate security investment, which could negatively affect our financial condition, cash flow and reported earnings. We continue to monitor the fair value of our one remaining auction rate security investment 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 security investment 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 (the maximum term of extension under the patent term restoration program). 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 other patents that we may hold, such as method of use patents.

Our method of use patents only protect the products 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.

Proof of direct infringement by a competitor for method of use patents can also prove difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, proof that a competitor contributes to or induces infringement of a patented method of use by another can also prove difficult because an off-label use of a product could prohibit a finding of contributory infringement and inducement of infringement requires proof of intent by the competitor.

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 directly infringe or contribute to or induce infringement of method of use patents, 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.

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. In September 2009, we announced that KRX-0401 (perifosine) has received Orphan-Drug designation from the FDA for the treatment of multiple myeloma. We believe that KRX-0401 (perifosine) may be eligible for additional orphan drug designations; however, we cannot assure that KRX-0401, or any other drug candidates we may acquire or in-license, will obtain such orphan drug designations.

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.

On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607), that was declared effective by the SEC on September 23, 2009, providing for the offering of up to \$40 million of our common stock and warrants to purchase our common stock. Subsequent to the registered direct offering that was completed on September 30, 2009, there remains approximately \$12.2 million of our common stock and warrants available for sale on this shelf registration statement. Future sales pursuant to this registration statement could depress the market for our common stock.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, our stockholders' 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 2,872,422 shares of our common stock to former stockholders of ACCESS Oncology upon the achievement of certain development and sales milestones.

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

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

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

#### ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

#### ITEM 2. PROPERTIES.

Our corporate and executive office is located in New York, New York. Our New York facility consists of approximately 11,700 square feet of leased space at 750 Lexington Avenue, New York, New York 10022. We are a party to an office sharing agreement with a third-party for a portion of our leased space 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 March 2010, we settled a dispute with ICON Central Laboratories ("ICON"), the central laboratory we used for the clinical development of Sulonex (sulodexide), concerning certain fees related mainly to the provision of storage services pursuant to a series of service agreements. ICON was claiming that we owed it \$816,647 in unpaid invoices, much of which is made up of charges for annual storage fees incurred after the effective date of termination of the agreements. Under the terms of the settlement agreement, we paid ICON \$400,000 in settlement of all claims.

In October 2009, we filed a statement of claim with the Financial Institution Regulatory Authority (“FINRA”) to commence an arbitration proceeding against an SEC registered broker-dealer. In this arbitration proceeding, we seek damages arising from that broker-dealer’s recommendations and purchases of auction rate securities for our cash management account. The claim will be determined by a panel of three FINRA arbitrators. In January 2010, the broker-dealer filed an answer to the statement of claim and denied liability. The parties are in the process of selecting an arbitration panel.

ITEM 4. [Removed and Reserved]

## 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.”

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, 2009	High	Low
Fourth Quarter	\$ 3.20	\$ 1.76
Third Quarter	\$ 2.69	\$ 0.71
Second Quarter	\$ 1.35	\$ 0.16
First Quarter	\$ 0.32	\$ 0.11
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

#### Holders

The number of record holders of our common stock as of March 15, 2010 was 71.

#### 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, 2009, 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, the 2007 Incentive Plan and the 2009 CEO 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	6,250,915	\$ 8.73	2,628,018
Equity compensation plans not approved by security holders	3,102,657	\$ 2.40	—
<b>Total</b>	<b>9,353,572</b>	<b>\$ 6.63</b>	<b>2,628,018</b>

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, 2004 through December 31, 2009, 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, 2004, 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, 2009, 2008, 2007, 2006 and 2005, and Balance Sheet Data as of December 31, 2009, 2008, 2007, 2006 and 2005, 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,				
	2009	2008	2007	2006	2005
	(in thousands, except per share data)				
<b>Statement of Operations Data:</b>					
<b>Revenue:</b>					
License revenue	\$ 21,616	\$ 1,180	\$ 204	\$ —	\$ —
Service revenue	3	103	52	431	574
Other revenue	3,575	—	727	—	—
<b>Total revenue</b>	<b>25,194</b>	<b>1,283</b>	<b>983</b>	<b>431</b>	<b>574</b>
<b>Operating expenses:</b>					
Cost of services	—	27	124	390	819
<b>Research and development:</b>					
Non-cash compensation	1,233	(67)	3,574	6,504	594
Other research and development	7,372	38,075	74,883	55,751	24,182
<b>Total research and development</b>	<b>8,605</b>	<b>38,008</b>	<b>78,457</b>	<b>62,255</b>	<b>24,776</b>
<b>Selling, general and administrative:</b>					
Non-cash compensation	1,867	6,815	7,086	8,408	775
Other selling, general and administrative	4,904	7,474	9,141	8,519	3,416
<b>Total selling, general and administrative</b>	<b>6,771</b>	<b>14,289</b>	<b>16,227</b>	<b>16,927</b>	<b>4,191</b>
<b>Total operating expenses</b>	<b>15,376</b>	<b>52,324</b>	<b>94,808</b>	<b>79,572</b>	<b>29,786</b>
<b>Operating income (loss)</b>	<b>9,818</b>	<b>(51,041)</b>	<b>(93,825)</b>	<b>(79,141)</b>	<b>(29,212)</b>
<b>Other income (expense):</b>					
Interest and other income (expense), net	667	(1,665)	4,555	6,393	2,317
Income taxes	—	—	(36)	—	—
<b>Income (loss) from continuing operations</b>	<b>10,485</b>	<b>(52,706)</b>	<b>(89,306)</b>	<b>(72,748)</b>	<b>(26,895)</b>
<b>Income (loss) from discontinued operations</b>	<b>—</b>	<b>(175)</b>	<b>(756)</b>	<b>(1,016)</b>	<b>—</b>

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Net income (loss)	\$ 10,485	\$ (52,881)	\$ (90,062)	\$ (73,764)	\$ (26,895)
Basic and diluted income (loss) per common share:					
Continuing operations	\$ 0.21	\$ (1.17)	\$ (2.05)	\$ (1.74)	\$ (0.78)
Discontinued operations	—	(0.01)	(0.02)	(0.02)	—
Basic and diluted income (loss) per common share	\$ 0.21	\$ (1.18)	\$ (2.07)	\$ (1.76)	\$ (0.78)

	2009	2008	As of December 31, 2007		2006	2005
			(in thousands)			
<b>Balance Sheet Data:</b>						
Cash, cash equivalents, interest receivable and short-term investment securities	\$ 34,000	\$ 15,467	\$ 62,386	\$ 112,920	\$ 86,783	
Working capital	29,489	9,282	42,319	102,774	83,890	
Long-term investment securities	1,914	7,185	2,296	12,690	13,950	
Total assets	40,818	26,634	81,061	140,313	105,097	
Deferred revenue, net of current portion	—	17,308	11,022	—	—	
Other liabilities	50	118	202	294	322	
Contingent equity rights	2,639	4,004	4,004	4,004	4,004	
Total stockholders' equity (deficiency)	32,097	(1,489)	44,422	123,821	94,678	

## 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 pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. We are developing KRX-0401 (perifosine), a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase (PI3K) pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, all of which are pathways associated with programmed cell death, cell growth, cell differentiation and cell survival. KRX-0401 has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. KRX-0401 is currently in a Phase 3 trial, under Special Protocol Assessment, or SPA, in multiple myeloma, with a Phase 3 trial in refractory metastatic colorectal cancer, under SPA, pending commencement, and in Phase 2 clinical development for several other tumor types. We are also developing Zerenex™ (ferric citrate), an oral, iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. Zerenex has completed five Phase 2 clinical studies as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, and our Phase 3 program for Zerenex, under an SPA, is pending commencement. Zerenex is also in Phase 2 development in Japan by our Japanese partner, JT and Torii. We also actively engage in business development activities that include seeking strategic relationships for our product candidates, as well as evaluating compounds and companies for in-licensing or acquisition. 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, JT and 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 and milestone payments arising from our agreement with JT and Torii. We recognize upfront license fee revenues ratably over the estimated period in which we will have certain significant ongoing responsibilities under the sublicense agreement, with unamortized amounts recorded as deferred revenue. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone,

and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract as we complete our performance obligations.

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

Our other revenues consist of fees and payments arising from technology transfer, termination and settlement agreements related to our prior license agreements.

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, 2009, 2008 and 2007 were \$7,372,000, \$38,075,000 and \$74,883,000, respectively.

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

	Years ended December 31,		
	2009	2008	2007
KRX-0401 (perifosine)	\$ 1,930,000	\$ 7,045,000	\$ 15,210,000
Zerenex	3,647,000	3,423,000	4,825,000
Other	679,000	677,000	2,088,000
Terminated programs (including Sulonex)	1,116,000	26,930,000	52,760,000
Total	\$ 7,372,000	\$ 38,075,000	\$ 74,883,000

Amounts in the above table exclude 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 and restricted stock. 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 expenses.

For awards of options and restricted stock to consultants and other third-parties, compensation expense is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. We record compensation expense based on the fair value of the award at the reporting date. 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. 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.

In addition, certain options and restricted stock issued to employees, consultants and other third-parties vest upon the achievement of certain milestones, therefore the total expense is uncertain until the milestone is met.

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, 2009 and 2008

**License Revenue.** License revenue increased by \$20,436,000 to \$21,616,000 for the year ended December 31, 2009, as compared to \$1,180,000 for the year ended December 31, 2008. The increase in license revenue during the year ended December 31, 2009, was primarily due to the recognition of all remaining deferred revenue related to the JT and Torii sublicense agreement originally signed in September 2007, and amended and restated on June 8, 2009. The Amended and Restated Sublicense Agreement, among other things, provided for the elimination of all significant on-going obligations under the sublicense agreement. In addition, during the year ended December 31, 2009, we recognized \$3.0 million in license revenue from a milestone received from JT and Torii due to their initiation of a Phase 2 clinical study of Zerenex in Japan. We may recognize additional license revenue in 2010 pursuant to development milestones of Zerenex in Japan.

**Service Revenue.** Service revenue decreased by \$100,000 to \$3,000 for the year ended December 31, 2009, as compared to service revenue of \$103,000 for the year ended December 31, 2008. We do not expect our service revenue to have a material impact on our financial results during 2010.

**Other Revenue.** Other revenue for the year ended December 31, 2009 was \$3,575,000, of which \$3,500,000 was due to the settlement of our dispute with Alfa Wassermann, in July 2009, over issues arising from the terminated license agreement for Sulonex (sulodexide) and \$75,000 was related to a payment earned in June 2009 from a December 2008 license termination agreement for KRX-0501. Payments associated with these terminated licenses are recognized as earned since we have no on-going responsibilities under the terminated license agreements or the termination agreement. There was no other revenue for the year ended December 31, 2008. We do not expect to recognize other revenue during 2010.

