

KERYX BIOPHARMACEUTICALS INC  
Form 424B5  
January 30, 2013

The information in this prospectus is not complete and may be changed. A registration statement relating to these securities has been filed with the Securities and Exchange Commission and is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Filed Pursuant to Rule 424(b)(5)  
Registration No.: 333-171517

**Subject to completion, dated January 29, 2013**

## **Prospectus Supplement (to Prospectus dated January 28, 2011)**

**\$55,000,000**

### **Common Stock**

We are offering \$55,000,000 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 January 28, 2013, the last reported sale price of our common stock on the Nasdaq Capital Market was \$6.06 per share.

|                                       | Per share | Total |
|---------------------------------------|-----------|-------|
| Public offering price                 | \$        | \$    |
| Underwriting discount and commissions | \$        | \$    |
| Proceeds to Keryx, before expenses    | \$        | \$    |

We have granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to \$8,250,000 of additional shares of common stock to cover any overallotments.

**Investing in our common stock involves a high degree of risk. See **Risk factors** beginning on page S-4.**

**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.**

The underwriters expect to deliver the common stock on or about \_\_\_\_\_, 2013 only in book-entry form through the facilities of The Depository Trust Company.

### ***Sole book-running manager***

# J.P. Morgan

, 2013

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### Prospectus

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## 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.

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. 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.



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Unless otherwise stated, all references in this prospectus to we, us, our, Keryx, the Company and similar designations 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.

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## 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, Management's Discussion and Analysis of Financial Condition and Results of Operations and elsewhere in this prospectus supplement and the accompanying prospectus, 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 pre-clinical and clinical development, manufacturing, regulatory approval, and commercialization (including market acceptance) of Zerenex<sup>TM</sup> (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 candidate;
- 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 and the accompanying prospectus reflect our views and assumptions only as of the date of this prospectus supplement and the accompanying prospectus, respectively. Except as required by law, we assume no responsibility for updating any forward-looking statements.

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

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## 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 renal disease. We are 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 in the United States, under a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA, as a treatment for hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, on dialysis.

On November 1, 2012, we announced the initiation of a U.S. Phase 2 study of Zerenex in managing serum phosphorus and iron deficiency in anemic patients with Stage 3 to 5 non-dialysis dependent chronic kidney disease, or NDD-CKD. The study plans to randomize approximately 150 patients from approximately 15 sites in the U.S. Patient enrollment is expected to take up to six months, with study completion expected in mid-2013.

On January 7, 2013, we announced that our Japanese partner, Japan Tobacco Inc. (JT), filed its New Drug Application (NDA) with the Japanese Ministry of Health, Labour and Welfare for marketing approval of ferric citrate in Japan for the treatment of hyperphosphatemia in patients with chronic kidney disease (CKD).

We also engage in business development activities that include seeking strategic relationships for our drug candidate, as well as evaluating compounds and companies for in-licensing or acquisition. To date, we have not received approval for the sale of any drug candidate in any market. Most recently, in April 2012 we announced that our Phase 3 trial for KRX-0401 (perifosine) for refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine and placebo. Following these results, we abandoned our development efforts and terminated our license relating to the KRX-0401 (perifosine) drug candidate, and re-focused our development efforts on our leading drug candidate, Zerenex. Therefore, we have not generated any product sales from any drug candidate. We have generated, and expect to continue to generate, revenue from the sublicensing of rights to Zerenex in Japan to JT and Torii Pharmaceutical Co., Inc. (Torii).

## Results of Phase 3 clinical trials of Zerenex

On January 28, 2013, we announced successful top-line results from our long-term Phase 3 study of Zerenex, our ferric iron-based phosphate binder drug candidate, for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with end-stage renal disease (ESRD) on dialysis. In this study, Zerenex met the study's primary endpoint, demonstrating a highly statistically significant change in serum phosphorus versus placebo over the four-week Efficacy Assessment Period of the study. In addition, Zerenex met the key secondary endpoints of

increasing ferritin and transferrin saturation (TSAT) and reducing the use of intravenous (IV) iron and erythropoiesis-stimulating agents (ESAs) versus the active control over the 52-week Safety Assessment Period of the study. This long-term study was the final component of our Phase 3 registration program, which was conducted pursuant to a Special Protocol Assessment (SPA) with the Food and Drug Administration (FDA). We expect to submit a New Drug

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Application (NDA) with the FDA and a Marketing Authorization Application (MAA) with the European Medicines Agency (EMA) for Zerenex in the second quarter of 2013.

**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. Information contained on our website does not constitute part of this prospectus supplement or the accompanying prospectus. 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.

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## The offering

**Common stock offered by us**

shares

**Common stock to be outstanding after the offering**

shares

**Option to purchase additional share**

Up to shares at any time within 30 days from the date of this prospectus supplement.

**Use of proceeds**

We intend to use the net proceeds from the sale of our common stock to fund pre-launch/launch inventory build-up and select pre-commercial/commercial activities related to Zerenex, and other general corporate purposes. See Use of Proceeds on page S-19.

**Risk factors**

See Risk Factors beginning on page S-4 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 71,925,801 shares of common stock outstanding as of September 30, 2012 and assumes no exercise of the underwriters overallotment option.

The number of shares of common stock to be outstanding after this offering does not take into account (as of September 30, 2012):

2,288,686 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2012, with a weighted average exercise price of \$5.91 per share; and  
an aggregate of 1,302,418 shares of common stock reserved for future issuance under our stock option and incentive plans.

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## **Risk factors**

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

### **Risks related to our business**

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

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred substantial operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of September 30, 2012, we had an accumulated deficit of \$386.0 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 candidate.

We have not yet commercialized any drug candidate and cannot be sure that we will ever be able to do so. Most recently, in April 2012 we announced that our Phase 3 trial for KRX-0401 (perifosine) for refractory advanced colorectal cancer did not meet the primary endpoint of improving overall survival versus capecitabine and placebo. Following these results, we abandoned our development efforts and terminated our license relating to the KRX-0401 (perifosine) drug candidate, and re-focused our development efforts on our leading drug candidate, Zerenex. Even if we commercialize a drug candidate, 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 candidate, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidate.

