KERYX BIOPHARMACEUTICALS INC
Form 424B5
January 23, 2014
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Filed Pursuant to Rule 424(b)(5)
Registration No. 333-190353

Prospectus supplement (to prospectus dated August 16, 2013)

6,900,000 shares

Common stock

We are offering 6,900,000 shares of our common stock, $0.001 par value per share, in this offering.

Our common stock is traded on the Nasdaq Capital Market under the symbol KERX. On January 22, 2014, the last reported sale price of our common stock on the Nasdaq Capital Market was $14.60 per share.

	Per share	Total
Public offering price	$ 14.5000	$ 100,050,000.00
Underwriting discount and commissions	$ 0.8700	$ 6,003,000.00
Proceeds to Keryx, before expenses	$ 13.6300	$ 94,047,000.00

Keryx has granted the underwriters an option for a period of 30 days from the date of this prospectus supplement to purchase up to 1,035,000 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 January 28, 2014 only in book-entry form through the facilities of The Depository Trust Company.

Sole book-running manager

J.P. Morgan

Oppenheimer & Co.

JMP Securities

Stifel

Roth Capital Partners

Brean Capital

Ladenburg Thalmann & Co. Inc.

H.C. Wainwright & Co., LLC

January 22, 2014

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Prospectus supplement

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

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prospectus supplement and the accompanying prospectus outside the United States. This prospectus supplement and the accompanying prospectus do not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement and the accompanying prospectus by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

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

Special cautionary notice regarding forward-looking statements

Certain matters discussed in this prospectus supplement and the accompanying prospectus, including matters discussed under the caption Management s Discussion and Analysis of Financial Condition and Results of Operations, included in the documents incorporated by reference herein, 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/or the documents incorporated by reference herein, 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™ (ferric citrate coordination complex) or any other products that we may acquire or in-license;
- expectations for incurring capital expenditures to expand our research and development and manufacturing capabilities;
- estimates regarding market size and projected growth, as well as our expectation of market acceptance of Zerenex;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;

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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;

expectations or investor speculation regarding the strength of our intellectual property position, or the availability of regulatory exclusivity;

estimates of the sufficiency of our existing cash and cash equivalents to finance our operating requirements, including expectations regarding the value and liquidity of our investments;

expected losses;

expectations for future capital requirements; and

ability to estimate costs related to litigation.

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. 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 coordination complex), an oral, ferric iron-based compound that has the capacity to bind to phosphate in the gastrointestinal tract and form non-absorbable complexes.

We have completed a U.S.-based Phase 3 clinical program for Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, on dialysis, conducted pursuant to a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA. Our New Drug Application, or NDA, is currently under review by the FDA with an assigned Prescription Drug User Fee Act, or PDUFA, goal date of June 7, 2014. We also plan to submit a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA.

Currently, our only drug candidate is Zerenex. We may engage in business development activities that include seeking strategic relationships for Zerenex, 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. 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 our Japanese partner, Japan Tobacco Inc., or JT, and Torii Pharmaceutical Co., Ltd., or Torii.

Recent developments

In January 2013, JT and Torii filed its 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, or CKD. On January 17, 2014, we announced that JT had received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare. Ferric citrate, to be marketed in Japan by JT s subsidiary, Torii, under the brand name Riona®, is indicated as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and non-dialysis dependent CKD.

Under our license agreement with JT and Torii we will receive a non-refundable payment of $10 million within 30 days of the achievement of the marketing approval milestone. We will also receive tiered double-digit percentage royalties on net sales of Riona® in Japan escalating up to the mid-teens, as well as up to an additional $55 million upon the achievement of certain annual net sales milestones.

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Zerenex has also completed a Phase 2 study in the U.S. for the management of elevated serum phosphorus levels and iron deficiency anemia in patients with Stage 3 to 5 non-dialysis dependent CKD. Top-line results from this Phase 2 study were announced on November 5, 2013. In this study, Zerenex met both co-primary endpoints, demonstrating highly statistically significant changes in serum phosphorus and transferrin saturation, or TSAT, versus placebo over the 12-week treatment period. In addition, Zerenex met the key secondary endpoints of increasing ferritin and hemoglobin, and decreasing fibroblast growth factor-23, or FGF-23, versus placebo.