**Non-Cash Compensation Expense (Research and Development).** Non-cash compensation expense (research and development) related to equity incentive grants increased by \$1,300,000 to \$1,233,000 for the year ended December 31, 2009, as compared to a credit of \$67,000 for the year ended December 31, 2008. Non-cash compensation expense in the year ended December 31, 2008 included a \$1,233,000 credit to expense related to the reversal of costs for stock options and restricted stock issued to our former President, who was terminated as part of the 2008 Restructuring.

**Other Research and Development Expenses.** Other research and development expenses decreased by \$30,703,000 to \$7,372,000 for the year ended December 31, 2009, as compared to \$38,075,000 for the year ended December 31, 2008. The decrease in other research and development expenses was due primarily to a \$26,856,000 reduction in research and development expenses related to the cessation of the development of Sulonex 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 17 – Restructuring below. In addition to the \$26,856,000 decrease in other research and development expenses related to Sulonex discussed above, there was a decrease of \$5,115,000 in research and development expenses related to KRX-0401, primarily due to reductions in headcount and other research and development expenses related to the development program, partially offset by a \$1,460,000 one-time accrual for a terminated early-stage pipeline product candidate. We expect our other research and development costs to increase substantially in 2010, as compared to 2009, due our Phase 3 clinical programs for KRX-0401 and Zerenex.

Non-Cash Compensation Expense (Selling, General and Administrative). Non-cash compensation expense (selling, general and administrative) related to equity incentive grants decreased by \$4,948,000 to \$1,867,000 for the year ended December 31, 2009, as compared to an expense of \$6,815,000 for the year ended December 31, 2008. The decrease was primarily due to a \$5,313,000 decrease in non-cash compensation related to equity incentive grants previously issued to Mr. Weiss, our former chief executive officer, who was terminated on April 23, 2009, offset by \$660,000 in non-cash compensation associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.



**Other Selling General and Administrative Expenses.** Other selling, general and administrative expenses decreased by \$2,570,000 to \$4,904,000 for the year ended December 31, 2009, as compared to an expense of \$7,474,000 for the year ended December 31, 2008. The decrease was due primarily to a \$1,237,000 decrease in legal fees and litigation costs and a reduction of expenses in the year ended December 31, 2009, as compared to the prior year, as a result of the 2008 Restructuring, partially offset by approximately \$833,000 of expense in the year ended December 31, 2009, for severance, pro rata bonus and notice pay related to the termination of our former chief executive officer on April 23, 2009. The year ended December 31, 2008, included a one-time premium payment for insurance of \$1,151,000. We expect our other selling, general and administrative expenses in 2010 to remain at a comparable level to those reported in 2009, excluding one-time charges.

**Interest and Other Income (Expense), Net.** Interest and other income (expense), net, increased by \$2,332,000 to income of \$667,000 for the year ended December 31, 2009, as compared to an expense of \$1,665,000 for the year ended December 31, 2008. The year ended December 31, 2008, included \$3,196,000 of impairment charges related to our investments in auction rate securities. Interest income related to our investments decreased in the year ended December 31, 2009, as compared to the year ended December 31, 2008, due to a lower level of invested funds and lower interest rates as compared to the prior year.

#### 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. Prior to the amendment in 2009, 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 represented the estimated period over which we had certain ongoing responsibilities under the original 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.

**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.

**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 former 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 17 - 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.

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.

Interest and Other Income (Expense), Net. Interest and other income (expense), 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 prior 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.

## 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.

On September 30, 2009, we completed a registered direct offering to certain investors of 8,000,000 shares of our common stock and warrants to purchase up to a total of 2,800,000 shares of our common stock for gross proceeds of approximately \$20 million. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.35 of a share of common stock. The purchase price per unit was \$2.50. Subject to certain ownership limitations, the warrants are exercisable at any time on or after the initial issue date and on or prior to October 1, 2010, at an exercise price of \$2.65 per warrant share. In addition, the placement agent received a warrant to purchase up to 108,000 shares of our common stock at an exercise price of \$3.125 per warrant share, exercisable at any time on or prior to October 1, 2010. Total proceeds to us from this public offering were approximately \$18.4 million, net of offering costs of approximately \$1.6 million. The shares and warrants were sold under a shelf registration statement on Form S-3 (File No. 333-161607) filed with the SEC on August 28, 2009, and declared effective by the SEC on September 23, 2009. The registration statement provides for the offering of up to \$40 million of our common stock and warrants. Subsequent to this registered direct offering, there remains approximately \$12.2 million of our common stock and warrants available for sale under the shelf registration statement. We may offer the remaining securities under our shelf registration from time to time in response to market conditions or other circumstances if we believe such a plan of financing is in our best interests and the best interests of our stockholders. We believe that the shelf registration provides us with the flexibility to raise additional capital to finance our operations as needed.

As of December 31, 2009, we had \$34.0 million in cash, cash equivalents, interest receivable, and short-term investment securities, an increase of \$18.5 million from December 31, 2008. In addition, at December 31, 2009, we had \$1.9 million invested in a non-current auction rate security, as discussed below. We currently anticipate that our cash, cash equivalents and investment securities as of December 31, 2009, exclusive of our auction rate security investment, anticipated milestones to be received, and expected exercises of expiring options and warrants, are sufficient to meet our anticipated working capital needs and fund our business plan for approximately 20 to 24 months from December 31, 2009.

Cash used in operating activities in continuing operations for the year ended December 31, 2009 was \$5.5 million, as compared to \$38.6 million for the year ended December 31, 2008. This decrease in cash used in operating activities was due primarily to the cessation of the Sulonex program in March 2008, the 2008 Restructuring, a \$3.0 million non-refundable milestone payment received from JT and Torii associated with their initiation of a Phase 2 trial for Zerenex in Japan, and \$2.75 million of the \$3.5 million settlement award received from Alfa Wassermann (\$0.75 million will be paid to us on or before July 30, 2010).

For the year ended December 31, 2009, net cash used in investing activities of \$9.7 million was primarily the result of the investment in held-to-maturity short-term securities. For the year ended December 31, 2009, net cash provided by financing activities totaled \$18.5 million and was primarily due to our registered direct offering of common stock and warrants completed in September 2009.

As of December 31, 2009, we have a \$1.9 million long-term investment in one auction rate student loan-backed security. 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 our investments 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. We are uncertain as to when, or if, the liquidity issue relating to our one remaining auction rate security will improve. Quarterly, we assess the fair value of our auction rate securities portfolio. As a result of this valuation process, we recorded impairment charges totaling \$0.1 and \$3.2 million during the years ended December 31, 2009 and 2008, respectively, 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 income (expense), net. For the year ended December 31, 2009, we reported other comprehensive income of \$0.2 million for a temporary unrealized gain related to the increase in estimated fair value for our one remaining auction rate security investment. The estimated fair value of our one remaining auction rate security investment (\$3.0 million par value) is \$1.9 million at December 31, 2009.

In 2009, we sold four of our auction rate security investments. The securities had a combined par value of \$7.0 million and a combined adjusted book value of \$5.4 million. Proceeds to us from the sale of these securities were \$5.6 million, representing a gain of \$0.2 million over adjusted book value. We will continue to attempt to sell our one remaining auction rate security until the auction is successful; however, there is no assurance as to when, or if, the market for auction rate securities will recover. The fair value of our auction rate security investment could change significantly based on market conditions and continued uncertainties in the credit markets. If these uncertainties continue, or if this security experiences credit rating downgrades, we may incur additional impairment charges with respect to this auction rate security, which could negatively affect our financial condition, cash flow and reported earnings, and the lack of liquidity of our remaining auction rate security investment could have a material impact on our ability to fund our operations.

#### OFF-BALANCE SHEET ARRANGEMENTS

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

#### OBLIGATIONS AND COMMITMENTS

As of December 31, 2009, we have known contractual obligations, commitments and contingencies of \$4,800,000. Of this amount, \$4,341,000 relates to research and development agreements (relating to our KRX-0401 and Zerenex clinical programs), of which \$2,284,000 is due within the next year. Certain of these commitments are contingent upon our continuing development of our drug candidates. The additional \$459,000 relates to our operating lease obligations, of which all is due within the next year.

Contractual obligations	Total	Payment due by period			
		Less than 1 year	1-3 years	3-5 years	More than 5 years
Research and development agreements	\$ 4,341,000	\$ 2,284,000	\$ 2,057,000	\$ —	—
Operating leases	459,000	459,000	—	—	—
<b>Total</b>	<b>\$ 4,800,000</b>	<b>\$ 2,743,000</b>	<b>\$ 2,057,000</b>	<b>\$ —</b>	<b>—</b>

We have undertaken to make contingent milestone payments to certain of our licensors of up to approximately \$41.1 million over the life of the licenses, of which approximately \$36.6 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 2,872,422 shares of our common stock) if KRX-0401 meets certain development milestones. 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.

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## 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. For 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.

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.

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**Revenue Recognition.** We recognize license revenue in accordance with the revenue recognition guidance of the Codification. We analyze each element of our licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to us of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. We recognize revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. We recognize milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, we defer the milestone payment and recognize it as revenue over the estimated period of performance under the contract.

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.

We recognize other revenues at the time such fees and payments are earned.

**Accounting Related to Goodwill.** As of December 31, 2009, there was approximately \$3.2 million of goodwill on our consolidated balance sheet. Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. We test for goodwill impairment 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 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 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.** 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. 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 in June 2008.

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Impairment of Investment Securities. As of December 31, 2009, we have a \$1.9 million long-term investment in one auction rate student loan-backed security. Auction rate securities are recorded at their fair value and classified as long-term investments. The uncertainties in the credit markets have affected our investments 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. We are uncertain as to when, or if, the liquidity issue relating to our one remaining auction rate security investment will improve. Quarterly, we assess the fair value of our auction rate securities portfolio. As a result of this valuation process, as described below, we recorded impairment charges totaling \$0.1 and \$3.2 million during the years ended December 31, 2009 and 2008, respectively, 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 income (expense), net. For the year ended December 31, 2009, we reported other comprehensive income of \$0.2 million for a temporary unrealized gain related to the increase in estimated fair value for our one remaining auction rate security investment. The estimated fair value of our one remaining auction rate security investment (\$3.0 million par value) is \$1.9 million at December 31, 2009.