### **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 disease that we are studying. 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 or at all. In addition, conducting multi-national studies adds another level of complexity and risk. As a result, we may be 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. For example, we recently abandoned our development efforts and terminated our license for KRX-0401 (perifosine) following negative results from the Phase 3 trial. We may also opt to change the delivery method, formulation or

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dosage which could affect efficacy results for the drug candidate. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

We have conducted two Phase 3 clinical trials initiated in May 2010 and September 2010 for Zerenex 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 approval for Zerenex under a SPA, based on protocol designs negotiated with the FDA, we may be subject to enhanced scrutiny. Regardless of the success of our Phase 3 clinical trial, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power, patient completion rates, changes in scientific or medical parameters or internal inconsistencies in the data prior to making its final decision. The FDA may also seek the guidance of an outside advisory committee prior to making its final decision. Additionally, the regulatory approval of new therapies could invalidate our SPA, or require us to conduct additional, expensive clinical trials to obtain regulatory approval.

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 successful Phase 3 program in the U.S., in conjunction with safety data generated from other clinical studies with Zerenex, will be 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 since our Phase 3 program in the U.S. was successful, we will not need to conduct any additional clinical trials to assess the safety or efficacy of 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 approval of an 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, which may delay or prevent EMA approval of Zerenex.

Additionally, we have never submitted an NDA or similar application for approval in the U.S., Europe, or in any country, which may result in a delay in, or the rejection of, our filing of an NDA, MAA 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 or MAA, some questions may remain unanswered by the time we submit our NDA and MAA, or may be difficult or impossible to answer to the satisfaction of the regulatory authorities. Unless the FDA, EMA, or similar regulatory authority in other countries, opts not to pursue these questions, filing of an NDA, MAA or similar application may be delayed or rejected. We also can provide no assurance that our Japanese partner, JT and Torii, will not encounter delays or rejections of their NDA or similar application filings with the Japanese regulatory authority.

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

Pre-clinical testing and clinical development are long, expensive and uncertain processes. If our drug candidate does



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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 toxicological, pre-clinical or clinical data or substantiation. For example, while ferric citrate is a Generally Recognized as Safe, or GRAS, substance in the U.S., and the FDA has not requested us to conduct a two-year carcinogenicity study in animals, there is no assurance that prior to, at the time of, or subsequent to the filing of an NDA that the FDA or some other regulatory authority will not ask us to conduct such a study. Consequently, it may take us many years to complete the testing of our drug candidate 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 we have conducted 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 earlier 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 candidate 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 candidate. In addition, top-line results reported on completed clinical trials are based on a preliminary analysis of then available data (both safety and efficacy) and there is the risk that such findings and conclusions could change following a more comprehensive review of the data by us or a regulatory authority.

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. We experienced such a setback with our Phase 3 KRX-0401 (perifosine) results in April 2012, and we can provide no assurance that we will not experience such setbacks with Zerenex or any other drug candidate we develop. If we experience delays in the testing or approval process for our existing drug candidate or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidate 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, data capture and analysis, and/or auditing could potentially invalidate the results.

**Because all of our proprietary technologies are licensed or sublicensed to us by third parties, termination of these license rights would prevent us from developing and commercializing**

Because all of our proprietary technologies are licensed or sublicensed to us by third parties, termination of these li

## **Zerenex.**

We do not own our drug candidate, Zerenex. We have licensed and sublicensed the rights, patent or otherwise, to Zerenex from a third party, Panion & BF Biotech, Inc., or Panion who in turn licenses certain rights to Zerenex from one of the investors of Zerenex. The license agreement with Panion requires us to

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meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the agreement, we must pay royalties on sales of product resulting from the licensed technologies and pay the patent filing, prosecution and maintenance costs related to the license. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreement, Panion could terminate the agreement, and we would lose the rights to Zerenex. In addition, if Panion breaches its agreement with the inventor from whom it licenses rights to Zerenex, Panion could lose its license, which could impair or delay our ability to develop and commercialize Zerenex. From time to time, we may have disagreements with our licensors or collaborators, or they and/or we may have disagreements with the original inventors, regarding the terms of our agreements or ownership of proprietary rights, which could lead to delays in the research, development and commercialization of our current, and any future, drug candidate, could require or result in litigation or arbitration, which would be time-consuming and expensive, or could lead to the termination of a license, or force us to negotiate a revised or new license agreement on terms less favorable than the original. In addition, in the event that the owners and/or licensors of the rights we license were to enter into bankruptcy or similar proceedings, we could potentially lose our rights to our drug candidates or our rights could otherwise be adversely affected, which could prevent us from developing or commercializing our drug candidates. Finally, our rights to develop and commercialize Zerenex, whether ourselves or with third parties, are subject to and limited by the terms and conditions of our licenses to Zerenex and the licenses and sublicenses we grant to others.

## **We rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not successfully manufacture and test our drug candidate, 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 drug candidate 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 drug candidate will depend on the ability of such third parties to manufacture our drug candidate on a large scale at a competitive cost and in accordance with current Good Manufacturing Practices, or cGMP, and other regulatory requirements, including requirements from federal, state and local environmental and safety regulatory agencies and foreign regulatory requirements, if applicable. Prior to approval, we will need to complete 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, capacity constraints, changing priorities within the contract manufacturers, compliance with FDA and foreign regulations, environmental compliance, production costs and development of advanced manufacturing techniques and process controls. Any of these difficulties, if they occur, and are not overcome to the satisfaction of the FDA or other regulatory agency, could lead to significant delays and possibly the termination of the development program for our drug candidate. 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 commercial batch sizes with our third party

We rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not successfully

manufacturers of Zerenex can lead to delays in our development timelines.

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 candidate. In addition, our contract manufacturers will be subject to ongoing periodic and unannounced

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We rely on third parties to manufacture and analytically test our drug candidate. If these third parties do not succeed

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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 will not occur that could change their regulatory standing. The same issues apply to contract analytical services which we use for testing of our drug candidate. 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 obtain FDA approval. Moreover, even with effective analytical tooling available, there is no assurance that we will be able to analyze all the raw materials and qualify all impurities to the satisfaction of the FDA, possibly requiring additional analytical studies, analytical method development, or preclinical studies, which could significantly delay our ability to file an NDA or receive regulatory approval for our drug candidate. Additionally, changes in the analytical specifications required by the FDA or other regulatory authority, such as United States Pharmacopeial Convention standards, from time to time, could delay our ability to file an NDA or receive regulatory approval for our drug candidate. Switching or engaging multiple third-party contractors to produce our product may be difficult because the number of potential manufacturers may be limited and the process by which multiple manufacturers make the drug substance or drug product must meet established specifications 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 add or change manufacturers after commercialization, the FDA and corresponding foreign regulatory agencies must approve any new 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 product on our own. From time to time, we may need to contract with third parties to:

manufacture our product candidate;  
assist us in developing, testing and obtaining regulatory approval for and commercializing our compound and technologies; and

market and distribute our drug product.

