KERYX BIOPHARMACEUTICALS INC
Form 424B5
May 04, 2011
PROSPECTUS SUPPLEMENT (TO PROSPECTUS DATED JANUARY 28, 2011)

7,021,277 Shares
Common Stock
$4.70 per share

We are offering 7,021,277 shares of our common stock, $0.001 par value per share, in this offering.

Our common stock is traded on the Nasdaq Capital Market under the symbol "KERX." On May 3, 2011, the last reported sale price of our common stock on the Nasdaq Capital Market was $4.92 per share.

Investing in our common stock involves a high degree of risk. See "Risk Factors" beginning on page S-5.

	Per share	Total
Public offering price	$4.700	$33,000,002
Underwriting discount and commissions	$0.282	$1,980,000
Proceeds, before expenses, to us	$4.418	$31,020,002

Delivery of the securities offered hereby is expected to be made on or about May 9, 2011.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus supplement or the accompanying prospectus. Any representation to the contrary is a criminal offense.

Sole Book-Running Manager
Stifel Nicolaus Weisel

Oppenheimer & Co.
Roth Capital Partners
Rodman & Renshaw, LLC
Brean Murray, Carret & Co.
Ladenburg Thalmann & Co. Inc.

The date of this prospectus supplement is May 4, 2011.

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Prospectus Supplement

Prospectus

ABOUT THIS PROSPECTUS SUPPLEMENT

This document is in two parts. The first part is this prospectus supplement, which describes the specific terms of this common stock offering and also adds to and updates information contained in the accompanying prospectus and the documents incorporated by reference herein. The second part, the accompanying prospectus, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. To the extent there is a conflict between the information contained in this prospectus supplement and the information contained in the accompanying prospectus or any document incorporated by reference therein filed prior to the date of this prospectus supplement, you should rely on the information in this prospectus supplement; provided that if any statement in one of these documents is inconsistent with a statement in another document having a later date — for example, a document incorporated by reference in the accompanying prospectus — the statement in the document having the later date modifies or supersedes the earlier statement.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit to any document that is incorporated by reference herein were made solely for the benefit of the parties to such agreement, including, in some cases, for the purpose of allocating risk among the parties to such agreements, and should not be deemed to be a representation, warranty or covenant to you. Moreover, such representations, warranties or covenants were accurate only as of the date when made. Accordingly, such representations, warranties and covenants should not be relied on as accurately representing the current state of our affairs.

You should rely only on the information contained in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering. We have not authorized, and the underwriters have not authorized, anyone to provide you with information that is different. The information contained in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering is accurate only as of the respective dates thereof, regardless of the time of delivery of this prospectus supplement, the accompanying prospectus or free writing prospectus, if any, or of any sale of our common stock. It is important for you to read and consider all information contained in this prospectus supplement and the accompanying prospectus, including the information incorporated by reference into this prospectus supplement and the accompanying prospectus, and any free writing prospectus that we have authorized for use in connection with this offering in making your investment decision. You should also read and consider the information in the documents to which we have referred you in the sections entitled “Where You Can Find More Information” and “Incorporation of Certain Information by Reference” in this prospectus supplement.

We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The distribution of this prospectus supplement and the accompanying prospectus and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States who come into possession of this prospectus supplement and the accompanying prospectus must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless otherwise stated, all references in this prospectus to “we,” “us,” “our,” “Keryx,” the “Company” and similar designation refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries. This prospectus supplement contains trademarks and trade names of Keryx Biopharmaceuticals, Inc., including our name and logo. Other service marks, trademarks and

trade names referred to in this document are the property of their respective owners.

SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

Certain matters discussed in this prospectus supplement and the accompanying prospectus 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" and elsewhere in this prospectus supplement, 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) and ZerenexTM (ferric citrate) 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 operating requirements, including expectations regarding the value and liquidity of our investments;
- expected losses; and
- expectations for future capital requirements.

The forward-looking statements contained in this prospectus supplement reflect our views and assumptions only as of the date this prospectus supplement. 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.

PROSPECTUS SUPPLEMENT SUMMARY

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus and in the documents we incorporate by reference. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the ‘‘Risk Factors’’ section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents incorporated by reference herein.

Our Business

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of 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, or 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, growth, differentiation and survival. KRX-0401 has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with other approved therapies. KRX-0401 is currently in Phase 3 clinical development for both refractory advanced colorectal cancer and multiple myeloma, and in Phase 1 and Phase 2 clinical development for several other tumor types. Each of the KRX-0401 Phase 3 programs is being conducted under Special Protocol Assessment, or SPA, agreements with the Food and Drug Administration, or FDA.

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

The table below summarizes the status of our product pipeline.

Product candidate	Target indication	Development status
KRX-0401 (perifosine)	Colorectal cancer	Phase 3 trial ongoing, under SPA
	Multiple myeloma	Phase 3 trial ongoing, under SPA
	Several other forms of cancer	Phase 1 & 2 trials ongoing
Zerenex™ (ferric citrate)	Hyperphosphatemia in patients with end-stage renal disease	U.S. Phase 3 program ongoing, under SPA
		Japan Phase 3 program ongoing by sublicensee (JT and Torii)

Company 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. For further information regarding us and our financial information, you should refer to our recent filings with the SEC. See "Where You Can Find More Information" and "Incorporation of Certain Information by Reference."