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

We review investment securities for impairment and 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. 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

On September 30, 2009, we adopted changes issued by the Financial Accounting Standards Board, or FASB, to the authoritative hierarchy of GAAP. These changes establish the FASB Accounting Standards Codification, or Codification, as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the SEC under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead the FASB will issue Accounting Standards Updates, or ASUs. ASUs will not be authoritative in their own right as they will only serve to update the Codification. These changes and the Codification itself do not change GAAP. Other than the manner in which new accounting guidance is referenced, the adoption of these changes had no impact on our consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements. This ASU eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The ASU also eliminates the use of the residual method and instead requires an entity to allocate revenue using the relative selling price method. Additionally, the guidance expands disclosure requirements with respect to multiple-deliverable revenue arrangements. This ASU is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. We are currently evaluating the potential impact of this standard on our consolidated financial statements.

## ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURE ABOUT MARKET RISK

The primary objective of our investment activities is to preserve principal while maximizing our income from investments and minimizing our market risk. We invest in government and investment-grade corporate debt in accordance with our investment policy, and also currently have an illiquid investment in an auction rate security. 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, 2009, our portfolio of financial instruments consists of cash equivalents and short-term interest bearing securities, including money market funds and government debt, and a long-term auction rate security investment. 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, 2009, we have a \$1.9 million long-term investment in one auction rate student loan-backed security. Auction rate securities are recorded at their fair value and classified as long-term investments. The uncertainties in the credit markets have affected our investments 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. We are uncertain as to when, or if, the liquidity issue relating to our one remaining auction rate security investment will improve. We will continue to attempt to sell our one remaining auction rate security until the auction is successful. If uncertainties in the credit and capital markets continue, these markets deteriorate further or this security experiences any credit rating downgrades, we may incur additional impairment charges with respect to this auction rate security investment, which could negatively affect our financial condition, cash flow and reported earnings. We continue to monitor the fair value of our auction rate security investment 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 security investment would decline approximately \$190,000. However, auction rate securities have different features and are subject to different risks and therefore, any market decline may impact our investment security 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, 2009, management carried out, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act). Our disclosure controls and procedures are designed to provide reasonable assurance that information we are required to disclose in the reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in applicable rules and forms. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of December 31, 2009, 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) or Rule 15d-15(f) under the Exchange Act). Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2009. 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, 2009, 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 control over financial reporting during the quarter ended December 31, 2009, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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

#### ITEM 9B. OTHER INFORMATION

Not Applicable.

### Part III

#### ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information required by this Item is incorporated herein by reference from our Proxy Statement for our 2010 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 2010 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 2010 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 2010 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 2010 Annual Meeting of Stockholders.

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## 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.

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## 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.

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- 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.

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- 10.1† 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.
- 10.2† 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.
- 10.3† 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.
- 10.4† 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.
- 10.5! 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.
- 10.6! 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.
- 10.7 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.
- 10.8† 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.
- 10.9! 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.
- 10.10† 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.
- 10.11! 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.
- 10.12† 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.

- 10.13! 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.
- 10.14! First Amendment to Amended and Restated License Agreement by and between Panion & BF Biotech, Inc. and Keryx Biopharmaceuticals, Inc. dated March 17, 2008.
- 10.15! Amended and Restated License Agreement dated June 8, 2009, by and between Keryx Biopharmaceuticals, Inc., Japan Tobacco, Inc. and Japan Torii Pharmaceutical Co. Ltd., filed as Exhibit 10.1 to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed on August 8, 2009, and incorporated herein by reference.

- 10.16 Settlement Agreement and General Release between Keryx Biopharmaceuticals, Inc. and Alfa Wassermann S.p.A. filed as Exhibit 10.2 to the Registrant's quarterly report on Form 10-Q for the quarter ended June 30, 2009, filed on August 8, 2009, and incorporated herein by reference.
  - 10.17† Employment Agreement with Ron Bentsur dated September 14, 2009, filed as Exhibit 10.1 to the Registrant's Form 8-K filed on September 16, 2009, and incorporated herein by reference.
  - 21.1 List of subsidiaries of Keryx Biopharmaceuticals, Inc.
  - 23.1 Consent of UHY LLP.
  - 23.2 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 25, 2010.
  - 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 25, 2010.
  - 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 25, 2010.
  - 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 25, 2010.
- ! Confidential treatment has been granted with respect to the omitted portions of this exhibit.  
† Indicates management contract or compensatory plan or arrangement.

Keryx Biopharmaceuticals, Inc.  
Consolidated Financial Statements as of December 31, 2009

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Report of Independent Registered Public Accounting Firm

To the Board of Directors and  
Stockholders of Keryx Biopharmaceuticals, Inc.

We have audited the accompanying consolidated balance sheet of Keryx Biopharmaceuticals, Inc. and subsidiaries (the "Company") as of December 31, 2009 and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for the year ended December 31, 2009. The Company's management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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, 2009 and the results of its operations and its cash flows for the year then ended in conformity with accounting principles generally accepted in the United States of America.

/s/ UHY LLP

New York, New York  
March 25, 2010

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Report of Independent Registered Public Accounting Firm

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

We have audited the accompanying consolidated balance sheet of Keryx Biopharmaceuticals, Inc. and subsidiaries (the "Company"), as of December 31, 2008, and the related consolidated statements of operations, stockholders' deficiency, and cash flows for each of the years in the two-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 the results of their operations and their cash flows for each of the years in the two-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. 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 was to evaluate market conditions to determine the appropriate timing and extent to which it would seek to obtain additional debt, equity or other type of financing. 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 a new accounting requirement issued by the Financial Accounting Standards Board.

/s/ KPMG LLP

New York, New York  
March 31, 2009

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

(in thousands, except share and per share amounts)

	2009	2008
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 16,386	\$ 13,143
Short-term investment securities	17,548	2,299
Interest receivable	66	25
Other current assets	1,521	508
Total current assets	35,521	15,975
Long-term investment securities	1,914	7,185
Property, plant and equipment, net	94	182
Goodwill	3,208	3,208
Other assets, net	81	84
Total assets	\$ 40,818	\$ 26,634
<b>Liabilities and stockholders' equity (deficiency)</b>		
Current liabilities:		
Accounts payable and accrued expenses	\$ 5,001	\$ 4,613
Accrued compensation and related liabilities	755	496
Current portion of deferred revenue	156	1,464
Liabilities of discontinued operations	120	120
Total current liabilities	6,032	6,693
Deferred revenue, net of current portion	—	17,308
Contingent equity rights	2,639	4,004
Other liabilities	50	118
Total liabilities	8,721	28,123
Commitments and contingencies (Note 14)		
Stockholders' equity (deficiency):		
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, 56,560,478 and 47,729,507 shares issued, 56,480,530 and 47,649,559 shares outstanding at December 31, 2009 and 2008, respectively)	57	48
Additional paid-in capital	353,650	330,738
Treasury stock, at cost, 79,948 shares at December 31, 2009 and 2008, respectively	(357)	(357)
Accumulated other comprehensive income	180	—
Accumulated deficit	(321,433)	(331,918)
Total stockholders' equity (deficiency)	32,097	(1,489)
Total liabilities and stockholders' equity (deficiency)	\$ 40,818	\$ 26,634

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)

	2009	2008	2007
<b>Revenue:</b>			
License revenue	\$ 21,616	\$ 1,180	\$ 204
Service revenue	3	103	52
Other revenue	3,575	—	727
<b>Total revenue</b>	<b>25,194</b>	<b>1,283</b>	<b>983</b>
<b>Operating expenses:</b>			
Cost of services	—	27	124
<b>Research and development:</b>			
Non-cash compensation	1,233	(67)	3,574
Other research and development	7,372	38,075	74,883
<b>Total research and development</b>	<b>8,605</b>	<b>38,008</b>	<b>78,457</b>
<b>Selling, general and administrative:</b>			
Non-cash compensation	1,867	6,815	7,086
Other selling, general and administrative	4,904	7,474	9,141
<b>Total selling, general and administrative</b>	<b>6,771</b>	<b>14,289</b>	<b>16,227</b>
<b>Total operating expenses</b>	<b>15,376</b>	<b>52,324</b>	<b>94,808</b>
<b>Operating income (loss)</b>	<b>9,818</b>	<b>(51,041)</b>	<b>(93,825)</b>
Interest and other income (expense), net	667	(1,665)	4,555
<b>Income (loss) from continuing operations before income taxes</b>	<b>10,485</b>	<b>(52,706)</b>	<b>(89,270)</b>
Income taxes	—	—	36
<b>Income (loss) from continuing operations</b>	<b>10,485</b>	<b>(52,706)</b>	<b>(89,306)</b>
Loss from discontinued operations	—	(175)	(756)
<b>Net income (loss)</b>	<b>\$ 10,485</b>	<b>\$ (52,881)</b>	<b>\$ (90,062)</b>
<b>Basic net income (loss) per common share:</b>			
Continuing operations	\$ 0.21	\$ (1.17)	\$ (2.05)
Discontinued operations	—	(0.01)	(0.02)
<b>Basic net income (loss) per common share</b>	<b>\$ 0.21</b>	<b>\$ (1.18)</b>	<b>\$ (2.07)</b>
<b>Diluted net income (loss) per common share:</b>			
Continuing operations	\$ 0.21	\$ (1.17)	\$ (2.05)
Discontinued operations	—	(0.01)	(0.02)
<b>Diluted net income (loss) per common share</b>	<b>\$ 0.21</b>	<b>\$ (1.18)</b>	<b>\$ (2.07)</b>

Weighted average shares used in computing basic net income (loss) per common share	49,940,730	44,902,398	43,583,950
Weighted average shares used in computing diluted net income (loss) per common share	50,498,982	44,902,398	43,583,950

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

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Keryx Biopharmaceuticals, Inc.  
Consolidated Statements of Changes in Stockholders' Equity (Deficiency)  
for the Years Ended December 31, 2009, 2008 and 2007

(in thousands, except share amounts)