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 product independently, which could result in delays. Furthermore, such failure could result in the termination of license rights to our product. 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 product. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our product, we are unable to control whether such product will be scientifically or commercially successful. Additionally, if these third parties fail to perform their obligations under our

If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties,

agreements with them or

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If we do not establish or maintain manufacturing, drug development and marketing arrangements with third parties,

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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 our current, and any future, drug candidate.

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 our drug candidate or marketing of any approved product.

### **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 significant 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 candidate(s).

### **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 product effectively.**

In the event our drug candidate is approved by the FDA, we may conduct our own sales and marketing effort to support the drug. We currently have limited experience in sales, marketing or distribution. To directly market and distribute any product, we must build and train a sales and marketing organization with appropriate technical expertise and distribution capabilities. We may attempt to build and train 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 product. 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 product, 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.

Our reliance on third parties, such as clinical research organizations, or CROs, may result in delays in completing, or

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 current or future products. Any accepted offer may preclude us from commercializing our product(s) effectively.

**Even if we obtain regulatory approval to market Zerenex, if it fails to achieve market acceptance, we may never record meaningful revenues.**

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

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perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidate, 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 product by medical practitioners and the target populations for our product;

the potential advantages that our product offers over existing treatment methods;

the cost-effectiveness of our product relative to competing products, which may be exacerbated as existing treatments go off-level;

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

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

the effectiveness of our sales, marketing and distribution efforts.

Because we expect sales of our product, if approved, to generate substantially all of our revenues in the long-term, the failure of our drug 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 product, or our drug product does not achieve market acceptance vis-à-vis existing treatments, 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 product 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.

Zerenex, if approved in the U.S., would have to 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. Our strategy to compete against these existing treatments depends in part on physicians and patients accepting that Zerenex provides certain advantages, such as the absence of hypercalcemia as compared to PhosLo, reduced pill burden as compared to Renagel and the lack of lanthanum build-up and a preferred route of administration (non-chewable) as compared to Fosrenol. In addition, we compete against existing treatments on price, which becomes more challenging as generic versions of these existing treatments come to market. For example, 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, generic formulations of Renagel® and Renvela® (expected in the U.S. beginning in March 2014), and generic formulations of Fosrenol®, may be launched, which could have a material effect on the pricing of phosphate binders.

Even if we obtain regulatory approval to market Zerenex, if it fails to achieve market acceptance, we may never recou



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In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug product. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to acquire and develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidate and may be commercialized earlier. Even if we are successful in developing effective drugs, our product(s) may not compete successfully with products produced by our competitors. Fresenius Medical Care and Vifor Pharma are collaborating on the development of an iron-based phosphate binder, PA-21, which we believe to be a chewable tablet formulation. Recently, Fresenius Medical Care and Vifor Pharma announced positive data from a multi-national, Phase 3 study of PA-21 in dialysis patients. If approved by the FDA and/or EMA, PA-21 could have a material effect on the market opportunities of Zerenex in the U.S. and Europe, respectively.

### **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 December 31, 2012, we had 25 full and part-time employees. To successfully develop our drug candidate, 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**

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

**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;

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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. In 2003, Congress passed the Medicare Prescription Drug, Improvement and Modernization Act of 2003, which for the first time established prescription drug coverage for Medicare beneficiaries, under Medicare Part D. Under this program, beneficiaries purchase insurance coverage from private insurance companies to cover the cost of their prescription drugs. However, third-party insurance coverage may not be available to patients for our product, if approved. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our product, its 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. For example, drug manufacturers are required to have a national rebate agreement with the Department of Health and Human Services, or HHS, in order to obtain state Medicaid coverage, which requires manufacturers to pay a rebate on drugs dispensed to Medicaid patients. On January 27, 2012, the Centers for Medicare and Medicaid Services, or CMS, issued a proposed regulation covering the calculation of Average Manufacturer Price, or AMP, which is the key variable in the calculation of these rebates.

Furthermore, in the U.S., health care reform legislation titled the Patient Protection and Affordable Care Act, or PPACA, was signed into law in March 2010. The impact of this legislation on our business is inherently difficult to predict as many of the details regarding the implementation of this legislation have not been determined. In a decision issued on June 29, 2012, the United States Supreme Court upheld the majority of PPACA. The Court's decision allows implementation of key provisions impacting drug and device manufacturers to go forward. This includes PPACA changes to the Medicare Part D Program (including closing the donut hole), Medicaid Drug Rebate Program (including the definition of AMP), and expansion of the 340B Drug Discount Program. The decision also allows the FDA and CMS to continue with implementation efforts, including related to the Biologics Price Competition and Innovation Act and the Physician Payments Sunshine Act, both of which were enacted as part of the PPACA. Regulations to implement PPACA 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 product.

For example, in July 2010, 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 delayed the inclusion of oral medications without intravenous equivalents, such as phosphate binders, in the bundle until January 1, 2014; however, on January 3, 2013, the United States Congress passed legislation known as the American Taxpayer Relief Act of 2012, which, among other things, delays by two years the

implementation of oral-only end-stage renal disease related drugs, including phosphate binders, in the bundled ESRD prospective payment system, until January 1, 2016. If

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phosphate binders are included in the bundle beginning in 2016, separate Medicare reimbursement will no longer be available for phosphate binders, as it is today under Medicare Part D. 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.

Finally, 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 candidate in clinical trials, and the future sale of any approved drug candidate and new technology, 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 candidate or limit commercialization of any approved product.

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.**

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 entered into its last third-party service contract in 2005 and its business was discontinued as of December 2011. 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.

