KERYX BIOPHARMACEUTICALS INC Form S-3/A November 30, 2016 Table of Contents

As filed with the Securities and Exchange Commission on November 30, 2016

Registration No. 333-214513

## **UNITED STATES**

## SECURITIES AND EXCHANGE COMMISSION

**WASHINGTON, D.C. 20549** 

**AMENDMENT NO. 1** 

TO

FORM S-3

REGISTRATION STATEMENT

**UNDER** 

THE SECURITIES ACT OF 1933

KERYX BIOPHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware (State or other jurisdiction of

13-4087132 (I.R.S. Employer

incorporation or organization)

**Identification No.)** 

One Marina Park Drive, 12th Floor

Boston, MA 02210

(617) 466-3500

(Address, including zip code, and telephone number, including area code, of registrant s principal executive offices)

**Gregory P. Madison** 

**Chief Executive Officer** 

Keryx Biopharmaceuticals, Inc.

One Marina Park Drive, 12th Floor

Boston, MA 02210

(617) 466-3500

(Name, address, including zip code, and telephone number, including area code, of agent for service)

## Copies to:

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Brian Adams, Esq.

Mintz, Levin, Cohn, Ferris,

**General Counsel and Corporate Secretary** 

Glovsky and Popeo, P.C.

Keryx Biopharmaceuticals, Inc.

**One Financial Center** 

One Marina Park Drive, 12th Floor

**Boston, MA 02111** 

Boston, MA 02210

(617) 542-6000

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**Approximate date of commencement of proposed sale to the public**: From time to time after the effective date of this registration statement as determined by the registrant.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box:

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box:

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering.

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box.

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box.

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

Large accelerated filer Accelerated filer

Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SECURITIES AND EXCHANGE COMMISSION, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.

#### **EXPLANATORY NOTE**

The registration statement contains:

a base prospectus which covers the offering, issuance and sale by us of up to \$250,000,000 in the aggregate of the securities identified above from time to time in one or more offerings; and

a sales agreement prospectus covering the offering, issuance and sale by us of up to a maximum aggregate offering price of \$75,000,000 of our common stock in an at-the-market offering that may be issued and sold under a sales agreement with Cantor Fitzgerald & Co.

The base prospectus immediately follows this explanatory note. The specific terms of any securities to be offered pursuant to the base prospectus will be specified in a prospectus supplement to the base prospectus. The sales agreement prospectus immediately follows the base prospectus and is deemed a prospectus supplement to the base prospectus. The \$75,000,000 of common stock that may be offered, issued and sold under the sales agreement prospectus is included in the \$250,000,000 of securities that may be offered, issued and sold by us under the base prospectus. Upon termination of the sales agreement with Cantor Fitzgerald & Co., any portion of the \$75,000,000 included in the sales agreement prospectus that is not sold pursuant to the sales agreement will be available for sale in other offerings pursuant to the base prospectus, and if no shares are sold under the sales agreement, the full \$250,000,000 of securities may be sold in other offerings pursuant to the base prospectus and a corresponding prospectus supplement.

THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

### SUBJECT TO COMPLETION, DATED NOVEMBER 30, 2016

## **PROSPECTUS**

\$250,000,000

**COMMON STOCK** 

PREFERRED STOCK

**DEBT SECURITIES** 

WARRANTS

**RIGHTS** 

**PURCHASE CONTRACTS** 

**UNITS** 

This prospectus will allow us to issue, from time to time at prices and on terms to be determined at or prior to the time of the offering, up to \$250,000,000 of any combination of the securities described in this prospectus, either individually or in units. We may also offer common stock or preferred stock upon conversion of or exchange for the debt securities; common stock upon conversion of or exchange for the preferred stock; common stock, preferred stock or debt securities upon the exercise of warrants, rights or performance of purchase contracts; or any combination of these securities upon the performance of purchase contracts.

This prospectus describes the general terms of these securities and the general manner in which these securities will be offered. We will provide you with the specific terms of any offering in one or more supplements to this prospectus. The prospectus supplements will also describe the specific manner in which these securities will be offered and may also supplement, update or amend information contained in this document. You should read this prospectus and any prospectus supplement, as well as any documents incorporated by reference into this prospectus or any prospectus supplement, carefully before you invest.

Our securities may be sold directly by us to you, through agents designated from time to time or to or through underwriters or dealers. For additional information on the methods of sale, you should refer to the section entitled Plan of Distribution in this prospectus and in the applicable prospectus supplement. If any underwriters or agents are involved in the sale of our securities with respect to which this prospectus is being delivered, the names of such underwriters or agents and any applicable fees, commissions or discounts and over-allotment options will be set forth in a prospectus supplement. The price to the public of such securities and the net proceeds that we expect to receive from such sale will also be set forth in a prospectus supplement.