	Common stock		Additional	Treasury stock		Accumulated		
	Shares	Amount	paid-in capital	Shares	Amount	other comp	Accumulated deficit	Total
Balance at December 31, 2006	43,516,669	44	\$ 312,841	56,100	\$ (89)	\$ -	\$ (188,975)	\$ 123,821
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	-	-	-	23,848	(268)	-	-	(268)
Issuance of common stock in connection with exercise of options	138,412	-*	271	-	-	-	-	271
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	-	-	10,660	-	-	-	-	10,660
Net loss	-	-	-	-	-	-	(90,062)	(90,062)
Balance at December 31, 2007	43,751,101	\$ 44	\$ 323,772	79,948	\$ (357)	\$ -	\$ (279,037)	\$ 44,422
Issuance of restricted stock	3,976,906	4	-	-	-	-	-	4
Forfeiture of restricted stock	(73,500)	(-)*	-	-	-	-	-	(-)*
Issuance of common stock in connection with exercise of options	75,000	-*	222	-	-	-	-	222
Compensation in respect of options and restricted stock granted to employees, directors and	-	-	6,744	-	-	-	-	6,744

third-parties									
Net loss	-	-	-	-	-	-	(52,881)	(52,881)	
Balance at									
December 31, 2008	47,729,507	\$ 48	\$ 330,738	79,948	\$ (357)	\$ -	\$ (331,918)	\$ (1,489)	
Issuance of common stock in public offering (net of offering costs of \$1,557)	8,000,000	8	15,553	-	-	-	-	15,561	
Issuance of common stock warrants in public offering	-	-	2,877	-	-	-	-	2,877	
Issuance of common stock in connection with acquisition	500,000	1	1,364	-	-	-	-	1,365	
Issuance of restricted stock	578,539	-*	-	-	-	-	-	-*	
Forfeiture of restricted stock	(361,742)	(-)*	-	-	-	-	-	(-)*	
Issuance of common stock in connection with exercise of warrants	64,174	-*	-*	-	-	-	-	-*	
Issuance of common stock in connection with exercise of options	50,000	-*	18	-	-	-	-	18	
Compensation in respect of options and restricted stock granted to employees, directors and third-parties	-	-	3,100	-	-	-	-	3,100	
Unrealized gain on long-term investment securities	-	-	-	-	-	180	-	180	
Net income	-	-	-	-	-	-	10,485	10,485	
Balance at									
December 31, 2009	56,560,478	\$ 57	\$ 353,650	79,948	\$ (357)	\$ 180	\$ (321,433)	\$ 32,097	

\* 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)

	2009	2008	2007
<b>CASH FLOWS FROM OPERATING ACTIVITIES</b>			
Net income (loss)	\$ 10,485	\$ (52,881)	\$ (90,062)
Loss from discontinued operations	—	(175)	(756)
Income (loss) from continuing operations	10,485	(52,706)	(89,306)
Adjustments to reconcile income (loss) from continuing operations to cash flows used in operating activities of continuing operations:			
Stock compensation expense	3,100	6,748	10,660
Depreciation and amortization	92	111	130
Gain on sale of investment securities	(173)	(81)	—
Impairment of investment securities	68	3,196	—
Other impairment charges	—	11,037	—
Changes in assets and liabilities, net of effects of acquisitions:			
(Increase) decrease in other current assets	(1,013)	749	706
(Increase) decrease in accrued interest receivable	(41)	258	242
Decrease in security deposits	—	260	—
Decrease in other assets	3	—	—
Increase (decrease) in accounts payable and accrued expenses	388	(14,059)	8,790
Increase (decrease) in accrued compensation and related liabilities	259	(758)	(281)
Decrease in other liabilities	(68)	(84)	(92)
(Decrease) increase in deferred revenue	(18,616)	6,727	11,845
Net cash used in operating activities of continuing operations	(5,516)	(38,602)	(57,306)
Net cash used in operating activities of discontinued operations	—	(131)	(239)
Net cash used in operating activities	(5,516)	(38,733)	(57,545)
<b>CASH FLOWS FROM INVESTING ACTIVITIES</b>			
Purchases of property, plant and equipment	(4)	(146)	(3,159)
Investment in held-to-maturity short-term securities	(17,593)	(33)	(6,136)
Proceeds from maturity of held-to-maturity short-term securities	2,343	20,869	24,020
Investment in available-for-sale short-term securities	—	(12,000)	(56,700)
Proceeds from sale of available-for-sale short-term securities	—	22,200	76,200
Proceeds from sale of available-for-sale long-term securities	5,557	1,700	—
Investment in held-to-maturity long-term securities	—	(1)	(6,372)
Proceeds from maturity of held-to-maturity long-term securities	—	—	3
Net cash (used in) provided by investing activities of continuing operations	(9,697)	32,589	27,856
Net cash provided by investing activities of discontinued operations	—	—	15
Net cash (used in) provided by investing activities	(9,697)	32,589	27,871

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)		
	2009	2008	2007
<b>CASH FLOWS FROM FINANCING ACTIVITIES</b>			
Proceeds from public offerings, net	\$ 18,438	\$ —	—
Proceeds from exercise of options and warrants	18	222	271
Purchase of treasury stock	—	—	(268)
Net cash provided by financing activities	18,456	222	3
<b>NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS</b>	<b>3,243</b>	<b>(5,922)</b>	<b>(29,671)</b>
Cash and cash equivalents at beginning of year	13,143	19,065	48,736
<b>CASH AND CASH EQUIVALENTS AT END OF YEAR</b>	<b>\$ 16,386</b>	<b>\$ 13,143</b>	<b>\$ 19,065</b>
<b>NON - CASH TRANSACTIONS</b>			
Issuance of common stock in connection with contingent equity rights	\$ 1,365	\$ —	—
Issuance of warrants to placement agent in public offering	100	—	—
Sale of manufacturing facility assets in settlement of liability	—	300	—
<b>SUPPLEMENTARY DISCLOSURES OF CASH FLOW INFORMATION</b>			
Cash paid for income taxes	\$ —	\$ —	36

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

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Keryx Biopharmaceuticals, Inc.  
Notes to the Consolidated Financial Statements

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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 pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. The Company owns a 100% interest in each of ACCESS Oncology, Inc. (“ACCESS Oncology”), Neryx Biopharmaceuticals, Inc., and Accumin Diagnostics, Inc. (“ADI”), all U.S. corporations incorporated in the State of Delaware. Most of the Company's biopharmaceutical development and substantially all of its administrative operations during 2009, 2008 and 2007 were conducted in the United States of America.

CHANGES IN COMPANY MANAGEMENT

On April 23, 2009, the Company’s Board of Directors voted to terminate the employment of Michael S. Weiss as the Company’s Chairman and Chief Executive Officer. Under the terms of Mr. Weiss’ employment agreement with the Company dated December 23, 2002, as amended on December 26, 2008 (the “Employment Agreement”), he remained an employee of the Company for a period of 90 days; however, during such notice period, he did not serve as the Company’s Chairman and Chief Executive Officer.

The Employment Agreement provided that Mr. Weiss was entitled to receive as severance (i) one year's base salary, (ii) payment of his salary during the 90 days following formal notice of termination of employment, and (iii) a pro rata bonus for the year of termination. In addition, under the terms of the Employment Agreement, all of Mr. Weiss’ outstanding stock options and shares of restricted stock vested, and all stock options will remain exercisable for two years following termination. In the year ended December 31, 2009, the Company recorded approximately \$833,000 of expense, in other selling, general and administrative expenses, associated with the cash severance, pro rata bonus and salary during the notice period (of which approximately \$245,000 is included in accrued compensation at December 31, 2009 and was paid in January 2010). Additionally, in the year ended December 31, 2009, the Company recorded approximately \$660,000 in non-cash compensation expense (selling, general and administrative) associated with the equity modifications of Mr. Weiss’ outstanding stock options and shares of restricted stock.

On May 20, 2009, the Company announced that it appointed Ron Bentsur as Chief Executive Officer of the Company. The terms of Mr. Bentsur’s employment are set forth in an employment agreement with the Company dated September 14, 2009. As an inducement to his employment, on May 20, 2009, the Company granted Mr. Bentsur options to purchase 600,000 shares of Company common stock at an exercise price of \$0.35, the fair market value of the stock as of the date of grant. The options will vest in equal annual installments over a four-year period or upon an earlier change in control of the Company. The options were granted as an inducement award and were not issued under the Company’s 2007 Incentive Plan.

On June 16, 2009, Ron Bentsur was appointed to the Board of Directors of the Company by unanimous vote of the Board of Directors, and Michael P. Tarnok was appointed Chairman of the Board by unanimous vote of the Board of Directors.

LIQUIDITY

The Company has incurred substantial operating losses since its inception and, except for 2009, expects to continue to incur operating losses for the foreseeable future and may never become profitable. As of December 31, 2009, the

Company has an accumulated deficit of \$321.4 million. The Company is dependent upon significant financing to provide the working capital necessary to execute its business plan. The Company currently anticipates that its cash, cash equivalents and investment securities as of December 31, 2009, exclusive of its auction rate security investment, anticipated milestones to be received, and expected exercises of expiring options and warrants, are sufficient to meet the Company's anticipated working capital needs and fund its business plan for approximately 20 to 24 months from December 31, 2009. 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 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.

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On September 30, 2009, the Company completed a registered direct offering to certain investors of 8,000,000 shares of its common stock and warrants to purchase up to a total of 2,800,000 shares of its common stock for gross proceeds of approximately \$20 million. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.35 of a share of common stock. The purchase price per unit was \$2.50. Subject to certain ownership limitations, the warrants are exercisable at any time on or after the initial issue date and on or prior to October 1, 2010, at an exercise price of \$2.65 per warrant share. In addition, the placement agent received a warrant to purchase up to 108,000 shares of common stock at an exercise price of \$3.125 per warrant share, exercisable at any time on or prior to October 1, 2010. Total proceeds to the Company from this public offering were approximately \$18.4 million, net of offering costs of approximately \$1.6 million. The shares and warrants were sold under a shelf registration statement filed with the SEC on August 28, 2009, and declared effective by the SEC on September 23, 2009. The registration statement provides for the offering of up to \$40 million of the Company's common stock and warrants. Subsequent to this registered direct offering, there remains approximately \$12.2 million of the Company's common stock and warrants available for sale under the shelf registration statement. The Company may offer the remaining securities under its shelf registration from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interest of the Company and its stockholders. The Company believes that the shelf registration provides it with the flexibility to raise additional capital to finance its operations as needed.

The Company's common stock is listed on the NASDAQ Capital Market and trades under the symbol "KERX."

#### RECENTLY ISSUED ACCOUNTING STANDARDS

On September 30, 2009, the Company adopted changes issued by the Financial Accounting Standards Board ("FASB") to the authoritative hierarchy of GAAP. These changes establish the FASB Accounting Standards Codification ("Codification") as the source of authoritative accounting principles recognized by the FASB to be applied by nongovernmental entities in the preparation of financial statements in conformity with GAAP. Rules and interpretive releases of the Securities and Exchange Commission ("SEC") under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. The FASB will no longer issue new standards in the form of Statements, FASB Staff Positions, or Emerging Issues Task Force Abstracts; instead the FASB will issue Accounting Standards Updates ("ASUs"). ASUs will not be authoritative in their own right as they will only serve to update the Codification. These changes and the Codification itself do not change GAAP. Other than the manner in which new accounting guidance is referenced, the adoption of these changes had no impact on the Company's consolidated financial statements.