The Offering

Common stock offered by us	7,021,277 shares
Common stock to be outstanding after the offering	68,571,187 shares
Use of Proceeds	We intend to use the net proceeds from the sale of our common stock to fund the ongoing development of KRX-0401 (perifosine) and Zerenex™ (ferric citrate), to potentially in-license, acquire and develop additional drug candidates, and other general corporate purposes. See "Use of Proceeds" on page S-18.
Risk Factors	See "Risk Factors" beginning on page S-5 for a discussion of factors that you should consider before buying shares of our common stock.
Nasdaq Capital Market Symbol	KERX

The number of shares of common stock to be outstanding after the offering is based on 61,549,910 shares of common stock outstanding as of March 31, 2011.

The number of shares of common stock to be outstanding after this offering does not take into account:

- 7,989,528 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2011, with a weighted average exercise price of $6.94 per share;
- 2,872,422 shares of common stock issuable to the former stockholders of ACCESS Oncology, Inc. upon the achievement of certain milestones related to KRX-0401, which we acquired upon our merger with ACCESS Oncology in February 2004; and
- an aggregate of 1,330,681 shares of common stock reserved for future issuance under our stock option and incentive plans.

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 this Offering

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.

We currently have two shelf registration statements on Form S-3, filed and declared effective by the SEC, providing for the offering of up to approximately $79 million of common stock and warrants after the completion of this offering.

- On August 28, 2009, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-161607) and declared effective by the SEC on September 23, 2009. The registration statement provided for the offering of up to $40 million of our common stock and warrants. Subsequent to the registered direct offering completed on September 30, 2009, there remains approximately $12.2 million of our common stock and warrants available for sale under the shelf registration statement.

- On January 3, 2011, we filed with the SEC a shelf registration statement on Form S-3 (File No. 333-171517) that was declared effective by the SEC on January 28, 2011, providing for the offering of up to $100 million of our common stock and warrants to purchase our common stock, or approximately $67 million after the completion of this offering.

Future sales pursuant to these registration statements 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, stockholders' holdings may also be diluted if we enter into arrangements with third parties permitting us to issue shares of common stock in lieu of certain cash payments upon the achievement of milestones.

Our stockholders would also experience dilution if we are required to issue up to 2,872,422 shares of our common stock to former stockholders of ACCESS Oncology, Inc. upon the achievement of certain development and sales milestones related to KRX-0401.

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

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

- developments concerning our drug candidates;

- announcements of technological innovations by us or our competitors;

- introductions or announcements of new products by us or our competitors;
- announcements by us of significant acquisitions, strategic partnerships, joint ventures or capital commitments;
- changes in financial estimates by securities analysts;

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

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

We have broad discretion to use the net proceeds from this offering and our investment of these proceeds may not yield a favorable return.

Our management has broad discretion as to how to spend the proceeds from this offering and may spend these proceeds in ways with which our stockholders may not agree. Pending any such uses, we plan to invest the net proceeds of this offering in short-term and long-term, investment-grade, interest-bearing securities. These investments may not yield a favorable return to our stockholders.

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 March 31, 2011, we had an accumulated deficit of $348.2 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 that 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 currently conducting or planning clinical trials that seek to enroll patients with the same diseases that 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 U.S. 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, we have limited clinical experience with our new one gram caplet formulation for Zerenex, and therefore, there is no assurance that this new formulation will be safe and efficacious when assessed in a large and/or long-term clinical trial setting. We used this one gram caplet formulation in our completed Phase 3 short-term study for Zerenex and are currently using it in our ongoing Phase 3 long-term study for Zerenex. 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 clinical trial for KRX-0401 (perifosine) in relapsed / refractory multiple myeloma patients pursuant to a SPA with the FDA. In April 2010, we initiated a Phase 3 clinical trial for KRX-0401 (perifosine) in patients with refractory advanced colorectal cancer also pursuant to a SPA with the FDA. In May 2010 and in September 2010, we initiated two Phase 3 clinical trials for Zerenex (ferric citrate) as a treatment of hyperphosphatemia in patients with end-stage renal disease pursuant to a SPA with the FDA. 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 FDA, we may be subject to enhanced scrutiny. Additionally, even if the primary endpoint in a Phase 3 clinical trial 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. Even though our product candidate, KRX-0401, is designated for “fast track” in the indications of metastatic colorectal cancer and relapsed/refractory multiple myeloma, we cannot assure you that we will receive “priority review” status. Even with “fast track” or “priority review” status, such designations do not necessarily mean a faster development process or regulatory review process or necessarily confer any advantage with respect to approval compared to conventional FDA procedures.