On November 8, 2013, we announced preliminary, unaudited data from an ongoing 48-week safety extension study of Zerenex for the treatment of hyperphosphatemia in patients with CKD on dialysis. The data presented appeared to corroborate the data observed in the completed long-term Phase 3 study.

Company information

We were incorporated in Delaware in October 1998 and commenced operations in November 1999. 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	6,900,000 shares
Common stock to be outstanding after the offering	89,216,467 shares
Option to purchase additional shares	Up to 1,035,000 additional 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 pre-commercial/commercial activities related to Zerenex, the ongoing development of Zerenex in pre-dialysis, and other general corporate purposes. See Use of Proceeds on page S-20.
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 82,316,467 shares of common stock outstanding as of October 25, 2013 and assumes no exercise of the underwriters overallotment option. Our shares outstanding as of the date of this prospectus supplement have not changed materially since October 25, 2013.

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

- 4,042,600 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2013, with a weighted average exercise price of $5.24 per share; and
- an aggregate of 3,712,002 shares of common stock reserved for future issuance under our stock option and incentive plans as of September 30, 2013.

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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 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 and our directors and officers have entered into lock-up agreements for a period of 30 days following this offering (which period 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;
- 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;

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expectations or investor speculation regarding the strength of our intellectual property position, or the availability of regulatory exclusivity;

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. For example, on February 1, 2013, a putative class of stockholders filed a securities class action against us, alleging misstatements or omissions in relation to our clinical trials for KRX-0401 (perifosine) which we abandoned in May 2012 following negative Phase 3 results. This litigation or any other 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.

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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, 2013, we had an accumulated deficit of $421.7 million. As we continue our research and development and pre-commercial 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, Zerenex (ferric citrate coordination complex).

We have not yet commercialized any drug candidate and cannot be sure that we will ever be able to do so. Even if we commercialize Zerenex, or a future 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 manufacture and commercialize our drug candidate.

Risks associated with our product development efforts

If we do not receive regulatory approvals to market our product candidate in a timely manner, or at all, our business will be materially harmed and our stock price may be adversely affected.

We are developing Zerenex (ferric citrate coordination complex), an oral, ferric iron-based compound that has the capacity to bind to phosphate and form non-absorbable complexes. We have completed a U.S.-based Phase 3 clinical program for Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with chronic kidney disease, or CKD, on dialysis, conducted pursuant to a Special Protocol Assessment, or SPA, agreement with the Food and Drug Administration, or FDA, and the Company s New Drug Application, or NDA, was submitted to the FDA for review in August 2013. On October 7, 2013, the FDA accepted for review the NDA that we submitted for Zerenex. We subsequently received the Filing Review Notification, also referred to as the Day 74 letter, which designated a standard 10-month review timeline and a FDA Prescription Drug User Fee Act, or PDUFA, goal date of June 7, 2014, which is the date by which the FDA intends to complete its review and issue a determination. The FDA is not bound by, and has in the past missed, its PDUFA goals, and it is unknown whether the review of our NDA filing for Zerenex will be completed within the FDA review goal or will be delayed.

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 CKD patients undergoing dialysis, and in non-dialysis dependent CKD patients. The Scientific Advice from the EMA indicates that our successful Phase 3 program in dialysis 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 CKD patients on dialysis. The Scientific Advice also provided us with a regulatory path forward in the non-dialysis dependent CKD setting in Europe. As a result, we believe that since our Phase 3 program in dialysis, and Phase 2 study in non-dialysis dependent CKD, in the U.S. were successful, we will not need to conduct any additional clinical trials to

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assess the safety or efficacy of Zerenex in order to obtain European approval in CKD, including the dialysis and non-dialysis dependent CKD settings. We are currently preparing our MAA filing for CKD patients, which filing is pending submission. 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 positive 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, or other pivotal, 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 and analyses, 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.