Our common stock is listed on The NASDAQ Capital Market under the symbol KERX. On November 29, 2016, the last reported sale price of our common stock was \$5.96 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on The NASDAQ Capital Market or any securities market or other securities exchange of the securities covered by the prospectus supplement. Prospective purchasers of our securities are urged to obtain current information as to the market prices of our securities, where applicable.

Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, you should consider carefully the risks that we have described on page 5 of this prospectus under the caption <a href="Risk Factors">Risk Factors</a>. We may include specific risk factors in supplements to this prospectus under the caption Risk Factors. This prospectus may not be used to sell our securities unless accompanied by a prospectus supplement.

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 , 2016.

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## **ABOUT THIS PROSPECTUS**

This prospectus is part of a registration statement that we filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. Under this shelf registration process, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants, rights or purchase contracts to purchase any of such securities, either individually or in units, in one or more offerings, with a total value of up to \$250,000,000. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will contain specific information about the terms of that offering.

This prospectus does not contain all of the information included in the registration statement. For a more complete understanding of the offering of the securities, you should refer to the registration statement, including its exhibits. The prospectus supplement may also add, update or change information contained or incorporated by reference in this prospectus. However, no prospectus supplement will offer a security that is not registered and described in this prospectus at the time of its effectiveness. This prospectus, together with the applicable prospectus supplements and the documents incorporated by reference into this prospectus, includes all material information relating to the offering of securities under this prospectus. You should carefully read this prospectus, the applicable prospectus supplement, the information and documents incorporated herein by reference and the additional information under the heading Where You Can Find More Information before making an investment decision.

You should rely only on the information we have provided or incorporated by reference in this prospectus or any prospectus supplement. We have not authorized anyone to provide you with information different from that contained or incorporated by reference in this prospectus. No dealer, salesperson or other person is authorized to give any information or to represent anything not contained or incorporated by reference in this prospectus. You must not rely on any unauthorized information or representation. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so. You should assume that the information in this prospectus or any prospectus supplement is accurate only as of the date on the front of the document and that any information we have incorporated herein by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus or any sale of a security.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit the registration statement to which this prospectus forms a part or to any document that is incorporated by reference in this prospectus and any prospectus supplement 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.

This prospectus may not be used to consummate sales of our securities, unless it is accompanied by a prospectus supplement. To the extent there are inconsistencies between any prospectus supplement, this prospectus and any documents incorporated by reference, the document with the most recent date will control.

Unless the context otherwise requires, Keryx, the Company, we, us, our and similar terms refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries.

Our trademarks include, without limitation, our name and corporate logo. Other service marks, trademarks and trade names contained in this prospectus, any prospectus supplement or the documents incorporated by reference herein and therein are the property of their respective owners.

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## PROSPECTUS SUMMARY

The following is a summary of what we believe to be the most important aspects of our business and the offering of our securities under this prospectus. We urge you to read this entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information incorporated by reference from our other filings with the SEC or included in any applicable prospectus supplement. Investing in our securities involves risks. Therefore, carefully consider the risk factors set forth in any prospectus supplements and in our most recent annual and quarterly filings with the SEC, as well as other information in this prospectus and any prospectus supplements and the documents incorporated by reference herein or therein, before purchasing our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities.

## About Keryx Biopharmaceuticals, Inc.

We are a biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our product, Auryxia® (ferric citrate), also known as Riona® in Japan and Fexeric® in Europe, is an oral, absorbable iron-based medicine, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. We believe that there currently are approximately 450,000 adults in the United States on dialysis of whom approximately 350,000 are on phosphate binders and eligible for treatment with Auryxia. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our investigational medicine in Phase 3, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. In 2015, we reported net U.S. Auryxia product sales of \$10.1 million.

On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue in converting active pharmaceutical ingredient, or API, to finished drug product at our contract manufacturer. This issue resulted in variable production yields of finished drug product and, as a result, we exhausted our reserve of finished drug product. Inventories of Auryxia were not sufficient to ensure uninterrupted patient access to this medicine. The supply interruption did not affect the safety profile of currently available Auryxia and did not affect the supply of Riona manufactured and sold by our Japanese partner in Japan. We are working with this manufacturer to resolve the production-related issue. In addition, since approval of Auryxia in 2014, we had been working to bring a secondary manufacturer online to supply finished drug product. We recently filed for approval of an additional manufacturer, Patheon Manufacturing Services LLC, or Patheon, with the FDA and entered into a long-term arrangement with Patheon in October 2016 to supply finished Auryxia drug product. On November 9, 2016, the FDA approved our application and Patheon is now an approved drug product manufacturer of Auryxia. With FDA approval of this manufacturer, we have rebuilt supply of Auryxia and made Auryxia available to wholesalers again.