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

The development, manufacturing, pricing, sale, marketing, and reimbursement of our product(s), 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 December 31, 2012. 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, issuance of an enforcement or warning letter, restrictions on our product or manufacturing processes, withdrawal of product(s) 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 and cash equivalents and the proceeds of this offering, exclusive of our anticipated milestone payments from JT and Torii and, investment in inventory, are sufficient to fund our anticipated operating cash requirements for the next 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 candidate;
- the timing of expenses associated with manufacturing and product development of the proprietary drug candidate 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 arrangement;
- the timing and expenses associated with capital expenditures to expand our manufacturing capabilities;
- the timing and expenses associated with building inventory and building our own commercial infrastructure to manufacture, market and sell our drug candidate and those that may be in-licensed, partnered or acquired; 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.

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## **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 product 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 product and technologies which may have an adverse effect on our business. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage. As many of the patents we use are licensed or sublicensed from third parties, we may not be able to enforce such licensed patents against third party infringers without the cooperation of the patent owner and the licensor, which may not be forthcoming. In addition, we may not be successful or timely in obtaining any patents for which we submit applications.

Additionally, the laws of foreign countries may not protect our intellectual property rights to the same extent as do the laws of the U.S. In addition, in jurisdictions outside the U.S. where we have patent rights, we may be unable to prevent unlicensed parties from selling or importing products or technologies derived elsewhere using our proprietary technology.

We also rely on trade secrets and know-how 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, licensees, 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 our drug product 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 drug candidate, Zerenex, is limited, which could adversely affect our ability to compete in the market and adversely affect the value of Zerenex.**

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

The first composition of matter and method patent relating to Zerenex in the United States (U.S. Patent No. 5,753,706) expires in February 2017. We cannot assure you that we can obtain any extension of the term of this

patent for delays caused by FDA regulatory review (the maximum term of extension under the Patent Term Extension provisions of 35 U.S.C. § 156 would extend the expected expiration date of this patent to 2022). Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are key, non-interchangeable components of the pharmaceutical product. Upon expiration of U.S. Patent No. 5,753,706, competitors who obtain the requisite regulatory approval can offer products with the same composition as our product, so long as the competitors do not infringe any other patents that we may hold, such as other composition of matter patents and/or method of use patents. Our method of use patents only protect the product when used or sold for the claimed methods. However, these types of patents do not limit a competitor from making and marketing a product that

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is identical to our product that is labeled for an indication that is outside of our patented methods, or for which there is a substantial use in commerce outside of our patented methods.

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 product(s) 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 product.

Because any potential date for regulatory approval is currently unknown, it is possible that the life of these patents following regulatory approval will be minimal, even if the above-discussed Patent Term Extension is obtained. Obtaining proof of direct infringement by a competitor for a method of use patent can be difficult because the competitors making and marketing a product typically do not engage in the patented use. Additionally, obtaining proof that a competitor contributes to, or induces, infringement of a patented method by another can be difficult because an off-label use of a product could prohibit a finding of contributory infringement. In addition, proving inducement of infringement requires proof of intent by the competitor. If we are required to defend ourselves against claims or to protect our own proprietary rights against others, it could result in substantial costs to us and the distraction of our management. An adverse ruling in any litigation or administrative proceeding could prevent us from marketing and selling Zerenex if we obtain regulatory approval, and increase the risk that a generic version of Zerenex could enter the market to compete with Zerenex, limit our development and commercialization of Zerenex, or otherwise harm our competitive position and result in additional significant costs. In addition, any successful claim of infringement asserted against us could subject us to monetary damages or injunction, which could prevent us from making or selling Zerenex. We also may be required to obtain licenses to use the relevant technology. Such licenses may not be available on commercially reasonable terms, if at all.

Moreover, physicians may prescribe 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, any limitations of our patent protection described above may adversely affect the value of our product candidate 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, pediatric exclusivity or other provisions of the Food, Drug and Cosmetic Act of 1938, as amended, or FDCA, such as new chemical entity exclusivity or new formulation exclusivity, to provide market exclusivity for a drug candidate. 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 the U.S., the FDA has the authority to grant additional data protection for approved drugs where the sponsor conducts specified testing in pediatric or adolescent populations. If granted, this pediatric exclusivity provides an additional six months which are added to the term of data protection as well as to the term of any relevant patents, to the extent these protections have not already expired. We may also seek to utilize market exclusivities in other territories, such as in the EU. We cannot assure that our drug candidate, Zerenex (ferric citrate), or any drug candidates we may acquire or in-license, will obtain such orphan drug designation, pediatric exclusivity, new chemical entity exclusivity or any other market exclusivity in the U.S., EU or any other territory, or that we will be the first to receive the respective regulatory approval for such drugs so as to be eligible for any market exclusivity protection.

The intellectual property that we own or have licensed relating to our drug candidate, Zerenex, is limited, which could



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**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 product.**

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 Zerenex or any other 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 licensor or us that seeks damages or an injunction of our commercial activities relating to Zerenex or other technologies could subject us to monetary liability, a temporary or permanent injunction preventing the development, marketing and sale of Zerenex or such technologies, and/or require our licensor or us to obtain a license to continue to use Zerenex or other technologies. We cannot predict whether our licensor or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

**Risks related to 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.

In connection with this offering, we have entered into a lock-up agreement for a period of 60 days following this offering and our directors and officers have entered into lock-up agreements for a period of 30 days following this offering (which periods may be extended under certain circumstances). We and our directors and officers may be released from lock-up prior to the expiration of the lock-up period at the sole discretion of J.P. Morgan Securities LLC. See Underwriting. Upon expiration or earlier release of the lock-up, we and our directors and officers may sell shares into the market, which could adversely affect the market price of shares of our common stock.

Future issuances of common stock could further 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 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 candidate, including the safety and efficacy results from clinical trials and regulatory filings and approvals;

  - announcements of technological innovations by us or our competitors;

  - introductions or announcements of new products by us or our competitors;

- announcements of significant acquisitions, strategic partnerships, joint ventures or capital commitments involving us or our competitors;

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changes in financial estimates by securities analysts;  
actual or anticipated variations in quarterly or annual operating results;  
expectations regarding our financial condition;  
expiration or termination of licenses, research contracts or other collaboration agreements, including the recent termination of the license for KRX-0401 (perifosine);  
conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;  
changes in the market valuations of similar companies;  
negative comments and sentiment in the media; and  
additions or departures of key personnel.