In October 2009, the FASB issued ASU No. 2009-13, Multiple-Deliverable Revenue Arrangements. This ASU eliminates the requirement to establish the fair value of undelivered products and services and instead provides for separate revenue recognition based upon management's estimate of the selling price for an undelivered item when there is no other means to determine the fair value of that undelivered item. The ASU also eliminates the use of the residual method and instead requires an entity to allocate revenue using the relative selling price method. Additionally, the guidance expands disclosure requirements with respect to multiple-deliverable revenue arrangements. This ASU is effective prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the potential impact of this standard on its consolidated financial statements.

#### PRINCIPLES OF CONSOLIDATION

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



## USE OF ESTIMATES

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

## CASH AND CASH EQUIVALENTS

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

## INVESTMENT SECURITIES

Investment securities at December 31, 2009 and 2008 consist of short-term government securities and long-term 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. 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 income (expense), net, and unrealized gains, if determined to be temporary, are included in accumulated other comprehensive income in stockholders’ equity. 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. The Company has classified its patent expenses in other selling, general and administrative.

## REVENUE RECOGNITION

The Company recognizes license revenue in accordance with the revenue recognition guidance of the Codification. The Company analyzes each element of its licensing agreement to determine the appropriate revenue recognition. The terms of the license agreement may include payment to the Company of non-refundable up-front license fees, milestone payments if specified objectives are achieved, and/or royalties on product sales. The Company recognizes revenue from upfront payments over the period of significant involvement under the related agreements unless the fee is in exchange for products delivered or services rendered that represent the culmination of a separate earnings process and no further performance obligation exists under the contract. The Company recognizes milestone payments as revenue upon the achievement of specified milestones only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, the Company defers the milestone payment and recognizes it as revenue over the estimated period of performance under the contract (see Note 9 – License Agreements).

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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 fees and payments arising from technology transfer, termination and settlement agreements related to the Company's prior license agreements. Other revenues are recognized at the time such fees and payments are earned. See Note 9 – License Agreements.

#### 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 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. This did not have an effect on the Company's results of operations and financial position.

#### 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 differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases, operating losses 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.

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 were generated 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

The Company recognizes all share-based payments to employees and to non-employee directors as compensation for service on the Board of Directors as compensation expense in the consolidated financial statements based on the fair values of such payments. Stock-based compensation expense recognized each period is based on the value of the portion of share-based payment awards that is ultimately expected to vest during the period. Forfeitures are estimated at the time of grant and revised, if necessary, in subsequent periods if actual forfeitures differ from those estimates.

For share-based payments to consultants and other third-parties, compensation expense is determined at the "measurement date." The expense is recognized over the vesting period of the award. Until the measurement date is reached, the total amount of compensation expense remains uncertain. The Company records 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.

#### BASIC AND DILUTED NET INCOME (LOSS) PER COMMON SHARE

Basic net income or loss per share is based upon the weighted average number of common shares outstanding during the period. Diluted net income or loss per share is based upon the weighted average number of common shares outstanding during the period, plus the effect of additional weighted average common equivalent shares outstanding during the period when the effect of adding such shares is dilutive. Common equivalent shares result from the assumed exercise of outstanding stock options and warrants (the proceeds of which are then assumed to have been used to repurchase outstanding stock using the treasury stock method). In addition, the assumed proceeds under the treasury stock method include the average unrecognized compensation expense of stock options that are in-the-money. This results in the "assumed" buyback of additional shares, thereby reducing the dilutive impact of stock options and warrants. Common equivalent shares have not been included in the net loss per share calculations for the years ended December 31, 2008 and 2007, because the effect of including them would have been anti-dilutive.

Basic and diluted net income (loss) per share were determined as follows:

(in thousands, except share and per share amounts)	For the year ended December 31		
	2009	2008	2007
<b>Basic:</b>			
Income (loss) from continuing operations	\$ 10,485	\$ (52,706)	\$ (89,306)
Loss from discontinued operations	—	(175)	(756)
Net income (loss)	\$ 10,485	\$ (52,881)	\$ (90,062)
Weighted average shares outstanding	49,940,730	44,902,398	43,583,950
Basic net income (loss) per common share:			
Continuing operations	\$ 0.21	\$ (1.17)	\$ (2.05)
Discontinued operations	—	(0.01)	(0.02)
Basic net income (loss) per common share	\$ 0.21	\$ (1.18)	\$ (2.07)
<b>Diluted:</b>			
Income (loss) from continuing operations	\$ 10,485	\$ (52,706)	\$ (89,306)
Loss from discontinued operations	—	(175)	(756)



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Net income (loss)	\$ 10,485	\$ (52,881)	\$ (90,062)
Weighted average shares outstanding	49,940,730	44,902,398	43,583,950
Effect of dilutive options and warrants	558,252	—	—
Weighted average shares outstanding assuming dilution	50,498,982	44,902,398	43,583,950
Diluted net income (loss) per common share:			
Continuing operations	\$ 0.21	\$ (1.17)	\$ (2.05)
Discontinued operations	—	(0.01)	(0.02)
Diluted net income (loss) per common share	\$ 0.21	\$ (1.18)	\$ (2.07)

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The Company did not include the following securities in the table below in the computation of diluted net income (loss) per common share because the securities were anti-dilutive during the periods presented:

	For the year ended December 31		
	2009	2008	2007
Stock options	8,417,920	9,114,459	10,869,173
Warrants	2,908,000	72,564	321,976
Total	11,325,920	9,187,023	11,191,149

#### COMPREHENSIVE INCOME (LOSS)

Comprehensive income (loss) is composed of net income (loss) and other comprehensive income. Other comprehensive income, for the year ended December 31, 2009, is comprised of unrealized gains on the Company's available-for-sale long-term investment securities that are excluded from net income and reported separately in stockholders' equity. Comprehensive income (loss) and its components are as follows:

(in thousands)	For the year ended December 31		
	2009	2008	2007
Net income (loss)	\$ 10,485	\$ (52,881)	\$ (90,062)
Unrealized gain on available-for-sale long-term investment securities	180	—	—
Comprehensive income (loss)	\$ 10,665	\$ (52,881)	\$ (90,062)

#### 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.

#### IMPAIRMENT

Long lived assets are reviewed for 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 ADI 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 ADI. 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.

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Goodwill is reviewed for impairment annually, or when events arise that could indicate that an impairment exists. The Company tests for goodwill impairment 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 and 2009, management conducted its annual assessments of goodwill and concluded that there were no impairments to its goodwill. The Company will continue to perform impairment tests 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 held-to-maturity investments with multiple financial institutions that invest in investment-grade securities with average maturities of less than twelve months. The Company also holds a long-term investment in an auction rate security. See Note 3 – Investment Securities and Note 4 – Fair Value Measurements.

#### SUBSEQUENT EVENTS

The Company has performed a review of events subsequent to the balance sheet date through the date the financial statements were available for issuance.

#### NOTE 2 – CASH AND CASH EQUIVALENTS

(in thousands)	December 31, 2009		December 31, 2008	
Money market funds	\$	13,400	\$	12,159
Checking and bank deposits		2,986		984
<b>Total</b>	<b>\$</b>	<b>16,386</b>	<b>\$</b>	<b>13,143</b>

Cash is maintained in FDIC insured accounts at credit qualified financial institutions. At times, such amounts may exceed the FDIC insurance limits. In October 2008, the FDIC increased its insurance from \$100,000 per depositor to \$250,000, and to an unlimited amount for non-interest bearing accounts. The coverage increase, which is temporary, extends through December 31, 2013 for interest bearing accounts and June 30, 2010 for non-interest bearing accounts. At December 31, 2009 uninsured cash balances totaled approximately \$14.8 million.

## 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 income (expense), net, and unrealized gains, if determined to be temporary, are included in accumulated other comprehensive income in stockholders' equity. The following tables summarize the Company's investment securities at December 31, 2009 and December 31, 2008:

(in thousands)	Amortized cost, as adjusted	December 31, 2009		Estimated fair value
		Gross unrealized holding gains	Gross unrealized holding losses	
<b>Short-term investments:</b>				
Obligations of domestic governmental agencies (mature between January 2010 and March 2010) (held-to-maturity)	\$ 12,532	\$ —*	\$ (1)	\$ 12,531
Bank deposits (matures July 2010) (held-to-maturity)	5,016	—	—	5,016
<b>Total short-term investment securities</b>	<b>\$ 17,548</b>	<b>\$ —*</b>	<b>\$ —</b>	<b>\$ 17,547</b>
<b>Long-term investments:</b>				
Auction rate security (matures 2038) (available-for-sale)	\$ 1,914	\$ —	\$ —	\$ 1,914

\*Amount less than one thousand dollars.

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

## NOTE 4 – FAIR VALUE MEASUREMENTS

As of January 1, 2008, the Company adopted an accounting standard that defines fair value, establishes a fair value hierarchy for assets and liabilities measured at fair value and requires expanded disclosures about fair value measurement. As a result, the Company measures certain financial assets and liabilities at fair value on a recurring basis in the financial statements. The 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, 2009, the Company has a \$1.9 million long-term investment in one auction rate student loan-backed security. 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 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. The Company is uncertain as to when, or if, the liquidity issue relating to its one remaining auction rate security investment will improve. Quarterly, the Company assesses 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 \$0.1 and \$3.2 million during the years ended December 31, 2009 and 2008, respectively, 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 income (expense), net. For the year ended December 31, 2009, the Company reported other comprehensive income of \$0.2 million for a temporary unrealized gain related to the increase in estimated fair value for the Company's one remaining auction rate security. The estimated fair value of the Company's one remaining auction rate security investment (\$3.0 million par value) is \$1.9 million at December 31, 2009.

In 2009, the Company sold four of its auction rate security investments. The securities had a combined par value of \$7.0 million and a combined adjusted book value of \$5.4 million. Proceeds to the Company from the sale of these securities were \$5.6 million, representing a gain of \$0.2 million over adjusted book value.

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

The Company reviews investment securities for impairment and 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 as of December 31, 2009 and 2008:

(in thousands)	Financial assets at fair value as of December 31, 2009		
	Level 1	Level 2	Level 3
Money market funds (1)	\$ 13,400	\$ —	\$ —
Obligations of domestic governmental agencies (held-to-maturity) (2)	12,532	—	—
Bank deposits (held-to-maturity)	5,016	—	—
Auction rate security (3)	—	—	1,914
Total	\$ 30,948	\$ —	\$ 1,914

Financial assets at fair value  
as of December 31, 2008

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(in thousands)	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 years ended December 31, 2008 and 2009:

(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
Total impairment charges included in net income (loss)	(68)
Sales of securities	(5,556)
Realized gain on sales of securities	173
Other comprehensive income (temporary unrealized gain)	180
Balance at December 31, 2009	\$ 1,914

(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, 2009		December 31, 2008	
Leasehold improvements	\$	20	\$	20
Office furniture and equipment		315		315
Computers, software and related equipment		440		436
		775		771
Accumulated depreciation and amortization		(681)		(589)
Net book value	\$	94	\$	182

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 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 subsequently sold during 2008. The sale of the assets offset a related 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 17 – Restructuring.