In May 2011, we announced positive Scientific Advice from the European Medicines Agency, or EMA, for the development of Zerenex for the management and control of serum phosphorus in ESRD patients undergoing dialysis, and in pre-dialysis chronic kidney disease, or CKD, patients. The Scientific Advice from the EMA indicates that our current Phase 3 program in the U.S., if successful, in conjunction with safety data generated from other clinical studies with Zerenex, is considered sufficient to support a European marketing authorization application, or MAA, to the EMA for the indication in ESRD patients on dialysis. As a result, we believe that we will not need to conduct any additional clinical trials with Zerenex in order to obtain European approval in the dialysis setting. The Scientific Advice also provided us with a regulatory path forward in the pre-dialysis CKD setting in Europe. Scientific Advice is legally non-binding and is based on the current scientific knowledge, which may be subject to future changes. Many companies which have been provided with Scientific Advice by the EMA have ultimately failed to obtain a MAA for their drugs. Additionally, even if the primary endpoint in a Phase 3 clinical trial is achieved, the Scientific Advice does not guarantee approval. The EMA 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.

Additionally, we have never filed a NDA, or similar application for approval in the U.S., 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, or similar regulatory authority in other countries, 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, or regulatory authority of another country as applicable, 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 pre-clinical or 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 and liver toxicities that have 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. We have submitted to the FDA data from our short-term and long-term rat and canine pre-clinical studies for Zerenex. While the FDA has reviewed the data from these studies and has permitted us to continue with our Phase 3 clinical program, we can provide no assurance that the FDA will not raise any safety concerns in the future from these studies. 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. 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. The risk also remains that a clinical program conducted by one of our partners may raise efficacy or 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. Top-line results are based on a preliminary analysis of then available data (both safety and efficacy) and there is the risk that that such findings and conclusions could change following a more comprehensive review of the data.

We may not be able to replicate in our Phase 3 clinical program for Zerenex, the efficacy and safety results for Zerenex observed in the previous Phase 3 and Phase 2 clinical trials and the Open-Label Extension, or OLE, clinical trial. The positive effects of Zerenex on intravenous iron and erythropoietin use observed in the OLE clinical trial may not be reproducible. Further, any negative effects of the potential absorption and/or accumulation of ferric (iron) or citrate would significantly limit the likelihood of obtaining regulatory approval for Zerenex. 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.

Independent Data Safety Monitoring Committees, or DSMCs, are monitoring the safety of our Phase 3 clinical trials for KRX-0401 (perifosine) and Zerenex (ferric citrate) and, in accordance with the protocols for the clinical trials, will periodically assess whether the Phase 3 trials should continue as planned. The DSMCs have the authority to recommend placing a trial on clinical hold, temporarily or permanently, or recommend termination of the clinical trial, based on an evaluation of safety and efficacy. The DSMCs are independent from us and we have no control or influence on their decisions.

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

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

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

Our ability to conduct clinical trials and commercialize our product candidates will depend on the ability of such third parties to manufacture our products on a large scale at a competitive cost and in accordance with current good manufacturing practice, or cGMP, and other regulatory requirements, including requirements from federal and state environmental and safety regulatory agencies. Prior to approval, we will need to conduct validation studies that the FDA must review and approve. Significant scale-up of manufacturing may result in unanticipated technical challenges and may require additional validation studies that the FDA must review and approve. Contract manufacturers often encounter difficulties in scaling up production, including problems involving raw material supplies, production yields, scaled-up product characteristics, 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 cGMP, as well as other governmental regulations and corresponding foreign standards. While we periodically audit our contractors for adherence to regulatory requirements, we cannot assure you that unforeseen changes at these contractors may occur that change their regulatory standing. 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 complete 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 one supplier to source the ferric citrate active pharmaceutical ingredient. The loss of this 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 commercializing our products effectively.

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, including, but not limited to, the perception of the long-term effects of the potential absorption and/or accumulation of ferric (iron) or citrate resulting from the use of Zerenex;
- 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 U.S. 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 Akt and the PI3K pathway. Zerenex, if approved in the U.S., would compete with other FDA approved phosphate binders such as Renagel® (sevelamer hydrochloride) and Renvela® (sevelamer carbonate), both marketed by Genzyme Corporation (a wholly-owned subsidiary of Sanofi-Aventis), 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 U.S. in October 2008. In addition, upon the expiration of their core patents (expected in the U.S. in 2014), generic formulations of Renagel® and Renvela® may be launched, which could have a material effect on the pricing of phosphate binders.

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 May 4, 2011, we had 25 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 prospects 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 U.S. 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 U.S. 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. In the U.S., health care reform legislation titled the Patient Protection and Affordable Care Act and the Reconciliation Act was signed into law on March 23, 2010. This comprehensive legislation will affect the terms of public and private health insurance and have a substantial impact on the pharmaceutical industry. For example, the new law will impose an annual fee on manufacturers of branded prescription pharmaceuticals that will impact our products. Regulations to implement this and other provisions related to the research, marketing and sale of prescription pharmaceutical products could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses. Government-financed comparative efficacy research could also result in new practice guidelines, labeling or reimbursement policies that discourages use of our products.

For example, in July 2010, the Centers for Medicare & Medicaid Services, or CMS, released its final rule to implement a bundled prospective payment system for end-stage renal disease facilities as required by the Medicare

Improvements for Patients and Providers Act, or MIPPA. The final rule did not include oral medications without IV equivalents, such as phosphate binders, in the bundle until January 1, 2014. If phosphate binders are bundled into the composite rate beginning in 2014, separate Medicare reimbursement will no longer be available for phosphate binders. While it is too early to project the impact bundling may have on the phosphate binder industry, the impact could potentially cause dramatic price reductions for phosphate binders.