Obtaining approval of a NDA and MAA by the FDA and EMA, respectively, is highly uncertain and like many product candidates, we may fail to obtain the respective approvals even though our NDA for Zerenex has been filed and accepted for review by the FDA. The NDA and MAA review processes are extensive, lengthy, expensive and uncertain, and the FDA and/or EMA may delay, limit or deny approval of Zerenex for many reasons, including:

- we may not be able to demonstrate to the satisfaction of the respective regulatory authority that Zerenex is safe and effective for any indication;
- the data arising from the clinical trials, including the Phase 3 results for dialysis patients and our recent Phase 2 results for non-dialysis dependent CKD, the development program or the NDA and/or MAA for Zerenex may not be satisfactory to the FDA and/or EMA;
- the respective regulatory authority may disagree with the number, design, size, conduct or implementation of our clinical trials or conclude that the data fails to meet statistical or clinical significance;
- the respective regulatory authority may not find the data from preclinical and clinical studies sufficient to demonstrate that Zerenex s clinical and other benefits outweigh its safety risks;
- the respective regulatory authority may disagree with our interpretation of data from preclinical studies or clinical trials, and may reject conclusions from preclinical studies or clinical trials, or determine that primary or secondary endpoints from clinical trials were not met, or reject safety conclusions from such studies;
- the respective regulatory authority may not accept data generated at our clinical trial sites;
- the respective regulatory authority may determine that we did not properly oversee our clinical trials or follow the regulatory authority s advice or recommendations in conducting our clinical trials;
- an advisory committee, if convened by the respective regulatory authority, may recommend against approval of our application or may recommend that the respective regulatory authority require, as a condition of approval, additional preclinical studies or clinical trials, limitations on approved labeling or distribution and use restrictions, or even if an advisory committee, if convened, makes a favorable recommendation, the respective regulatory authority may still not approve Zerenex; and
- the respective regulatory authority may identify deficiencies in the chemistry, manufacturing and controls, or CMC, sections of our NDA, our manufacturing processes, facilities or analytical

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methods or those of our third party contract manufacturers, and this may lead to significant delays in the approval of Zerenex or to the rejection of the Zerenex NDA.

Additionally, we have never submitted a MAA in Europe, which may result in a delay in, or the rejection of, our MAA filing. 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 at the time of NDA and/or MAA submission, or may be difficult or impossible to answer to the satisfaction of the regulatory authorities. Unless the FDA and/or EMA opts not to pursue these questions, our NDA and/or MAA filing may be delayed or rejected.

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 agreement with the FDA. Many companies which have been granted SPAs 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, and agreed to by, the FDA, we may be subject to enhanced scrutiny. Regardless of the success of our Phase 3 clinical trials, a SPA does not guarantee approval. The FDA may raise issues of safety, study conduct, bias, deviation from the protocol, statistical power and analyses, 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 agreement, or require us to conduct additional, expensive clinical trials in order to obtain regulatory approval.

Accordingly, we may not receive the regulatory approvals needed to market Zerenex. Any failure or delay in completion of the development program or the FDA and/or EMA review processes would delay or foreclose commercialization of Zerenex and severely harm our business and financial condition.

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 our 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, in May 2012, we abandoned our development efforts and terminated our license for KRX-0401

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(perifosine) following negative results from the Phase 3 trial. We may also opt to change the delivery method, formulation or dosage which could affect efficacy results for the drug candidate. Accordingly, we may not be able to complete our current or future clinical trials within an acceptable time frame, if at all.

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.

We have not received, and may never receive, regulatory approval for the commercial sale of any drug candidate. We may need to conduct significant additional research and human testing before we receive product approvals with the FDA, EMA or with regulatory authorities of other countries. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product. It requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. The FDA, EMA or a regulatory authority of another country, as applicable, may pose additional questions or request further toxicological, drug-drug interaction, 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, inconclusive, or insufficient 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 for CKD patients on dialysis, 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. For example, we can provide no assurance we will not encounter safety and efficacy issues in subsequent trials for Zerenex with non-dialysis dependent CKD patients. Moreover, the risk remains that the safety and efficacy data from our pivotal Phase 3 program for dialysis dependent CKD patients may be insufficiently persuasive for the approval of the drug, or may raise safety concerns that may prevent approval of the drug, for the indication sought. 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. In addition, qualitative, quantitative and statistical interpretation of any of the prior pre-clinical and clinical safety and efficacy data of our drug candidate may be viewed as flawed by the FDA, EMA or any other regulatory agency. In addition, there can be no assurance that safety and/or efficacy concerns from the prior data were not overlooked or misinterpreted by us or our