Depreciation expense for the years ended December 31, 2009, 2008 and 2007 was approximately \$92,000, \$111,000 and \$130,000, respectively. The following table summarizes depreciation expense for the years ended December 31, 2009, 2008 and 2007.

(in thousands)	For the year ended December 31		
	2009	2008	2007
Depreciation expense:			
Cost of services	\$ —	\$ —	\$ —
Research and development	55	84	86
General and administrative	37	27	44
Total	\$ 92	\$ 111	\$ 130

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## NOTE 6 – GOODWILL

On April 6, 2006, ADI, a wholly-owned subsidiary of the Company, completed the acquisition of Accumin™, a novel, patent protected, diagnostic for the direct measurement of total, intact urinary albumin, from AusAm Biotechnologies, Inc. (“AusAm”). The 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 ADI transaction has been accounted for as a purchase by the Company. The excess of the purchase price over the net assets acquired in the ADI 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 ADI product and ceased all operations related to the Diagnostic segment. See Note 8 – Discontinued Operations.

## NOTE 7 - OTHER ASSETS

(in thousands)	December 31, 2009	December 31, 2008
Patents and other intangible assets	\$ 352	\$ 352
Long-term deposits	62	62
Deferred registration fees	19	22
	433	436
Accumulated amortization	(352)	(352)
	\$ 81	\$ 84

Amortization expense for the years ended December 31, 2009, 2008 and 2007 was approximately \$0, \$0, and \$14,000, 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 ADI 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. 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:

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(in thousands)	2009	2008	2007
Diagnostic revenue	\$ —	\$ —	\$ 66
Operating expenses:			
Cost of diagnostics sold	—	—	38
Research and development	—	4	6
Selling, general and administrative	—	171	778
Total operating expenses	—	175	822
Loss from discontinued operations	\$ —	\$ (175)	\$ (756)

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 ADI 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 ADI. 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, 2009 and 2008 on the accompanying consolidated balance sheets. The major assets and liabilities categories are as follows:

(in thousands)	December 31, 2009		December 31, 2008	
<b>Assets</b>				
Assets of discontinued operations	\$	—	\$	—
<b>Liabilities</b>				
Accounts payable and accrued expenses	\$	120	\$	120
Liabilities of discontinued operations	\$	120	\$	120

#### 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. Effective as of June 8, 2009, the Company entered into an Amended and Restated Sublicense Agreement (the “Revised Agreement”) with JT and Torii, which, among other things, provided for the elimination of all significant on-going obligations under the sublicense agreement. Accordingly, in accordance with the Company’s revenue recognition policies, all remaining deferred revenue pertaining to this sublicense has been recognized in the year ended December 31, 2009.

Prior to the Revised Agreement, an upfront payment of \$12.0 million, which was received in October 2007, was 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 represented the estimated period over which the Company had certain significant ongoing responsibilities under the original sublicense agreement. An additional milestone payment of \$8.0 million, for the achievement of certain milestones reached in March 2008, was received in April 2008, and was being recognized as license revenue on a straight-line basis over the life of the original agreement (as discussed above). As a result of the signing of the Revised Agreement, as discussed above, the unamortized portion of the upfront payment of \$12.0 million and the additional milestone payment of \$8.0 million, approximately \$18.0 million, was recognized in the year ended December 31, 2009.

In March 2009, JT and Torii informed the Company that they had initiated a Phase 2 clinical study of Zerenex in Japan, which triggered a \$3.0 million non-refundable milestone payment, which was received by the Company in March 2009. As a result, the Company recorded license revenue of \$3.0 million in accordance with its revenue recognition policy, which is included in the year ended December 31, 2009.

The Company may receive up to an additional \$77.0 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 July 2009, the Company settled a dispute with Alfa Wassermann S.p.A. over issues arising from the terminated license agreement for Sulonex (sulodexide). Under the terms of the settlement agreement, Alfa Wassermann will pay the Company \$3,500,000 (of which \$2,750,000 was received on July 31, 2009, and \$750,000 will be paid on or before July 30, 2010), and the Company is required to deliver to Alfa Wassermann all of its data, information and other intellectual property related to Sulonex.



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.

On December 16, 2009, the Company announced the initiation of a Phase 3 registration trial of KRX-0401 (perifosine) for treatment of patients with advanced multiple myeloma. The achievement of this event triggered contingent milestone stock consideration payable to the former stockholders of ACCESS Oncology in the amount of an aggregate of 500,000 shares of Keryx common stock valued at \$1,365,000.

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

- 750,000 shares of the Company’s common stock upon the first new drug application acceptance by the Food and Drug Administration, or FDA, for any of the acquired ACCESS Oncology drug candidates;
- 1,750,000 shares of the Company’s common stock upon the first FDA approval of any of the acquired ACCESS Oncology drug candidates; and
- 372,422 shares of the Company’s common stock following the first 12-month period that sales of all of the acquired ACCESS Oncology drug candidates combined exceeds \$100 million.

In no event will the Company issue more than 4,000,000 shares of its common stock pursuant to the merger agreement. These 4,000,000 shares include 1,127,578 shares issued or issuable to date and any contingent shares as described above. Accordingly, the remaining amount of the Company’s common stock deliverable to the former ACCESS Oncology stockholders as milestone consideration will be no more than 2,872,422 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. On the date of the acquisition, the excess of the net assets acquired over the purchase price represented negative goodwill of approximately \$4,004,000. Since the negative goodwill was 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) was recorded as a liability, thereby eliminating the negative goodwill. The maximum value of the contingent equity rights at the date of acquisition 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 consisted 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). On December 16, 2009, upon the issuance of 500,000 shares of contingent milestone consideration discussed above, the value of the contingent equity rights was reduced by \$1,365,000 to \$2,639,000.



## 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 September 30, 2009, the Company completed a registered direct offering to certain investors of 8,000,000 shares of its common stock and warrants to purchase up to a total of 2,800,000 shares of its common stock for gross proceeds of approximately \$20 million. The common stock and warrants were sold in units, with each unit consisting of one share of common stock and a warrant to purchase 0.35 of a share of common stock. The purchase price per unit was \$2.50. Subject to certain ownership limitations, the warrants are exercisable at any time on or after the initial issue date and on or prior to October 1, 2010, at an exercise price of \$2.65 per warrant share. In addition, the placement agent received a warrant to purchase up to 108,000 shares of common stock at an exercise price of \$3.125 per warrant share, exercisable at any time on or prior to October 1, 2010. Total proceeds to the Company from this public offering were approximately \$18.4 million, net of offering costs of approximately \$1.6 million. The shares and warrants were sold under a shelf registration statement on Form S-3 (File No. 333-161607) filed with the SEC on August 28, 2009, and declared effective by the SEC on September 23, 2009. The registration statement provides for the offering of up to \$40 million of the Company's common stock and warrants.

Subsequent to this registered direct offering, there remains approximately \$12.2 million of the Company's common stock and warrants available for sale under the shelf registration statement. The Company may offer the remaining securities under its shelf registration from time to time in response to market conditions or other circumstances if it believes such a plan of financing is in the best interest of the Company and its stockholders. The Company believes that the shelf registration provides it with the flexibility to raise additional capital to finance its operations as needed.

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

### 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, 2009, 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, 2009, up to 362,051 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 former Chief Executive Officer of the Company, Michael S. Weiss, to purchase up to 2,002,657 shares of authorized but unissued common stock. The option had a term of 10 years from the date of the grant. The option granted to Mr. Weiss 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. On April 23, 2009, the Company's board of directors voted to terminate the employment of Mr. Weiss as the Company's Chairman and Chief Executive Officer. As a result, as of December 31, 2009, 2,002,657 options remain outstanding and vested under this plan, and will remain exercisable until two years from the date of the termination of his employment. 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 former President of the Company to purchase up to 1,000,000 shares of authorized but unissued common stock. The option had 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, 2009, 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, 2009, up to an additional 1,046,215 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, 2009, up to an additional 1,219,752 shares may be issued under the 2007 Incentive Plan.

g. The 2009 CEO Incentive Plan was adopted in May 2009. Under the 2009 CEO Incentive Plan, the Company's board of directors granted an option to Ron Bentsur, the Company's newly-appointed Chief Executive Officer, to purchase up to 600,000 shares of authorized but unissued common stock. The option has a term of 10 years from the date of grant. The option will vest in equal annual installments over a four-year period or upon an earlier change in control of the Company.

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Shares available for the issuance of stock options or other stock-based awards under the Company's stock option and incentive plans were 2,628,018 shares at December 31, 2009.

### Stock Options

The following table summarizes stock option activity for the years ended December 31, 2009, 2008 and 2007:

	Number of shares	Weighted-average exercise price	Weighted-average Contractual Term (in years)	Aggregate Intrinsic Value
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		
Granted	700,000	0.55		
Exercised	(50,000)	0.36		\$ 85,300
Forfeited	(159,467)	6.75		
Expired	(251,420)	11.16		
Outstanding at December 31, 2009	9,353,572	\$ 6.63	3.3	\$ 6,513,185
Vested and expected to vest at December 31, 2009	9,321,998	\$ 6.64	3.3	\$ 6,468,325
Exercisable at December 31, 2009	8,316,711	\$ 6.87	2.6	\$ 5,174,085

The following table summarizes information about stock options outstanding at December 31, 2009:

Range of exercise prices	Options outstanding			Options exercisable		
	Number outstanding	Weighted-average remaining contractual life (years)	Weighted-average exercise price	Number exercisable	Weighted-average exercise price	
\$ 0.10 -						
\$ 2.19 - 4.59	4,784,319	3.6	\$ 1.14	4,104,319	\$ 1.24	
- 8.98 - 9.25	497,171	4.0	7.57	426,504	7.41	
- 14.64	4,072,082	2.8	12.96	3,785,888	12.90	
\$ 0.10 - \$ 14.64	9,353,572	3.3	\$ 6.63	8,316,711	\$ 6.87	

Upon the exercise of stock options, the Company issues new shares of its common stock. As of December 31, 2009, 3,328,833 options issued to employees, and 93,000 options issued to consultants, are milestone-based, of which 3,203,833 options issued to employees, and 43,000 options issued to consultants, are vested and exercisable.