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 this authority may result in delays or increased costs during the period of product development, clinical trials and regulatory review and approval, which may also increase costs related to complying with new post-approval regulatory requirements, and increase potential FDA 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 and the future sale of any approved drug candidates and new technologies 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 intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We also may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

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

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

In connection with the clinical trial management and site recruitment services we previously provided, 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, Inc. in 2004, previously provided 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 contract 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 performed. 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 U.S. and numerous entities outside of the U.S. We are a relatively small company with 25 full and part-time employees as of May 4, 2011. 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 cash, cash equivalents and investment securities may not be adequate to finance our operating cash requirements for the length of time that we have estimated.

We currently anticipate that our cash, cash equivalents and investment securities as of March 31, 2011, the May 2011 offering, and the $5.0 million milestone payment received from JT/Torii in April 2011 are sufficient to fund our anticipated operating cash requirements for over 24 months. Our forecast of the period of time through which our cash, cash equivalents and investment securities will be adequate to support our current 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, but are not limited to, 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; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

If our cash is insufficient to meet future operating 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.

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 is 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 the second half of 2013 and we cannot assure you that we can obtain an extension to the second half of 2018 (the maximum term of extension under the patent term restoration program). Our composition of matter patent covering Zerenex expires in the second half of 2017 and we cannot assure you that we can obtain an extension to 2022 (the maximum term of extension under the patent term restoration program). 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 patents for KRX-0401 and Zerenex, 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 our patented method, or for which there is a substantial use in commerce outside our patented method.

- Our pending patent applications may not issue as patents and may not issue in all countries in which we develop, manufacture or potentially sell our products or in countries where others develop, manufacture and potentially sell products using our technologies. Moreover, our pending patent applications, if issued as patents, may not provide additional protection for our products.

Proof of direct infringement by a competitor for method of use patents can 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 FDCA 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 U.S., or, diseases that affect more than 200,000 individuals in the U.S. 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, and in July 2010, we announced that KRX-0401 has

received Orphan-Drug designation from the FDA for the treatment of neuroblastoma. We believe that KRX-0401 may be eligible for additional orphan-drug designations; however, we cannot assure you that KRX-0401, or any other drug candidates we may acquire or in-license, will obtain such orphan-drug designations. Additionally, upon FDA approval, we believe that perifosine would qualify as a New Chemical Entity, which provides for five years of exclusivity following approval; however, we cannot assure you that perifosine will qualify and gain the additional exclusivity period.

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.

USE OF PROCEEDS

The net proceeds to us from the sale of 7,021,277 shares of our common stock will be approximately $30.8 million after deducting underwriting discounts and estimated offering expenses payable by us.

We expect to use the net proceeds from this offering:

- to fund the ongoing development of KRX-0401 (perifosine) and Zerenex™ (ferric citrate);
- to potentially in-license, acquire and develop additional drug candidates; and
- for general corporate purposes.

The timing and amounts of our actual expenditures will depend on several factors, including the progress of our clinical trials, the progress of our research and development programs, the results of other pre-clinical and clinical studies and the timing and costs of regulatory approvals. Pending the uses described above, we will invest the net proceeds in short-term and long-term, investment grade, interest-bearing securities.

CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2011:

- on an actual basis; and
- on an as adjusted basis to reflect:
  - § the sale of the 7,021,277 shares of common stock offered by us in this offering after deducting underwriting discounts and estimated offering expenses payable by us; and
  - § the receipt on April 28, 2011, of a $5.0 million milestone payment from our Japanese partner for Zerenex (ferric citrate), Japan Tobacco Inc. and Torii Pharmaceutical Co., Ltd., related to the commencement of a Phase 3 clinical program of ferric citrate in Japan.

You should read this information together with our financial statements and the notes to those statements incorporated by reference into this prospectus supplement and the related prospectus.

	As of March 31, 2011	
	Actual	As Adjusted
	(unaudited)	
	(in thousands, except share data)	
Cash and cash equivalents	22,865	53,653
Stockholders' equity:		
Preferred stock, $0.001 par value per share, 5,000,000 shares authorized; none issued and outstanding, actual and as adjusted	—	—
Common stock, $0.001 par value per share, 95,000,000 shares authorized; 61,629,858 shares actual and 68,651,135 shares as adjusted, issued; 61,549,910 shares actual and 68,571,187 shares as adjusted, issued and outstanding	62	69
Additional paid-in capital	365,880	396,661
Treasury stock, at cost, 79,948 shares, actual and as adjusted	(357)	(357)
Accumulated deficit	(348,169)	(348,169)
Total stockholders' equity	17,416	48,204
Total capitalization	17,416	48,204

The table excludes the following shares:

- 7,989,528 shares of common stock issuable upon the exercise of stock options outstanding as of March 31, 2011, with a weighted average exercise price of $6.94 per share;
- 2,872,422 shares of common stock issuable to the former stockholders of ACCESS Oncology, Inc. upon the achievement of certain milestones related to KRX-0401, which we acquired upon our merger with ACCESS Oncology in February 2004; and
- an aggregate of 1,330,681 shares of common stock reserved for future issuance under our stock option and incentive plans.