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

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

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock without the approval of our stockholders. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

**We have broad discretion to use the net proceeds from this offering and our investment of these proceeds pending any such use 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.

We have broad discretion to use the net proceeds from this offering and our investment of these proceeds pending a

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## Use of proceeds

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

We expect to use the net proceeds from this offering:

to fund pre-launch/launch inventory build-up and select pre-commercial/commercial activities related to Zerenex;  
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 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.

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TABLE OF CONTENTS**Price range of our common stock**

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol KERX. On January 28, 2013, the last reported sale price of our common stock was \$6.06 per share.

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

|  | High    | Low     |
|--|---------|---------|
| 2011                                     |         |         |
| First Quarter                            | \$ 5.19 | \$ 3.81 |
| Second Quarter                           | 5.42    | 4.28    |
| Third Quarter                            | 4.94    | 2.99    |
| Fourth Quarter                           | 3.37    | 2.38    |
| 2012                                     |         |         |
| First Quarter                            | \$ 5.07 | \$ 2.51 |
| Second Quarter                           | 2.16    | 1.28    |
| Third Quarter                            | 2.83    | 1.79    |
| Fourth Quarter                           | 3.14    | 2.31    |
| 2013                                     |         |         |
| First Quarter (through January 28, 2013) | \$ 6.06 | \$ 2.73 |

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## **Dividend policy**

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

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TABLE OF CONTENTS**Capitalization**

The following table sets forth our capitalization as of September 30, 2012:

on an actual basis; and

on an as adjusted basis to reflect the sale of the shares of common stock offered by us in this offering (assuming no exercise of the underwriters' overallotment option) after deducting underwriting discounts and estimated offering expenses payable by us.

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.

| September 30, 2012 (unaudited)<br>(in thousands, except share data)   | Actual    | As adjusted |
|---|-----------|-------------|
| Cash and cash equivalents   | \$20,248  | \$          |
| 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; 72,005,749 shares actual and shares as adjusted, issued; 71,925,801 shares actual and shares as adjusted, issued and outstanding | 72        |             |
| Additional paid-in capital  | 402,849   |             |
| Treasury stock, at cost, 79,948 shares, actual and as adjusted  | (357 )    | (357 )      |
| Accumulated deficit   | (385,980) | (385,980)   |
| Total stockholders' equity  | 16,584    |             |
| Total capitalization  | \$53,416  | \$          |

The table excludes the following shares (as of September 30, 2012):

2,288,686 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2012, with a weighted average exercise price of \$5.91 per share; and  
an aggregate of 1,302,418 shares of common stock reserved for future issuance under our stock option and incentive plans.

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## Tax considerations

The following is a summary of material United States federal income tax consequences relating to the acquisition, ownership and disposition of our common stock as of the date hereof. Except where noted, this summary deals only with our common stock that is held as a capital asset by a non-U.S. holder (as defined below).

For purposes of this summary, a non-U.S. holder means a person (other than a partnership or any other entity treated as a partnership for United States federal income tax purposes) that is not for United States federal income tax purposes any of the following:

- an individual citizen or resident of the United States;
- a corporation (or any other entity treated as a corporation for United States federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia;
- an estate the income of which is subject to United States federal income taxation regardless of its source; or
- a trust if it (1) is subject to the primary supervision of a court within the United States and one or more United States persons have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable United States Treasury regulations ( Treasury Regulations ) to be treated as a United States person.

This summary is based upon provisions of the Internal Revenue Code of 1986, as amended (the Code ) and Treasury Regulations, administrative rulings and judicial decisions currently in effect, all as of the date hereof and all subject to change at any time, possibly with retroactive effect, or to different interpretation by the Internal Revenue Service ( IRS ). This summary does not address all aspects of United States federal taxes and does not address any foreign, state, local or other tax considerations that may be relevant to non-U.S. holders in light of their personal circumstances. In addition, this summary does not represent a detailed description of the United States federal income tax consequences applicable to holders that are subject to special treatment under the United States federal income tax laws (including a holder that is a United States expatriate, controlled foreign corporation, passive foreign investment company, real estate investment trust, regulated investment company, dealer in securities or currencies, financial institution, tax-exempt entity, insurance company, person holding our common stock as part of a hedging, integrated, conversion or constructive sale transaction or a straddle, trader in securities that elects to use a mark-to-market method of accounting, person liable for the alternative minimum tax, person who acquired our common stock as compensation for services, or a partnership or other pass-through entity, or partner in a partnership or beneficial owner of a pass-through entity that holds our common stock for United States federal income tax purposes). We cannot provide assurance that a change in law will not alter significantly the tax considerations that we describe in this summary.

If a partnership holds our common stock, the tax treatment of a partner will generally depend upon the status of the partner and the activities of the partnership. Non-U.S. holders that are partners of a partnership holding our common stock should consult their tax advisors.

Non-U.S. holders considering the purchase of our common stock should consult their own tax advisors concerning the particular United States federal income and estate tax consequences of the ownership of our common stock, as well as the consequences arising under the laws of any other taxing jurisdiction.

## Dividends

Distributions paid on our common stock will be taxable as dividends to the extent paid out of current or accumulated earnings and profits, as determined under United States federal income tax principles.



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Dividends paid to a non-U.S. holder of our common stock generally will be subject to withholding of United States federal income tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty. However, dividends that are effectively connected with the conduct of a trade or business by the non-U.S. holder within the United States (and, if required by an applicable income tax treaty, are attributable to a United States permanent establishment) are not subject to withholding tax, provided certain certification and disclosure requirements are satisfied. Instead, such dividends are subject to United States federal income tax on a net income basis in the same manner as if the non-U.S. holder were a United States person as defined under the Code. Any such effectively connected dividends received by a foreign corporation may be subject to an additional branch profits tax at a 30% rate or such lower rate as may be specified by an applicable income tax treaty.

A non-U.S. holder of our common stock who wishes to claim the benefit of an applicable treaty rate and avoid backup withholding, as discussed below, for dividends will be required (a) to complete IRS Form W-8BEN (or other applicable form) and certify under penalty of perjury that such holder is not a United States person as defined under the Code and is eligible for treaty benefits or (b) if the common stock is held through certain foreign intermediaries, to satisfy the relevant certification requirements of applicable Treasury Regulations. Special certification and other requirements apply to certain non-U.S. holders that are pass-through entities rather than corporations or individuals.