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## Restricted Stock

Certain employees, directors 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 three to four years. The following table summarizes restricted share activity for the years ended December 31, 2009, 2008 and 2007:

	Number of Shares	Weighted Average Grant Date Fair Value	Aggregate Intrinsic Value
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	
Granted	578,539	0.76	
Vested	(2,707,233)	0.32	\$ 1,325,377
Forfeited	(361,742)	0.34	
Outstanding at December 31, 2009	1,492,136	\$ 0.59	\$ 3,730,340

On September 14, 2009, the Company entered in an employment agreement with Ron Bentsur, its Chief Executive Officer. The agreement terminates on May 20, 2012, provided, however, that Mr. Bentsur's opportunity to earn the milestone awards described below will be effective until May 20, 2014, subject to certain early termination events. Mr. Bentsur has the opportunity to earn certain milestone awards as follows:

(1) 100,000 shares of restricted stock were granted to Mr. Bentsur on September 22, 2009, for the achievement of a \$1.00 share price of the Company's common stock for 120 consecutive days (based upon the average closing price of the Company's common stock for a 120-day period after May 20, 2009). The restricted stock will vest in equal installments over each of the first three anniversaries of the date of grant provided that Mr. Bentsur remains an employee of the Company during such vesting period, or immediately upon achievement of milestone #2 below.

(2) 250,000 shares of restricted stock will be granted to Mr. Bentsur upon the achievement of a \$2.50 share price of the Company's common stock for 120 consecutive days (based upon the average closing price of the Company's common stock for a 120-day period after May 20, 2009). Such restricted stock will vest in equal installments over each of the first three anniversaries of the date of grant provided that Mr. Bentsur remains an employee of Keryx during such vesting period.

(3) 400,000 shares of restricted stock will be granted to Mr. Bentsur upon the first to occur of (a) the Company's filing of an accepted new drug application, or NDA, with the U.S. Food and Drug Administration for Zerenex or Perifosine, or (b) the Company's outlicensing of Zerenex or Perifosine in the U.S. to a third party. Such restricted stock will vest in equal installments over each of the first three anniversaries of the date of grant provided that Mr. Bentsur remains an employee of the Company during such vesting period. This milestone #3 may be achieved with respect to NDAs or qualifying outlicenses for multiple indications of the same product, but not for subsequent outlicenses of the product relating to an indication for which the milestone is met. Upon achievement of milestone #4 below with respect to a

product, the restricted stock granted for one indication of the product under milestone #3 above will vest in full.

(4) 500,000 shares of restricted stock will be granted to Mr. Bentsur, upon the first to occur of (a) the Company's first commercial sale of Zerenex or Perifosine in the U.S. off an approved NDA, (b) the Company's receipt of the first royalty upon the commercial sale of Zerenex or Perifosine in the U.S. by a partner to whom the Company has sold exclusive or non-exclusive commercial rights, or (c) the Company's complete outlicensing of the entire product rights of Zerenex or Perifosine in the U.S. Such restricted stock will vest on the first anniversary of the date of grant provided that Mr. Bentsur remains an employee of the Company during such vesting period.

(5) 100,000 shares of restricted stock will be granted to Mr. Bentsur upon each event of the Company's outlicensing Zerenex in a foreign market, other than Japan, resulting in a greater than \$10 million non-refundable cash payment to the Company with a gross deal value to the Company of at least \$50 million. Such restricted stock will vest in equal installments over each of the first three anniversaries of the date of grant provided that Mr. Bentsur remains an employee of the Company during such vesting period.

As of December 31, 2009, Mr. Bentsur has been granted a total of 100,000 shares of restricted stock based on the milestone awards listed above. On March 23, 2010, upon achievement of the second milestone, listed above, Mr. Bentsur was granted 250,000 shares of restricted stock, and the 100,000 restricted shares previously granted to Mr. Bentsur for the first milestone were immediately vested.

## Warrants

The following table summarizes warrant activity for the years ended December 31, 2009, 2008 and 2007:

	Warrants	Weighted- average exercise price	Aggregate Intrinsic Value
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	
Issued	2,908,000	2.67	
Exercised	(64,174)	0.01	\$ 134,335
Expired	(8,390)	0.01	
Outstanding at December 31, 2009	2,908,000	\$ 2.67	\$ —

The terms of outstanding warrants as of December 31, 2009 are as follows:

Range of exercise prices	Number outstanding	Warrants outstanding		Warrants exercisable	
		Weighted- average remaining contractual life (years)	Weighted- average exercise price	Number exercisable	Weighted- average exercise price
\$ 2.65	2,800,000	0.75	\$ 2.65	2,800,000	\$ 2.65
3.125	108,000	0.75	3.125	108,000	3.125

As discussed above, as part of the registered direct offering completed on September 30, 2009, the Company issued warrants to purchase up to 2,800,000 shares of the Company's common stock. The warrants have an exercise price of \$2.65 per warrant share and, subject to certain ownership limitations, are exercisable at any time on or after the initial issue date and on or prior to October 1, 2010. The grant date fair value was \$1.03 per warrant, for a total fair value of \$2,877,000, which is included in additional paid-in capital on the consolidated balance sheet. In addition, the Company issued to the placement agent in the transaction warrants to purchase up to 108,000 shares of its common stock at an exercise price of \$3.125 per warrant share, exercisable at any time on or prior to October 1, 2010, with a grant date fair value of \$0.93 per warrant. The fair value of the warrants described above is estimated at the date of grant using the Black-Scholes pricing model. For as long as the warrants issued in the registered direct offering are outstanding, if there is no effective registration statement covering the resale of the warrant shares by the holders, such warrants may be exercisable, in whole or in part, at such time by means of a "cashless exercise."



## Stock-Based Compensation

The fair value of stock options granted is estimated at the date of grant using the Black-Scholes pricing 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	2009	2008	2007
Risk-free interest rates	2.0%	2.6%	4.1%
Dividend yield	—	—	—
Volatility	123.7%	76.3%	68.4%
Weighted-average expected term	4.7 years	4.3 years	4.8 years

The weighted average grant date fair value of options granted was \$0.44, \$2.40 and \$5.69 per option for the years ended December 31, 2009, 2008 and 2007, respectively. The Company used historical information to estimate forfeitures within the valuation model. As of December 31, 2009, there was \$1.0 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 1.9 years and 2.0 years, respectively. The amounts do not include, as of December 31, 2009, 175,000 options outstanding, 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.

On April 23, 2009, the Company's Board of Directors voted to terminate the employment of Michael S. Weiss as the Company's Chairman and Chief Executive Officer (see Note 1). Under the terms of Mr. Weiss' employment agreement, 1,800,000 shares of restricted stock vested, which is included in the restricted share activity table above. In addition, all of Mr. Weiss' outstanding stock options vested and will remain exercisable for two years following termination. In the second quarter of 2009, the Company recorded approximately \$660,000 in non-cash compensation expense (selling, general and administrative) associated with the equity modifications of Mr. Weiss' outstanding stock options and shares of restricted stock.

The following table summarizes stock-based compensation expense information about stock options and restricted stock for the years ended December 31, 2009, 2008 and 2007:

(in thousands)	Year ended December 31,		
	2009	2008	2007
Stock-based compensation expense associated with restricted stock (1)	\$ 1,220	\$ (114)	\$ 1,028
Stock-based compensation expense associated with option grants (2)	1,880	6,862	9,632
	\$ 3,100	\$ 6,748	\$ 10,660

(1) Includes a \$290,000 credit to compensation expense in the year ended December 31, 2008, related to restricted stock issued the Company's former President, who was terminated as part of the 2008 Restructuring.

(2) Includes \$660,000 of non-cash compensation expense in the year ended December 31, 2009, related to equity modifications of stock options and restricted stock issued to the previous Chief Executive Officer, who was terminated in April 2009.

NOTE 12 – INCOME TAXES

The Company accounts for income taxes under the asset and liability method. Deferred tax assets and liabilities are determined based on differences between the financial reporting and tax basis of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. A valuation allowance is established when necessary to reduce deferred tax assets to the amount expected to be realized. In determining the need for a valuation allowance, management reviews both positive and negative evidence, including current and historical results of operations, future income projections and the overall prospects of the Company's business. Based upon management's assessment of all available evidence, the Company believes that it is more-likely-than-not that the deferred tax assets will not be realizable; and therefore, a valuation allowance is established. The valuation allowance for deferred tax assets was \$133.1million and \$141.8 million as of December 31, 2009 and 2008, respectively.

As of December 31, 2009, the Company has U.S. net operating loss carryforwards ("NOL's") of approximately \$270.6 million, of which approximately \$36.5 million were derived from certain stock option exercises and any such benefit realized will be credited to additional paid in capital. For income tax purposes, these NOL's will expire in the years 2019 through 2029. Due to the Company's various equity transactions, the utilization of certain NOL's could be subject to annual limitations imposed by Internal Revenue Code Section 382 relating to the change of control provision and/or the separate return limitation year losses limitation.

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 Yisum revenue (see Note 9). No income tax expense was attributable to income from continuing operations for the years ended December 31, 2009 and 2008. 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,		
	2009	2008	2007
Income (losses) from continuing operations before income taxes, as reported in the consolidated statements of operations	\$ 10,485	\$ (52,706)	\$ (89,270)
Computed "expected" tax expense (benefit)	3,670	(18,447)	(31,245)
Increase (decrease) in income taxes resulting from:			
Expected expense (benefit) from state & local taxes	846	(4,869)	(4,563)
Change in state and local effective tax rate	4,876	(4,387)	4,533
Unrecognized compensation deduction	—	—	7,053
Permanent differences	(125)	523	447
Withholding tax	—	—	36
Other	83	(60)	159
Prior year true-up	(658)		
Change in the balance of the valuation allowance for deferred tax assets allocated to income tax expense	(8,692)	27,240	23,616
	\$ —	\$ —	\$ 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,		
	2009	2008	2007
Deferred tax expense (benefit)	\$ 8,520	\$ (27,154)	\$ (23,883)
Federal deferred tax benefit relating to the exercise of stock options	172	(86)	267
(Decrease) Increase in the valuation allowance for deferred tax asset	(8,692)	27,240	23,616
	\$ —	\$ —	\$ —

The tax effects of temporary differences that give rise to significant portions of the deferred tax assets and deferred tax liabilities at December 31, 2009 and 2008 are presented below.