UNDERWRITING

Subject to the terms and conditions set forth in an underwriting agreement, the underwriters named below have agreed to purchase from us the aggregate number of shares of common stock set forth opposite their names below:

Underwriters	Number of Shares
Stifel, Nicolaus & Company, Incorporated	4,095,745
Oppenheimer & Co. Inc.	585,107
Roth Capital Partners, LLC	585,107
Rodman & Renshaw, LLC	585,106
Brean Murray, Carret & Co., LLC	585,106
Ladenburg Thalmann & Co. Inc.	585,106
Total	7,021,277

The underwriting agreement provides that the obligations of the underwriters are subject to various conditions, including approval of legal matters by counsel. The nature of the underwriters' obligations commits each underwriter to purchase and pay for all of the shares of common stock listed above next to such underwriter's name if any are purchased.

The underwriting agreement provides that we will indemnify the underwriters against liabilities specified in the underwriting agreement under the Securities Act, or will contribute to payments that the underwriters may be required to make relating to these liabilities.

Stifel, Nicolaus & Company, Incorporated expects to deliver the shares of common stock to purchasers on or about May 9, 2011.

Commissions and Discounts

The underwriters propose to offer the shares of common stock directly to the public at the public offering price set forth on the cover page of this prospectus, and at this price less a concession not in excess of $0.1692 per share of common stock to other dealers. After this offering, the offering price, concessions and other selling terms may be changed by the underwriters. Our common stock is offered subject to receipt and acceptance by the underwriters and to the other conditions, including the right to reject orders in whole or in part.

The following table summarizes the compensation to be paid to the underwriters by us and the proceeds, before expenses, payable to us:

	Per share	Total
Public offering price	$ 4.700	$ 33,000,002
Underwriting discount	$ 0.282	$ 1,980,000
Proceeds, before expenses, to us	$ 4.418	$ 31,020,002

We have agreed to pay JMP Securities LLC a financial advisory fee equal to approximately $165,000, which amount will reduce the total underwriting commissions to be paid to the underwriters.

The expenses of the offering that are payable by us are estimated to be $232,000 (excluding underwriting discounts and commissions).

In compliance with the guidelines of the Financial Industry Regulatory Authority, Inc., or FINRA, the maximum discount or commission to be received by any FINRA member or independent broker-dealer may not exceed 8% of the aggregate offering price of the shares offered hereby.

Indemnification of Underwriters

We will indemnify the underwriters against some civil liabilities, including liabilities under the Securities Act. If we are unable to provide this indemnification, we will contribute to payments the underwriters may be required to make in respect of those liabilities.

No Sales of Similar Securities

The underwriters will require all of our directors and officers to agree not to offer, sell, agree to sell, directly or indirectly, or otherwise dispose of any shares of common stock or any securities convertible into or exchangeable for shares of common stock without the prior written consent of Stifel, Nicolaus & Company, Incorporated for a period of 90 days after the date of this prospectus.

The restrictions described in the immediately preceding paragraph do not apply to:

- transactions relating to shares of common stock or other securities acquired in open market transactions after the completion of this offering, provided that no filing under Section 16(a) of the Exchange Act shall be required or shall be voluntarily made in connection with subsequent sales of common stock or other securities acquired in such open market transactions;

- transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock as a bona fide gift, (ii) transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock to the immediate family of the individual, to a trust the beneficiaries of which are exclusively the individual and/or a member or members of the immediate family of the individual, or to any corporation, partnership, limited liability company or other entity all of the beneficial ownership interests of which are held exclusively by the individual and/or a member or members of the immediate family of the individual, (iii) transfers of shares of common stock or any security convertible into or exercisable or exchangeable for common stock upon death by will or intestate succession, (iv) transfers to any affiliate (as defined in Rule 405 of the Securities Act), limited partners, general partners, limited liability company members or stockholders of such persons, or if such person is a corporation to any wholly-owned subsidiary of such corporation, and (v) transfers by operation of law, including a qualified domestic order, provided that, in each case, any such recipient agrees to be bound by the terms of the restrictions described above and no filing is made or required to be made under Section 16(a) of the Exchange Act;

- the exercise of any option to purchase shares of common stock, provided that the underlying common stock continues to be subject to the restrictions described above;

- transactions pursuant to any trading plan established pursuant to Rule 10b5-1 of the Exchange Act that has been entered into by the individual prior to the date of the agreement;

- the entry into any trading plan established pursuant to Rule 10b5-1 of the Exchange Act, provided that no sales or other dispositions may occur under such plan until the expiration of the restricted period; or

- with regard to shares of restricted stock granted under our equity incentive plans, transactions pursuant to an automatic sales plan which sells that number of shares of vested restricted stock necessary to fund income tax obligations due as the result of such vesting event.

We have agreed that for a period of 90 days after the date of this prospectus, we will not, without the prior written consent of Stifel, Nicolaus & Company, Incorporated, offer, sell or otherwise dispose of any shares of common stock

or any other securities of ours convertible or exchangeable into common stock, except for (i) the issuance of shares of common stock under our equity incentive plans existing on the date of the underwriting agreement, and (ii) the issuance of shares of common stock upon the conversion, exercise or exchange of convertible, exercisable or exchangeable securities of ours outstanding as of the date of the underwriting agreement.