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consultants, 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 a regulatory authority. For example, in January 2013, we announced successful top-line results from our long-term Phase 3 study of Zerenex for the treatment of elevated serum phosphorus levels, or hyperphosphatemia, in patients with ESRD on dialysis. Updated results were presented in June 2013 at the World Congress of Nephrology. We can provide no assurance that our findings and conclusions from our long-term Phase 3 study of Zerenex will not change following a more comprehensive review of the data by 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 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 inventors of Zerenex. The license agreement with Panion requires us to meet development milestones and imposes development and commercialization due diligence requirements on us. In addition, under the agreement, we must pay royalties based on a mid-single digit percentage of net sales of product resulting from the licensed technologies (including Zerenex) 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 (including upon certain insolvency events), 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

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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, manufacture 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, the FDA must review and approve our validation studies for drug substance and drug product. 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, technical difficulties, 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 and drug substance and drug product processes become critical to commercial success. For example, given the large quantity of materials required for Zerenex production and the large quantities of Zerenex that will be required for commercial success, the commercial viability of Zerenex, if approved, will also depend on adequate supply of starting materials that meet quality, quantity and cost standards and the ability of our contract manufacturers to produce drug substance and drug product in large scale. Failure to achieve this level of supply can jeopardize and prevent the successful commercialization of the product. Moreover, issues that may arise in our current transition to commercial batch sizes with our third party manufacturers of Zerenex can lead to significant 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 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, and are ultimately held responsible for their regulatory compliance, we

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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 quality, impurity and release testing of our drug candidate. We are required by law to have adequate control over raw materials, components and finished products furnished by our third-party manufacturers, which we establish by contract and through periodic oversight, but unforeseen circumstances could affect our third-party manufacturers compliance with applicable regulations and standards. As we continue to scale up production, we continue to develop analytical tools for ferric citrate drug substance 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 methods 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 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 receive regulatory approval for our drug candidate. Switching or engaging multiple third-party contractors to produce our drug substance or drug product may be difficult and time consuming 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 and time consuming for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. For Zerenex, the loss of any of our drug substance or drug product manufacturers 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 additional third parties, or renew or revise contracts with existing 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 significant delays. Furthermore, such failure could result in the termination of license rights to our product. If these manufacturing, development or marketing agreements

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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. We cannot predict the form or scope that any such collaboration might take, and we may pursue other strategic alternatives if terms or proposed collaborations are not attractive. 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 agreements with them or fail to perform their work in a satisfactory manner, in spite of our efforts to monitor and ensure the quality of such work, we may face delays in achieving the business or regulatory milestones required for commercialization of our current, and any future, drug candidate.

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 and other vendors to conduct and manage clinical studies and to assist us in guiding our products through the FDA review and approval process. If the CROs or applicable vendors fail to perform their obligations under our agreements with them or fail to perform clinical trials in a satisfactory or timely manner, we may face significant delays in completing our clinical trials, submitting our regulatory filings, or approval, as well as the 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 and or EMA, 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 and time consuming 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.

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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:

- 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 marketing claims that the FDA will permit us to make in the labeling and advertising of Zerenex, including potential marketing claims related to the effect of Zerenex on iron storage parameters and on the reduction in the use of IV iron and ESAs;
- 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-patent;
- 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. In addition, our estimates regarding market size and projected growth are based on third party studies, which while we believe them to be reasonable, may not prove to be accurate when Zerenex becomes available in the market. Some of the studies have also observed a slow down of growth in the incidence of renal disease and patients on dialysis.

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

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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), PhosLo® (calcium acetate), marketed by Fresenius Medical Care, Fosrenol® (lanthanum carbonate), marketed by Shire Pharmaceuticals Group plc, and Velphoro® (sucroferric oxyhydroxide), marketed by Fresenius Medical Care North America, 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 is differentiated in the marketplace versus these FDA approved phosphate binders. In addition, we would have to 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.

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.

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, 2013, we had 33 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;

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our inability to retain the management, key personnel and other employees of the acquired business;

our inability to maintain the acquired company s relationship with key third parties, such as alliance partners;

exposure to legal claims for activities of the acquired business prior to the acquisition;

the diversion of our management s attention from our core business; and

the potential impairment of goodwill and write-off of in-process research and development costs, adversely affecting our reported results of operations.

The status of reimbursement from third-party payors for newly approved health care drugs is uncertain and failure to obtain adequate reimbursement could limit our ability to generate revenue.