A non-U.S. holder of our common stock eligible for a reduced rate of United States withholding tax pursuant to an income tax treaty may obtain a refund of any excess amounts withheld by filing an appropriate claim for refund with the IRS.

## **Gain on disposition of our common stock**

Any gain realized on the disposition of our common stock by a non-U.S. holder generally will not be subject to United States federal income tax unless:

- the gain is effectively connected with a trade or business of the non-U.S. holder in the United States (and, if required by an applicable income tax treaty, is attributable to a United States permanent establishment of the non-U.S. holder);

- the non-U.S. holder is an individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or

- we are or have been a United States real property holding corporation for United States federal income tax purposes at any time during the shorter of the five-year period ending on the date of the disposition or such non-U.S. holder's holding period for our common stock and such non-U.S. holder held (at any time during the shorter of the five-year period ending on the date of the disposition or such non-U.S. holder's holding period) more than 5% of our common stock.

An individual non-U.S. holder described in the first bullet point immediately above will be subject to tax on the net gain derived from the sale under regular graduated United States federal income tax rates. If a non-U.S. holder that is a foreign corporation falls under the first bullet point immediately above, it will be subject to tax on its net gain in the same manner as if it were a United States person as defined under the Code and, in addition, may be subject to a branch profits tax equal to 30% of its effectively connected earnings and profits or at such lower rate as may be specified by an applicable income tax treaty.

We believe we have not been and are not currently a United States real property holding corporation for United States federal income tax purposes; however, no assurance can be given that we will not become one in the future. If, however, we are or become a United States real property holding corporation, so long as our common stock continues to be regularly traded on an established securities market, only a non-U.S. holder who holds, or held (at any time

during the shorter of the five-year period ending on the date of disposition or the non-U.S. holder's holding period) more than 5% of our common stock will be subject to United States federal income tax on the disposition of the common stock. Non-U.S.

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holders should consult their own tax advisors about the consequences that could result if we are, or become, a United States real property holding corporation.

## **Information reporting and backup withholding**

We must report annually to the IRS and to each non-U.S. holder the amount of dividends paid to such holder and the tax withheld with respect to such dividends, regardless of whether withholding was required. Copies of the information returns reporting such dividends and withholding may also be made available to the tax authorities in the country in which the non-U.S. holder resides under the provisions of an applicable income tax treaty.

A non-U.S. holder will be subject to backup withholding for dividends paid to such holder unless such holder certifies under penalty of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that such holder is a United States person as defined under the Code), or such holder otherwise establishes an exemption.

Information reporting and, depending on the circumstances, backup withholding will apply to the proceeds of a sale of our common stock within the United States or conducted through certain United States-related financial intermediaries, unless the beneficial owner certifies under penalty of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that the beneficial owner is a United States person as defined under the Code), or such owner otherwise establishes an exemption.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a refund or a credit against a non-U.S. holder's United States federal income tax liability provided the required information is furnished to the IRS.

## **FATCA withholding requirements**

Under the recently enacted Foreign Account Tax Compliance Act ( FATCA ) and the Treasury Regulations promulgated thereunder, the relevant withholding agent may be required to withhold 30% of any dividends on our common stock paid on or after January 1, 2014, and on the gross proceeds from the sales of our common stock on or after January 1, 2017 to (i) a foreign financial institution unless such foreign financial institution agrees to verify, report and disclose its U.S. accountholders and meets certain other specified requirements or (ii) a non-financial foreign entity that is the beneficial owner of the payment unless such entity certifies that it does not have any substantial United States owners or provides the name, address and taxpayer identification number of each substantial United States owner and such entity meets certain other specified requirements.

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## Underwriting

We are offering the shares of common stock described in this prospectus supplement through a number of underwriters. J.P. Morgan Securities LLC is acting as sole book-running manager of the offering and as representative of the underwriters. We have entered into an underwriting agreement with the underwriters. Subject to the terms and conditions of the underwriting agreement, we have agreed to sell to the underwriters, and each underwriter has severally agreed to purchase, at the public offering price less the underwriting discounts and commissions set forth on the cover page of this prospectus supplement, the number of shares of common stock listed next to its name in the following table:

| Name                       | Number of<br>Shares |
|----------------------------|---------------------|
| J.P. Morgan Securities LLC |                     |
| Total                      |                     |

The underwriters are committed to purchase all the common shares offered by us if they purchase any shares. The underwriting agreement also provides that if an underwriter defaults, the purchase commitments of non-defaulting underwriters may also be increased or the offering may be terminated.

The underwriters propose to offer the common shares directly to the public at the initial public offering price set forth on the cover page of this prospectus supplement and to certain dealers at that price less a concession not in excess of \$ per share. After the initial public offering of the shares, the offering price and other selling terms may be changed by the underwriters. Sales of shares made outside of the United States may be made by affiliates of the underwriters.

The underwriters have an option to buy up to \$8,250,000 of additional shares of common stock from us to cover sales of shares by the underwriters which exceed the number of shares specified in the table above. The underwriters have 30 days from the date of this prospectus supplement to exercise this over allotment option. If any shares are purchased with this over-allotment option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If any additional shares of common stock are purchased, the underwriters will offer the additional shares on the same terms as those on which the shares are being offered.

The underwriting fee is equal to the public offering price per share of common stock less the amount paid by the underwriters to us per share of common stock. The underwriting fee is \$ per share. The following table shows the per share and total underwriting discounts and commissions to be paid to the underwriters assuming both no exercise and full exercise of the underwriters option to purchase additional shares.

|           | Without<br>over-allotment<br>exercise | With full<br>over-allotment<br>exercise |
|-----------|---------------------------------------|---|
| Per Share | \$                                    | \$                                      |
| Total     | \$                                    | \$                                      |

We estimate that the total expenses of this offering, including registration, filing and listing fees, printing fees and legal and accounting expenses, but excluding the underwriting discounts and commissions, will be approximately \$ .

A prospectus in electronic format may be made available on the web sites maintained by one or more underwriters, or selling group members, if any, participating in the offering. The underwriters may agree to allocate a number of shares to underwriters and selling group members for sale to their online

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brokerage account holders. Internet distributions will be allocated by the representative to underwriters and selling group members that may make Internet distributions on the same basis as other allocations.