The 90-day restricted period in all of the agreements is subject to extension if (i) during the last 17 days of the restricted period we issue an earnings release or material news or a material event relating to us occurs or (ii) prior to the expiration of the restricted period, we announce that we will release earnings results during the 16-day period beginning on the last day of the lock-up period, in which case the restrictions imposed in these lock-up agreements shall continue to apply until the expiration of the 18-day period beginning on the issuance of the earnings release or the occurrence of the material news or material event, unless Stifel, Nicolaus & Company, Incorporated waives the extension in writing.

Nasdaq Capital Market Listing

Our common stock is listed on the Nasdaq Capital Market under the symbol “KERX.”

Short Sales, Stabilizing Transactions and Penalty Bids

The underwriters have informed us that they will not engage in over-allotment, stabilizing or syndicate covering transactions in connection with this offering.

Miscellaneous

The underwriters have provided, and may in the future provide, various investment banking and other financial services for us for which services they have received, and may receive in the future, customary fees.

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company.

LEGAL MATTERS

Alston & Bird LLP, New York, New York, has passed upon certain legal matters regarding the shares offered by this prospectus supplement. Certain legal matters will be passed upon for the underwriters by Goodwin Procter LLP, Boston, Massachusetts.

EXPERTS

The consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2010 and December 31, 2009, and for the years ended December 31, 2010 and December 31, 2009, have been incorporated by reference herein in reliance upon the report of UHY LLP, independent registered public accounting firm, and upon the authority of said firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy, at prescribed rates, any documents we have filed with the SEC at its Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We also file these documents with the SEC electronically. You can access the electronic versions of these filings on the SEC's Internet website found at http://www.sec.gov. You can also obtain copies of materials we file with the SEC from our Internet website found at www.keryx.com. Information contained on website does not constitute part of this prospectus supplement or the accompanying prospectus. Our stock is quoted on the Nasdaq Capital Market under the symbol "KERX."

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" the information we file with them which means that we can disclose important information to you by referring you to those documents instead of having to repeat the information in this prospectus supplement and accompanying prospectus. The information incorporated by reference is considered to be part of this prospectus supplement and accompanying prospectus, and later information that we file with the SEC will automatically update and supersede this information. We incorporate by reference the documents listed below and any future filings made with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act between the date of this prospectus supplement and the termination of the offering (other than, unless otherwise specifically indicated, current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items):

- Our Annual Report on Form 10-K for the year ended December 31, 2010;
- Our proxy statement or Schedule 14A filed with the SEC on April 29, 2011; and
- Our Current Reports on Form 8-K filed with the SEC on April 18, 2011 and May 2, 2011.

We will provide to each person, including any beneficial owner, to whom a copy of this prospectus supplement and the related prospectus is delivered, a copy of any or all of the information that we have incorporated by reference into this prospectus supplement and the related prospectus. We will provide this information upon written or oral request at no cost to the requester. You may request this information by contacting our corporate headquarters at the following address: 750 Lexington Avenue, New York, New York 10022, Attn: Chief Financial Officer, or by calling (212) 531-5965.

PROSPECTUS

$100,000,000

Keryx Biopharmaceuticals, Inc.

Common Stock
Warrants

We may offer and sell an indeterminate number of shares of our common stock and/or warrants from time to time under this prospectus. You should read this prospectus and any prospectus supplement carefully before you invest.

We may offer our common stock and/or warrants in one or more offerings in amounts, at prices, and on terms determined at the time of the offering. We may sell our common stock and warrants through agents we select or through underwriters and dealers we select. If we use agents, underwriters or dealers, we will name them and describe their compensation in a prospectus supplement.

This prospectus provides a general description of the securities we may offer. Each time we sell securities, we will provide specific terms of the securities offered in a supplement to this prospectus. The prospectus supplement may also add, update or change information contained in this prospectus. You should read this prospectus and the applicable prospectus supplement carefully before you invest in any securities. This prospectus may not be used to consummate a sale of securities unless accompanied by the applicable prospectus supplement.

Our common stock is traded on the Nasdaq Capital Market under the symbol “KERX.” On December 31, 2010, the per share closing price of our common stock as reported on the Nasdaq Capital Market was $4.58 per share.

Investing in our securities involves certain risks. See “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2009, as well as our Quarterly Reports on Form 10-Q for the periods ended March 31, 2010, June 30, 2010 and September 30, 2010, which have been filed with the SEC and are incorporated by reference into this prospectus. You should read the entire prospectus carefully before you make your investment decision.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

The date of this prospectus is January 28, 2011.

Table of Contents

KERYX BIOPHARMACEUTICALS, INC.

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, which we also refer to as perifosine, a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase 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, growth, differentiation and 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 Phase 3 clinical development for both refractory advanced colorectal cancer and multiple myeloma, and in Phase 1 and 2 clinical development for several other tumor types. Each of the KRX-0401 Phase 3 programs is being conducted under Special Protocol Assessment, or SPA, agreements with the FDA.

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

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 partners, Japan Tobacco and Torii.

Our principal executive offices are located at 750 Lexington Avenue, New York, New York 10022, and our telephone number is (212) 531-5965. We maintain a website on the Internet at www.keryx.com and our e-mail address is info@keryx.com. Our Internet website, and the information contained on it, are not to be considered part of this prospectus.