Our ability to commercialize pharmaceutical products may depend, in part, on the extent to which reimbursement for the products will be available from:

government and health administration authorities;
private health insurers;
managed care programs; and
other third-party payors.

Significant uncertainty exists as to the coverage and reimbursement status of newly approved health care products. Third-party payors, including Medicare and Medicaid, 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 significantly 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

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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 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, which could significantly reduce the commercial potential of our drug candidate, if approved.

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 post-marketing clinical trials related to serious risks, labeling changes based on new safety information, and compliance with risk evaluation 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. Finally, on July 9, 2012, the Food and Drug Administration Safety and Innovation Act was enacted to, among other things, renew the drug user fee program, expand the FDA s inspection records access and require manufacturers to establish appropriate oversight and controls over their suppliers and the supply chain, including raw material suppliers and contract manufacturers, as a part of cGMP compliance.

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

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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.

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 33 full and part-time employees as of December 31, 2013. 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 and cash equivalents 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 at September 30, 2013, exclusive of our anticipated milestone payments from JT and Torii, are sufficient to fund our anticipated operating cash requirements for approximately the next 12 to 15 months from September 30, 2013. The actual amount of cash that we will need to operate is subject to many factors, including, but not limited to, the timing and expenditures associated with the build-up of pre-launch/launch inventory and capacity expansion, the timing and expenditures associated with submitting the MAA in Europe for Zerenex and the respective regulatory review processes for our U.S. NDA and EU MAA filings, the timing and expenditures associated with pre-commercial/commercial activities related to Zerenex, and the timing, design and conduct of clinical trials for

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Zerenex. We may depend upon significant additional financings to provide the cash necessary to execute our current operations, including the commercialization of Zerenex.

Our forecast of the period of time through which our cash and cash equivalents 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 and expenditures associated with the build-up of pre-launch/launch inventory and capacity expansion;
- the timing and expenditures associated with submitting the MAA filing for Zerenex and the respective regulatory review processes for our U.S. NDA and EU MAA filings;
- the timing and expenditures associated with pre-commercial/commercial activities related to Zerenex;
- the timing, design and conduct of, and results from, clinical trials for Zerenex;
- the timing of expenses associated with manufacturing and product development of Zerenex and those proprietary drug candidates 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 our own commercial infrastructure to manufacture, market and sell our drug candidate and those that may be in-licensed, partnered or acquired;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs related to litigation.

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 to 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. If our competitors prepare and file patent applications in the U.S. that claim technology also claimed by us, we may have to participate in interference or derivation proceedings in front of the U.S. Patent and Trademark Office to determine priority of invention, which could result in substantial cost, even if the eventual outcome is favorable to us. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that before we commercialize any of our products, any related patent may expire or remain in existence for only a short period following commercialization, thus reducing any advantage of the patent. 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:

Composition of matter patents can provide protection for pharmaceutical products to the extent that the specifically covered compositions are key, non-interchangeable components of

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the pharmaceutical product. 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 amount of term of extension available under the Patent Term Extension provisions of 35 U.S.C. § 156 would extend the term of this patent to February 2022). 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. We license additional composition of matter and use patents expiring in 2024 with independent claims covering forms of ferric citrate (the active pharmaceutical ingredient, or API, of Zerenex), pharmaceutical compositions that include the API, pharmaceutical compositions having ferric citrate in an amount effective to reduce serum phosphate levels, and methods of treating hyperphosphatemia and metabolic acidosis.

Our methods 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 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 may 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, for example, 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, 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 NCE, 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 a relevant patent, to the extent these protections have not already expired.

The FDCA provides a five-year period of non-patent marketing exclusivity within the U.S. to the first applicant to gain approval of an NDA for a NCE. A drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which consists of the molecule(s) or ion(s) responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an abbreviated new drug application, or ANDA, or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement. The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application (for example, for new indications, dosages, or strengths of an existing drug). This three-year exclusivity covers only the conditions associated with the new clinical investigations and does not prohibit the FDA from approving ANDAs for drugs containing the original active agent. Five-year and three-year exclusivity will not delay the submission or tentative approval of a full NDA; however, an applicant submitting a full NDA would be required to conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

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 coordination complex), 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

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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.

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.