We have agreed that, during the period beginning from the date of this prospectus supplement and continuing to and including the date 60 days after the date of this prospectus supplement (as may be extended as set forth below, the

Company Lock-Up Period ), we will not offer, sell, contract to sell or otherwise dispose of, any securities of ours, including but not limited to any securities that are convertible into or exchangeable for, or that represent the right to receive, shares of our common stock or any such substantially similar securities (other than (i) pursuant to equity incentive plans existing on the date of the underwriting agreement, or (ii) upon the conversion, exercise or exchange of convertible, exercisable or exchangeable securities outstanding as of the date of the underwriting agreement).

Our directors and executive officers have entered into lock-up agreements with the underwriters prior to the commencement of this offering pursuant to which each of them have agreed that, during the period beginning from the date of this prospectus supplement and continuing to and including the date 30 days after the date of this prospectus supplement (as may be extended as set forth below, the D&O Lock-Up Period ), they will not offer, sell, contract to sell, pledge (except a pledge for the benefit of the company pursuant to an agreement entered or to be entered into between the company and the relevant director or executive officer), grant any option to purchase, make any short sale or otherwise dispose of any shares of our common stock, or any options or warrants to purchase any shares of our common stock, or any securities convertible into, exchangeable for or that represent the right to receive shares of our common stock, whether now owned or hereafter acquired, owned directly by the relevant director or executive officer (including holding as a custodian) or with respect to which the relevant director or executive officer has beneficial ownership within the rules and regulations of the SEC (collectively Shares ). The foregoing restriction expressly precludes the relevant director or executive officer from engaging in any hedging or other transaction which is designed to or which reasonably could be expected to lead to or result in a sale or disposition of such director or executive officer's Shares even if such Shares would be disposed of by someone other than such director or executive officer. Such prohibited hedging or other transactions would include without limitation any short sale or any purchase, sale or grant of any right (including without limitation any put or call option) with respect to any of such director or executive officer's Shares or with respect to any security that includes, relates to, or derives any significant part of its value from such Shares (regardless of whether any such transaction is to be settled by delivery of our common stock, such other securities, in cash or otherwise). Further, our directors and executive officers have agreed not to make any demand for, or exercise any right with respect to, the registration of any shares of our common stock or securities convertible into or exercisable or exchangeable for our common stock during the D&O Lock-Up Period. However, these restrictions do not apply to:

transactions relating to shares of our 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 the relevant director or officer's Shares (i) as a bona fide gift or gifts, *provided* that the donee or donees thereof agree to be bound in writing by the restrictions set forth in the lock-up agreement, (ii) upon death by will or intestacy, *provided* that the recipient agrees to be bound in writing by the restrictions set forth in the lock-up agreement, (iii) to the relevant director or officer's immediate family or to any trust for the direct or indirect benefit of the relevant director or officer or their immediate family, *provided* that the recipient or the trustee of the trust, as the case may be, agrees to be bound in writing by the restrictions set forth in the lock-up agreement, (iv) to any affiliate (as such term is defined in Rule 405 of the Securities Act) of the relevant director or officer, *provided* that in each case the recipient agrees to be bound in writing by the restrictions set forth in the lock-up agreement, (v) by operation of law, including a qualified domestic order, provided that the recipient agrees to be bound in writing by the restrictions set forth in the lock-up agreement, and



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*provided further* with respect to (i), (ii), (iii), (iv) and (v) above that any such transfer shall not involve a disposition for value and no public reports, including but not limited to reports pursuant to Section 16(a) of the Exchange Act, reporting a reduction in beneficial ownership of shares of our common stock are required to be filed by the relevant director or officer during the Lock-Up Period and no such reports are voluntarily filed by the relevant director or officer during the Lock-Up Period, or (vi) with the prior written consent of J.P. Morgan Securities LLC; transactions pursuant to any written plan meeting the requirements of Rule 10b5-1 under the Exchange Act that has been entered into by the relevant director or officer prior to the date of the relevant lock-up agreement; entry into a written plan meeting the requirements of Rule 10b5-1 under the Exchange Act after the date of the relevant lock-up agreement relating to the sale of securities of the company, if then permitted by the company, *provided* that the securities subject to such plan may not be sold until after the expiration of the Lock-Up Period, and *provided further* that no public reports, including but not limited to reports pursuant to Section 16(a) of the Exchange Act, are required to be filed by any party in connection with such plan during the Lock-Up Period; exercise any options or warrants to purchase shares of our common stock, *provided* that the underlying common stock continues to be subject to the restrictions set forth in the lock-up agreement; or with regard to shares of restricted stock granted under our equity incentive plans, effect 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.

Notwithstanding the foregoing, if (i) during the last 17 days of the Company Lock-Up Period or the D&O Lock-Up Period (each, a Lock-Up Period ), we release earnings results or announce material news or a material event, or (ii) prior to the expiration of a Lock-Up Period, we announce that we will release earnings results during the 15-day period following the last day of such Lock-Up Period, then, in each case, such Lock-Up Period in each of the applicable agreements described above will be automatically extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the announcement of the material news or material event, as applicable, unless J.P. Morgan Securities LLC waives, in writing, such extension.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933.

Our common stock is listed/quoted on the NASDAQ Capital Market under the symbol **KERX** .

In connection with this offering, the underwriters may engage in stabilizing transactions, which involves making bids for, purchasing and selling shares of common stock in the open market for the purpose of preventing or retarding a decline in the market price of the common stock while this offering is in progress. These stabilizing transactions may include making short sales of the common stock, which involves the sale by the underwriters of a greater number of shares of common stock than they are required to purchase in this offering, and purchasing shares of common stock on the open market to cover positions created by short sales. Short sales may be covered shorts, which are short positions in an amount not greater than the underwriters over-allotment option referred to above, or may be naked shorts, which are short positions in excess of that amount. The underwriters may close out any covered short position either by exercising their over-allotment option, in whole or in part, or by purchasing shares in the open market. In making this determination, the underwriters will consider, among other things, the price of shares available for purchase in the open market compared to the price at which the underwriters may purchase shares through the over-allotment option. A naked short position is more likely to be created if the underwriters are concerned that there may be downward pressure on the price of the

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common stock in the open market that could adversely affect investors who purchase in this offering. To the extent that the underwriters create a naked short position, they will purchase shares in the open market to cover the position.