THE OFFERING

Use of Proceeds	We intend to use the net proceeds of any offering as set forth in the applicable prospectus supplement.
Nasdaq Symbol	KERX

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and current reports, proxy statements and other information with the Securities and Exchange Commission, or SEC. You may read and copy, at prescribed rates, any documents we have filed with the SEC at its Public Reference Room located at 100 F Street, N.E., Washington, D.C. 20549. You may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. We also file these documents with the SEC electronically. You can access the electronic versions of these filings on the SEC's Internet website found at http://www.sec.gov. You can also obtain copies of materials we file with the SEC from our Internet website found at www.keryx.com. Our stock is quoted on the Nasdaq Capital Market under the symbol "KERX."

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IMPORTANT INFORMATION ABOUT THIS PROSPECTUS

This prospectus is part of a "shelf" registration statement that we filed with the SEC. By using a shelf registration statement, we may sell our securities, as described in this prospectus, from time to time in one or more offerings. We may use the shelf registration statement to offer and sell securities described in this prospectus. Each time we sell securities, we will provide a prospectus supplement to this prospectus that contains specific information about the terms of such offering. The supplement may also add, update or change information contained in this prospectus. Before purchasing any securities, you should carefully read both this prospectus and any supplement, together with the additional information incorporated into this prospectus or described under the heading "Where You Can Find More Information."

You should rely only on the information contained or incorporated by reference in this prospectus and any prospectus supplement. We have not authorized any other person to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We will not make an offer to sell securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus, as well as information we previously filed with the SEC and have incorporated by reference, is accurate as of the date on the front cover of this prospectus only, or when such document was filed with the SEC. Our business, financial condition, results of operations and prospects may have changed since the relevant date.

We will not use this prospectus to offer and sell securities unless it is accompanied by a prospectus supplement that more fully describes the terms of the offering.

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with the SEC. This means that we can disclose important information to you by referring you to those documents without restating that information in this document. The information incorporated by reference into this prospectus is considered to be part of this prospectus, and information we file with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, or the Exchange Act, after the date of this prospectus and prior to the termination of this offering, will automatically update and supersede the information contained in this prospectus and documents listed below. We incorporate by reference into this prospectus the documents listed below, except to the extent information in those documents differs from information contained in this prospectus, and any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including exhibits:

(a) Our Annual Report on Form 10-K for the year ended December 31, 2009;

(b) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010;

(c) Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2010;

(d) Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010;

(e) Our Current Reports on Form 8-K filed with the SEC on January 5, 2010, January 25, 2010, July 14, 2010, July 21, 2010, August 5, 2010, September 29, 2010, October 26, 2010 and November 30, 2010; and

(f) The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on June 30, 2000 (File No. 000-30929).

We will provide to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, a copy of any or all of the information that we have incorporated by reference into this prospectus. We will provide this information upon written or oral request at no cost to the requester. You may request this information by contacting our corporate headquarters at the following address: 750 Lexington Avenue, New York, New York 10022, Attn: Chief Financial Officer, or by calling (212) 531-5965.

DESCRIPTION OF SECURITIES WE MAY OFFER

This prospectus contains summary descriptions of our common stock and warrants to purchase common stock that we may offer from time to time. These summary descriptions are not meant to be complete descriptions of each security. The particular terms of any security will be described in the related prospectus supplement.

DESCRIPTION OF COMMON STOCK

The following summary of the terms of our common stock may not be complete and is subject to, and qualified in its entirety by reference to, the terms and provisions of our amended and restated certificate of incorporation and our amended and restated bylaws. You should refer to, and read this summary together with, our amended and restated certificate of incorporation and amended and restated bylaws to review all of the terms of our common stock that may be important to you.

Common Stock

Under our certificate of incorporation, we are authorized to issue a total of 95,000,000 shares of common stock, par value $0.001 per share. As of December 31, 2010 we had issued and outstanding 61,441,535 shares of our common stock. There are approximately 63 holders of record. All outstanding shares of our common stock are fully paid and nonassessable. Our common stock is listed on the Nasdaq Capital Market under the symbol “KERX.”

Dividends

Holders of our common stock are entitled to participate equally in dividends when our Board of Directors declares dividends on our common stock out of legally available funds. We have never declared or paid any cash dividends on our common stock and do not anticipate paying any such cash dividends in the foreseeable future. Future dividends, if any, will be determined by our Board of Directors and will be based upon our earnings, capital requirements and operating and financial condition, among other factors, at the time any such dividends are considered by our Board of Directors.

Voting Rights

The holders of our common stock are entitled to one vote for each share of common stock held. Generally, the vote of the majority of the shares represented at a meeting of the stockholders and entitled to vote is sufficient for actions that require a vote of the stockholders.

iquidation and Dissolution

In the event of our liquidation, dissolution, or winding up, voluntarily or involuntarily, holders of our common stock will have the right to a ratable portion of the assets remaining after satisfaction in full of the prior rights of our creditors and of all liabilities.

Other

Holders of our common stock are not entitled to any preemptive or preferential right to purchase or subscribe for shares of capital stock of any class and have no conversion or sinking fund rights.