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Use of proceeds

The net proceeds to us from the sale of 6,900,000 shares of our common stock will be approximately $93,747,000.00 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 pre-commercial/commercial activities related to Zerenex, the ongoing development of Zerenex in pre-dialysis, and other 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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Price range of our common stock

Our common stock is listed on the NASDAQ Capital Market and trades under the symbol KERX. On January 22, 2014, the last reported sale price of our common stock was $14.60 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	$ 9.08	$ 2.73
Second Quarter	8.75	6.92
Third Quarter	10.22	7.87
Fourth Quarter	14.68	8.76
2014		
First Quarter (through January 22, 2014)	$ 15.38	$ 12.16

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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Capitalization

The following table sets forth our capitalization as of September 30, 2013:

- on an actual basis; and
- on an as adjusted basis to reflect the sale of the 6,900,000 shares of common stock offered by us in this offering (assuming no exercise of the underwriters over-allotment 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, 2013 (unaudited)

(in thousands, except share data)	**Actual**	**As adjusted**
Cash and cash equivalents	$ 67,738	$ 161,485
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, 130,000,000 shares authorized; 81,938,915 shares actual and 88,838,915 shares as adjusted, issued; 81,858,967 shares actual and 88,758,967 shares as adjusted, issued and outstanding	82	89
Additional paid-in capital	480,517	574,257
Treasury stock, at cost, 79,948 shares, actual and as adjusted	(357)	(357)
Accumulated deficit	(421,672)	(421,672)
Total stockholders equity	58,570	152,317
Total capitalization	$ 58,570	$ 152,317

The table excludes the following shares:

- 4,042,600 shares of common stock issuable upon the exercise of stock options outstanding as of September 30, 2013, with a weighted average exercise price of $5.24 per share; and
- an aggregate of 3,712,002 shares of common stock reserved for future issuance under our stock option and incentive plans as of September 30, 2013.

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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.

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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. 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

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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. 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 Foreign Account Tax Compliance Act (FATCA) and Treasury Regulations promulgated and official guidance issued thereunder, the relevant withholding agent may be required to withhold 30% of any dividends on our common stock paid on or after July 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 shares
J.P. Morgan Securities LLC	3,829,500
Oppenheimer & Co. Inc.	690,000
JMP Securities LLC	536,130
Stifel Nicolaus & Company, Incorporated	459,540
Roth Capital Partners, LLC	459,540
Brean Capital, LLC	382,950
Ladenburg Thalmann & Co. Inc.	382,950
H.C. Wainwright & Co., LLC	159,390
Total	6,900,000

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 $0.5220 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 1,035,000 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.

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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 $0.8700 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 over-allotment exercise		With full over-allotment exercise	
Per Share	$	0.8700	$	0.8700
Total	$	6,003,000.00	$	6,903,450.00

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 $300,000.

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 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

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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 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

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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 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.

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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 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

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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.

In addition, Maxim Group LLC and Trout Capital LLC are acting as our advisors.

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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.

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Experts

The consolidated financial statements of Keryx Biopharmaceuticals, Inc. and subsidiaries as of and for the year ended December 31, 2012 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.

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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. 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 KERX.

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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, 2012 (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, 2013, June 30, 2013, and September 30, 2013; and

- Our Current Reports on Form 8-K filed with the SEC on January 7, 2013, January 28, 2013, February 5, 2013, June 4, 2013, June 13, 2013, June 21, 2013, August 8, 2013, October 4, 2013, October 8, 2013, October 21, 2013, November 5, 2013, November 8, 2013, and January 16, 2014.

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

$150,000,000

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/or 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 August 15, 2013, the per share closing price of our common stock as reported on the NASDAQ Capital Market was $8.58 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, 2012, as well as our Quarterly Reports on Form 10-Q for the periods ended March 31, 2013 and June 30, 2013, 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 August 16, 2013.

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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 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.

We have recently completed a U.S.-based Phase 3 clinical program for Zerenex for the treatment of hyperphosphatemia (elevated phosphate levels) in patients with end-stage renal disease, or ESRD, on dialysis, conducted pursuant to a Special Protocol Assessment, or SPA, agreement with the U.S. Food and Drug Administration, or FDA. We expect to submit a New Drug Application, or NDA, with the FDA in the third quarter of 2013 and we expect to submit a Marketing Authorization Application, or MAA, with the European Medicines Agency, or EMA, in the fourth quarter of 2013.