(in thousands)	December 31, 2009	December 31, 2008
Deferred tax assets (liabilities):		
Net operating loss carryforwards	\$ 116,533	\$ 119,880
Non-cash compensation	14,001	13,528

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Deferred revenue	—	4,737
Unrealized loss on securities	1,242	1,292
Research and development	330	939
Intangible assets due to different amortization methods	761	1,009
Accrued compensation	104	299
Other temporary differences	98	77
Deferred tax asset, excluding valuation allowance	133,069	141,761
Less valuation allowance	(133,069)	(141,761)
Net deferred tax assets	\$ —	\$ —

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The Company files income tax returns in the U.S federal and various state and local jurisdictions. For federal and state income tax purposes, the 2007, 2008 and 2009 tax years remain open for examination under the normal three year statute of limitations. The audits of the Company's U.S. federal income tax returns for 2004 through 2006 were completed in 2008 and the unrecognized tax benefits balance was reduced from \$7.05 million to \$0 at December 31, 2008. Currently, the Company's New York City tax returns for tax years 2006 and 2007 are under audit. The Company believes that it is more-likely-than-not that its tax positions on the 2006 and 2007 New York City income tax returns will prevail, and therefore, no uncertain tax position liabilities are recorded for 2009.

Effective January 1, 2007, the Company adopted guidance under ASC Topic 740-10 which clarifies the accounting and disclosure for uncertainty in income taxes. The adoption of this interpretation did not have a material impact on the Company's financial statements.

The Company is continuing its practice of recognizing interest and penalties related to income tax matters in income tax expense. There was no accrual for interest and penalties related to uncertain tax positions for 2009, 2008 and 2007. The Company does not believe that there will be a material change in its unrecognized tax positions over the next twelve months. All of the unrecognized tax benefits, if recognized, would be offset by the valuation allowance.

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

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

(in thousands)	For the year ended December 31,		
	2009	2008	2007
Interest income	\$ 315	\$ 1,349	\$ 4,550
Other income	247	101	5
Gain on sale of auction rate securities	173	81	—
Impairment expense of auction rate securities	(68)	(3,196)	—
	\$ 667	\$ (1,665)	\$ 4,555

In 2009 and in 2008, the Company recorded impairment charges totaling \$68,000 and \$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). Other income consists of rental income from the sublease of a portion of the Company's leased space.

#### 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 KRX-0401 and Zerenex) under which it is obligated to make payments of approximately \$4,341,000 through June 2012. The following table shows future research and development payment obligations by period as of December 31, 2009.

(in thousands)	2010	2011	2012	2013	2014
Research and development agreements	\$ 2,284	\$ 1,543	\$ 514	—	—

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

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## Leases

The Company leases its office space under a lease agreement that expires in October 2010. Total rental expense was approximately \$540,000, \$658,000 and \$723,000 for the years ended December 31, 2009, 2008, and 2007, respectively. The Company recognized sublet income of \$247,000 and \$101,000 for the years ended December 31, 2009 and 2008 related to office sharing agreements.

Future minimum lease commitments as of December 31, 2009, in the aggregate total approximately \$459,000 through October 2010. The following table shows future minimum lease commitments by period as of December 31, 2009.

(in thousands)	2010	2011	2012	2013	2014
Operating leases	\$ 459	—	—	—	—

During 2004, the Company entered into a lease arrangement with its former President 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 expensed \$16,000 and \$65,000 in 2008 and 2007, pursuant to the terms of this former arrangement. All amounts were 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 \$41.1 million over the life of the licenses, of which approximately \$36.6 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 2,872,422 shares of the Company's common stock) if KRX-0401 meets certain development and sales milestones. The contingent equity rights have been recognized as a non-current liability on the consolidated balance sheet. See Note 10 – Contingent Equity Rights. The uncertainty relating to the timing of the commitments described in this paragraph prevents the Company from including them in the tables above.

## NOTE 15 – SEGMENT INFORMATION

Until September 2008, the Company had three reportable segments, which included the Diagnostics segment. Following the termination of the ADI 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 pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease, and also includes license revenue, other revenue and associated costs.

Segment information for the years ended December 31, 2009, 2008 and 2007 was as follows:

(in thousands)	2009	Revenue 2008	2007
Services	\$ 3	\$ 103	\$ 52

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Products	25,191	1,180	931
<b>Total</b>	<b>\$ 25,194</b>	<b>\$ 1,283</b>	<b>\$ 983</b>

(in thousands)	Operating income (loss)		
	2009	2008	2007
Services	\$ 3	\$ 76	\$ (72)
Products	9,815	(51,117)	(93,753)
<b>Total</b>	<b>\$ 9,818</b>	<b>\$ (51,041)</b>	<b>\$ (93,825)</b>

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

(in thousands)	Income (loss) from continuing operations		
	2009	2008	2007
Operating income (losses) of reportable segments	\$ 9,818	\$ (51,041)	\$ (93,825)
Interest and other income (expense)	667	(1,665)	4,555
Income taxes	—	—	(36)
Consolidated income (loss) from continuing operations	\$ 10,485	\$ (52,706)	\$ (89,306)

(in thousands)	Assets (1)	
	As of December 31,	
	2009	2008
Services	\$ —	\$ —
Products	4,904	3,982
Total assets of reportable segments	4,904	3,982
Cash, cash equivalents, interest receivable and investment securities	35,914	22,652
Assets of discontinued operations	—	—
Consolidated total assets	\$ 40,818	\$ 26,634

(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, 2009 and 2008 was as follows:

(in thousands)	Goodwill	
	December 31, 2009	December 31, 2008
Services	—	—
Products	\$ 3,208	\$ 3,208
Total	\$ 3,208	\$ 3,208

#### NOTE 16 - LITIGATION

In March 2010, the Company settled a dispute with ICON Central Laboratories ("ICON"), the central laboratory it used for the clinical development of Sulonex (sulodexide), concerning certain fees related mainly to the provision of storage services pursuant to a series of service agreements. ICON was claiming that the Company owed it \$816,647 in unpaid invoices, much of which is made up of charges for annual storage fees incurred after the effective date of termination of the agreements. Under the terms of the settlement agreement, the Company paid ICON \$400,000 in settlement of all claims, which, at December 31, 2009, was included in accounts payable and accrued expenses on the Company's balance sheet.

In October 2009, the Company filed a statement of claim with the Financial Institution Regulatory Authority ("FINRA") to commence an arbitration proceeding against an SEC registered broker-dealer. In this arbitration proceeding, the Company is seeking damages arising from that broker-dealer's recommendations and purchases of auction rate securities for the Company's cash management account. The claim will be determined by a panel of three FINRA

arbitrators. In January 2010, the broker-dealer filed an answer to the statement of claim and denied liability. The parties are in the process of selecting an arbitration panel.

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## NOTE 17 – 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, the Company’s current Chief Financial Officer.

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
<b>Research and development</b>	
Impairment of manufacturing facility	\$ 11,037
Manufacturing facility restoration	2,063
Severance	624
Non-cash compensation	(1,569)
Total research and development	12,155
<b>Selling, general and administrative</b>	
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 18 – QUARTERLY CONSOLIDATED FINANCIAL DATA (UNAUDITED)

	2009			
	Mar. 31	June 30	Sept. 30	Dec. 31
	(in thousands, except per share data)			
<b>Revenue:</b>				
License revenue	\$ 3,327	\$ 18,289	\$ —	\$ —
Service revenue	3	—	—	—
Other revenue	—	75	3,500	—
<b>Total revenue</b>	<b>3,330</b>	<b>18,364</b>	<b>3,500</b>	<b>—</b>
<b>Operating expenses:</b>				
Cost of services	—	—	—	—
<b>Research and development:</b>				
Non-cash compensation	201	361	388	283
Other research and development	1,374	1,456	1,527	3,015
<b>Total research and development</b>	<b>1,575</b>	<b>1,817</b>	<b>1,915</b>	<b>3,298</b>
<b>Selling, general and administrative:</b>				
Non-cash compensation	370	1,028	250	219
Other selling, general and administrative	1,041	1,528	904	1,431
<b>Total selling, general and administrative</b>	<b>1,411</b>	<b>2,556</b>	<b>1,154</b>	<b>1,650</b>
<b>Total operating expenses</b>	<b>2,986</b>	<b>4,373</b>	<b>3,069</b>	<b>4,948</b>
<b>Operating income (loss)</b>	<b>344</b>	<b>13,991</b>	<b>431</b>	<b>(4,948)</b>
<b>Other income (expense)</b>				
Interest and other income (expense), net	107	141	129	290
Income taxes	—	—	—	—
<b>Income (loss) from continuing operations</b>	<b>451</b>	<b>14,132</b>	<b>560</b>	<b>(4,658)</b>
<b>Loss from discontinued operations</b>	<b>—</b>	<b>—</b>	<b>—</b>	<b>—</b>
<b>Net income (loss)</b>	<b>\$ 451</b>	<b>\$ 14,132</b>	<b>\$ 560</b>	<b>\$ (4,658)</b>
<b>Basic net income (loss) per common share</b>				
Continuing operations	0.01	0.30	0.01	(0.08)
Discontinued operations	—	—	—	—
<b>Basic net income (loss) per common share</b>	<b>\$ 0.01</b>	<b>\$ 0.30</b>	<b>\$ 0.01</b>	<b>\$ (0.08)</b>
<b>Diluted net income (loss) per common share</b>				
Continuing operations	0.01	0.29	0.01	(0.08)
Discontinued operations	—	—	—	—
<b>Diluted net income (loss) per common share</b>	<b>\$ 0.01</b>	<b>\$ 0.29</b>	<b>\$ 0.01</b>	<b>\$ (0.08)</b>



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

\*Amount less than once cent

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 25, 2010

KERYX BIOPHARMACEUTICALS,  
INC.

By: /s/ Ron Bentsur  
Ron Bentsur  
Chief Executive Officer  
and Director

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Ron Bentsur 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 25, 2010, and in the capacities indicated:

Signatures	Title
/s/ Ron Bentsur Ron Bentsur	Chief Executive Officer and Director (principal executive officer)
/s/ James F. Oliviero James F. Oliviero	Chief Financial Officer (principal financial and accounting officer)
/s/ Michael P. Tarnok Michael P. Tarnok	Chairman of the Board of Directors
/s/ Kevin Cameron Kevin Cameron	Director
/s/ Senator Wyche Fowler, Jr. Senator Wyche Fowler, Jr.	Director
/s/ Jack Kaye Jack Kaye	Director





EXHIBIT INDEX

Exhibit Number	Exhibit Description
21.1	List of subsidiaries of Keryx Biopharmaceuticals, Inc.
23.1	Consent of UHY LLP.
23.2	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 25, 2010.
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 25, 2010.
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 25, 2010.
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 25, 2010.

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