Transfer Agent

American Stock Transfer and Trust Company serves as the transfer agent and registrar for all of our common stock.

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DESCRIPTION OF WARRANTS

We may issue warrants to purchase shares of our common stock. We may issue warrants independently or together with other securities. Warrants sold with other securities may be attached to or separate from the other securities.

The prospectus supplement relating to any warrants we offer will include specific terms relating to the offering. These terms will include some or all of the following:

- the title of the warrants;
- the aggregate number of warrants offered;
- the designation, number and terms of the shares of common stock purchasable upon exercise of the warrants and procedures by which those numbers may be adjusted;
- the exercise price of the warrants;
- the dates or periods during which the warrants are exercisable;
- the designation and terms of any securities with which the warrants are issued;
- if the warrants are issued as a unit with another security, the date on and after which the warrants and the other security will be separately transferable;
- if the exercise price is not payable in U.S. dollars, the foreign currency, currency unit or composite currency in which the exercise price is denominated;
- any minimum or maximum amount of warrants that may be exercised at any one time;
- any terms relating to the modification of the warrants;
- any terms, procedures and limitations relating to the transferability, exchange or exercise of the warrants; and
- any other specific terms of the warrants.

PLAN OF DISTRIBUTION

We may sell the securities covered in this prospectus in any of three ways (or in any combination):

- through underwriters or dealers;
- directly to a limited number of purchasers or to a single purchaser; or
- through agents.

Each time that we use this prospectus to sell securities, we will also provide a prospectus supplement that contains the specific terms of the offering. The prospectus supplement will set forth the terms of the offering of the securities, including:

- the name or names of any underwriters, dealers or agents and the amounts of any securities underwritten or purchased by each of them; and
- the public offering price of the common stock and the proceeds to us and any discounts, commissions or concessions allowed or reallowed or paid to dealers.

Any public offering price and any discounts or concessions allowed or reallowed or paid to dealers may be changed from time to time.

If underwriters are used in the sale of any securities, the securities will be acquired by the underwriters for their own account and may be resold from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. The securities may be either offered to the public through underwriting syndicates represented by managing underwriters, or directly by underwriters. Generally, the underwriters' obligations to purchase the securities will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the securities if they purchase any of securities.

We may sell the securities through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the securities and any commissions we pay to them. Generally, any agent will be acting on a best efforts basis for the period of its appointment.

We may authorize underwriters, dealers or agents to solicit offers by certain purchasers to purchase the securities from us at the public offering price set forth in the prospectus supplement pursuant to delayed delivery contracts providing for payment and delivery on a specified date in the future. The contracts will be subject only to those conditions set forth in the prospectus supplement, and the prospectus supplement will set forth any commissions we pay for solicitation of these contracts.

Agents and underwriters may be entitled to indemnification by us against certain civil liabilities, including liabilities under the Securities Act of 1933, as amended, or to contribution with respect to payments which the agents or underwriters may be required to make in respect thereof. Agents and underwriters may be customers of, engage in transactions with, or perform services for us in the ordinary course of business.

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or

others to settle those sales or to close out any related open borrowings of securities, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of securities. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment).

In compliance with the guidelines of the Financial Services Regulatory Authority, Inc., or FINRA, the maximum compensation to be received by a FINRA member or independent broker-dealer may not exceed 8% of the offering proceeds. It is anticipated that the maximum compensation to be received in any particular offering of securities will be less than this amount.

LEGAL MATTERS

The legality and validity of the securities offered from time to time under this prospectus will be passed upon by Alston & Bird LLP, New York, New York.

EXPERTS

The consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2009, and for the year ended December 31, 2009, have been incorporated by reference herein and in the registration statement in reliance upon the report of UHY LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2008, and for the years ended December 31, 2008 and December 31, 2007, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent registered public accounting firm, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing. The audit report covering the consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of December 31, 2008, and for the years ended December 31, 2008 and December 31, 2007, contains an explanatory paragraph that states that our substantial recurring losses from operations, deficiency in equity, limited cash, cash equivalents and short-term investment securities, and illiquid investments in auction rate securities raise substantial doubt about our ability to continue as a going concern. The consolidated financial statements do not include any adjustments that might result from the outcome of that uncertainty. The audit report also refers to our change in 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.

7,021,277 Shares
Common Stock

PROSPECTUS SUPPLEMENT

May 4, 2011

Sole Book-Running Manager
Stifel Nicolaus Weisel

Oppenheimer & Co.
Roth Capital Partners
Rodman & Renshaw, LLC
Brean Murray, Carret & Co.
Ladenburg Thalmann & Co. Inc.

Neither we nor the underwriters have authorized anyone to provide information different from that contained in this prospectus supplement and the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering. When you make a decision about whether to invest in our common stock, you should not rely upon any information other than the information in this prospectus supplement or the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering. Neither the delivery of this prospectus supplement or the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering, nor the sale of our common stock means that information contained in this prospectus supplement and the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering, is correct after their respective dates. This prospectus supplement and the accompanying prospectus, including any free writing prospectus that we have authorized for use in this offering, is not an offer to sell or a solicitation of an offer to buy these shares of common stock in any circumstance under which the offer or solicitation is unlawful.