The underwriters have advised us that, pursuant to Regulation M of the Securities Act of 1933, they may also engage in other activities that stabilize, maintain or otherwise affect the price of the common stock, including the imposition of penalty bids. This means that if the representative of the underwriters purchases common stock in the open market in stabilizing transactions or to cover short sales, the representative can require the underwriters that sold those shares as part of this offering to repay the underwriting discount received by them.

These activities may have the effect of raising or maintaining the market price of the common stock or preventing or retarding a decline in the market price of the common stock, and, as a result, the price of the common stock may be higher than the price that otherwise might exist in the open market. If the underwriters commence these activities, they may discontinue them at any time. The underwriters may carry out these transactions on the NASDAQ Capital Market, in the over-the-counter market or otherwise.

In addition, in connection with this offering certain of the underwriters (and selling group members) may engage in passive market making transactions in our common stock on The Nasdaq Stock Market prior to the pricing and completion of this offering. Passive market making consists of displaying bids on The Nasdaq Stock Market no higher than the bid prices of independent market makers and making purchases at prices no higher than these independent bids and effected in response to order flow. Net purchases by a passive market maker on each day are generally limited to a specified percentage of the passive market maker's average daily trading volume in the common stock during a specified period and must be discontinued when such limit is reached. Passive market making may cause the price of our common stock to be higher than the price that otherwise would exist in the open market in the absence of these transactions. If passive market making is commenced, it may be discontinued at any time.

Other than in the United States, no action has been taken by us or the underwriters that would permit a public offering of the securities offered by this prospectus supplement in any jurisdiction where action for that purpose is required. The securities offered by this prospectus supplement may not be offered or sold, directly or indirectly, nor may this prospectus supplement or any other offering material or advertisements in connection with the offer and sale of any such securities be distributed or published in any jurisdiction, except under circumstances that will result in compliance with the applicable rules and regulations of that jurisdiction. Persons into whose possession this prospectus supplement comes are advised to inform themselves about and to observe any restrictions relating to the offering and the distribution of this prospectus supplement. This prospectus supplement does not constitute an offer to sell or a solicitation of an offer to buy any securities offered by this prospectus supplement in any jurisdiction in which such an offer or a solicitation is unlawful.

This document is only being distributed to and is only directed at (i) persons who are outside the United Kingdom or (ii) to investment professionals falling within Article 19(5) of the Financial Services and Markets Act 2000 (Financial Promotion) Order 2005 (the "Order") or (iii) high net worth entities, and other persons to whom it may lawfully be communicated, falling with Article 49(2)(a) to (d) of the Order (all such persons together being referred to as "Relevant Persons"). The securities are only available to, and any invitation, offer or agreement to subscribe, purchase or otherwise acquire such securities will be engaged in only with, Relevant Persons. Any person who is not a Relevant Person should not act or rely on this document or any of its contents.

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State"), from and including the date on which the European Union Prospectus Directive (the "EU Prospectus Directive") was implemented in that Relevant Member State (the "Relevant Implementation Date") an offer of securities described in this prospectus supplement may not be made to the public in that Relevant Member

State prior to the publication of a prospectus in relation

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to the shares which has been approved by the competent authority in that Relevant Member State or, where appropriate, approved in another Relevant Member State and notified to the competent authority in that Relevant Member State, all in accordance with the EU Prospectus Directive, except that, with effect from and including the Relevant Implementation Date, an offer of securities described in this prospectus may be made to the public in that Relevant Member State at any time:

to any legal entity which is a qualified investor as defined under the EU Prospectus Directive;  
to fewer than 100 or, if the Relevant Member State has implemented the relevant provision of the 2010 PD Amending Directive, 150 natural or legal persons (other than qualified investors as defined in the EU Prospectus Directive); or  
in any other circumstances falling within Article 3(2) of the EU Prospectus Directive, provided that no such offer of securities described in this prospectus shall result in a requirement for the publication by us of a prospectus pursuant to Article 3 of the EU Prospectus Directive.

For the purposes of this provision, the expression an offer of securities to the public in relation to any securities in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and the securities to be offered so as to enable an investor to decide to purchase or subscribe for the securities, as the same may be varied in that Member State by any measure implementing the EU Prospectus Directive in that Member State. The expression EU Prospectus Directive means Directive 2003/71/EC (and any amendments thereto, including the 2010 PD Amending Directive, to the extent implemented in the Relevant Member State) and includes any relevant implementing measure in each Relevant Member State, and the expression 2010 PD Amending Directive means Directive 2010/73/EU.

Certain of the underwriters and their affiliates have provided in the past to us and our affiliates and may provide from time to time in the future certain commercial banking, financial advisory, investment banking and other services for us and such affiliates in the ordinary course of their business, for which they have received and may continue to receive customary fees and commissions. In addition, from time to time, certain of the underwriters and their affiliates may effect transactions for their own account or the account of customers, and hold on behalf of themselves or their customers, long or short positions in our debt or equity securities or loans, and may do so in the future.

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### **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 Davis Polk & Wardwell LLP, New York, New York.

### **Experts**

The consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of and for the year ended December 31, 2011 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 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, free of charge, from our Internet website found at [www.keryx.com](http://www.keryx.com). Information contained on our 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 KERYX.

### **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, 2011 (including portions of our Definitive Proxy Statement on Schedule 14A incorporated into Part III thereof);

Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2012, June 30, 2012, and September 30, 2012; and

Our Current Reports on Form 8-K filed with the SEC on January 19, 2012, April 2, 2012, April 23, 2012, May 8, 2012 (with respect to Item 1.01 only), June 20, 2012, November 7, 2012, January 7, 2013 and January 28, 2013.

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, but not delivered with 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.

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**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.**

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## **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](http://www.keryx.com) and our e-mail address is [info@keryx.com](mailto: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](http://www.keryx.com). Our stock is quoted on the Nasdaq Capital Market under the symbol KERX.

# 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**.

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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.

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### **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.

### **Liquidation 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.

## **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;

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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 reallocated or paid to dealers.

Any public offering price and any discounts or concessions allowed or reallocated 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.



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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.

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*\$55,000,000*

*Common Stock*

**Prospectus supplement**  
***Sole book-running manager***

**J.P. Morgan**

, 2013

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.

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