Zerenex is also in Phase 2 development in the U.S. for the management of phosphorus and iron deficiency in anemic patients with Stages 3 to 5 non-dialysis dependent chronic kidney disease, or CKD.

In January 2013, our Japanese partner, Japan Tobacco Inc., or JT, and Torii Pharmaceutical Co., Ltd., or Torii, filed its 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 CKD.

Currently, our only drug candidate is Zerenex. We may engage in business development activities that include seeking strategic relationships for Zerenex, 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. 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.

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

THE OFFERING

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

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WHERE YOU CAN FIND MORE INFORMATION

We file reports with the SEC on an annual basis using Form 10-K, quarterly reports on Form 10-Q and current reports on Form 8-K. You may read and copy any such reports and amendments thereto at the SEC s Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549 on official business days during the hours of 10:00 a.m. to 3:00 p.m. Please call the SEC at 1-800-SEC-0330 for information on the Public Reference Room. Additionally, the SEC maintains a website that contains annual, quarterly, and current reports, proxy statements, and other information that issuers (including us) file electronically with the SEC. The SEC s website address is http://www.sec.gov. You can also obtain copies of materials we file with the SEC from our Internet website found at www.keryx.com. Our stock is quoted on the NASDAQ Capital Market under the symbol KERX.

IMPORTANT INFORMATION ABOUT THIS PROSPECTUS

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

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

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

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

(a) Our Annual Report on Form 10-K for the year ended December 31, 2012;

(b) Our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2013 and June 30, 2013;

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(c) Our Current Reports on Form 8-K filed with the SEC on January 7, 2013, January 28, 2013, February 5, 2013, June 4, 2013, June 13, 2013 and June 21, 2013; and

(d) Our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 30, 2013.

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.

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DESCRIPTION OF SECURITIES WE MAY OFFER

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

DESCRIPTION OF COMMON STOCK

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

Common Stock

Under our certificate of incorporation, we are authorized to issue a total of 130,000,000 shares of common stock, par value $0.001 per share. As of July 24, 2013, we had issued and outstanding 81,815,467 shares of our common stock. There are approximately 51 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

Subject to the dividend rights of the holders of any outstanding series of preferred stock, holders of our common stock are entitled to receive ratably such dividends and other distributions of cash or any other right or property as may be declared by our board of directors out of our assets or funds legally available for such dividends or distributions.

Voting Rights

The holders of our common stock are entitled to one vote for each share of common stock owned by that stockholder on every matter properly submitted to the stockholders for their vote. Stockholders are not entitled to vote cumulatively for the election of directors.

Liquidation and Dissolution

In the event of any voluntary or involuntary liquidation, dissolution or winding up of our affairs, holders of common stock would be entitled to share ratably in our assets that are legally available for distribution to stockholders after payment of liabilities. If we have any preferred stock outstanding at such time, holders of the preferred stock may be entitled to distributions and/or liquidation preferences. In either such case, we must pay the applicable distribution to the holders of our preferred stock (if any) before we may pay distributions to the holders of common stock.

Other

Holders of our common stock have no conversion, redemption, preemptive, subscription or similar rights.

Transfer Agent

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

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DESCRIPTION OF WARRANTS

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

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

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

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PLAN OF DISTRIBUTION

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

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

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

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

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

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

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

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

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

We may enter into derivative transactions with third parties, or sell securities not covered by this prospectus to third parties in privately negotiated transactions. If the applicable prospectus supplement indicates, in connection with those derivatives, the third parties may sell securities covered by this prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use securities pledged by us or borrowed from us or others to settle those sales or to close out any related open borrowings of securities, and may use securities received from us in settlement of those derivatives to close out any related open borrowings of securities. The third party in such sale transactions will be an underwriter and will be identified in the applicable prospectus supplement (or a post-effective amendment).

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

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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, 2012 and 2011, and for the years then ended, have been incorporated by reference herein and in the registration statement 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.

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6,900,000 shares

Common stock

Prospectus supplement

Sole book-running manager

J.P. Morgan

Oppenheimer & Co.

JMP Securities

Stifel

Roth Capital Partners

Brean Capital

Ladenburg Thalmann & Co. Inc.

H.C. Wainwright & Co., LLC

January 22, 2014

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. 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.