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with stage 3-5 non-dialysis dependent chronic kidney disease, or NDD-CKD. We believe there are approximately 650,000 adults in the United States with CKD currently being treated for IDA. The Phase 3 study s primary endpoint was the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period of the study. Secondary endpoints in the Phase 3 study include the change from baseline to

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the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The top-line results showed that treatment with ferric citrate in the registration trial demonstrated statistically significant differences as compared to placebo for the primary and all pre-specified secondary endpoints. The majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period as compared to 19 percent in the placebo group (p <0.001). Additionally, the safety profile of the drug candidate was consistent with previously reported clinical studies of ferric citrate, with the majority of adverse events reported as mild to moderate. We believe the initial data support our plan to submit a supplemental new drug application, or sNDA, with the FDA seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD. We have completed the sNDA and are ready to submit it to the FDA pending final agreement on its pediatric plan.

Our Japanese partner, Japan Tobacco Inc. or JT, together with its subsidiary Torii Pharmaceutical Co. Ltd., or Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and NDD-CKD, in January 2014. Torii began to market the product under the brand name Riona in May 2014. Additionally, in the third quarter of 2016, JT and Torii commenced enrollment in a Phase 2 clinical trial of ferric citrate for the treatment of IDA. Under the license agreement with JT and Torii, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional \$55.0 million upon the achievement of certain annual net sales milestones. We in turn owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, which provides 10 years of data and marketing exclusivity in the European Union. We are currently seeking potential partners to commercialize Fexeric in the European Union.

Currently, our only product is Auryxia. In January 2015, we began to recognize product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, license revenue from the sublicensing of rights to ferric citrate in Japan to our Japanese partner. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

## **Additional Information**

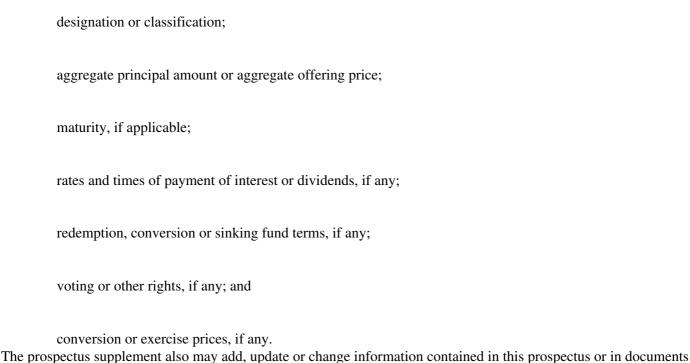
We were incorporated in Delaware in October 1998 and commenced operations in November 1999. In January 2016, we moved our executive offices to One Marina Park Drive, 12<sup>th</sup> Floor, Boston, Massachusetts 02210. Our telephone number is (617) 466-3500. Our website address is *www.keryx.com*. The information contained on our website is not incorporated by reference into, and does not form any part of, this prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports, are available free of charge through the Investors SEC Filings and Annual Reports section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the SEC.

## **Offerings Under This Prospectus**

Under this prospectus, we may offer shares of our common stock and preferred stock, various series of debt securities and/or warrants, rights or purchase contracts to purchase any of such securities, either individually or in

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units, with a total value of up to \$250,000,000, from time to time at prices and on terms to be determined by market conditions at the time of the offering. This prospectus provides you with a general description of the securities we may offer. Each time we offer a type or series of securities under this prospectus, we will provide a prospectus supplement that will describe the specific amounts, prices and other important terms of the securities, including, to the extent applicable:



we have incorporated by reference into this prospectus. However, no prospectus supplement will offer a security that is not registered and described in this prospectus at the time of its effectiveness.

We may sell the securities directly to investors or to or through agents, underwriters or dealers. We, and our agents or underwriters, reserve the right to accept or reject all or part of any proposed purchase of securities. If we offer securities through agents or underwriters, we will include in the applicable prospectus supplement:

the names of those agents or underwriters;
applicable fees, discounts and commissions to be paid to them;
details regarding over-allotment options, if any; and
the net proceeds to us.

This prospectus may not be used to consummate a sale of any securities unless it is accompanied by a prospectus supplement.

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## **RISK FACTORS**

Investing in our securities involves significant risk. The prospectus supplement applicable to each offering of our securities may contain a discussion of the risks applicable to an investment in us. Prior to making a decision about investing in our securities, you should carefully consider the specific factors discussed under the heading. Risk Factors in the applicable prospectus supplement, together with all of the other information contained or incorporated by reference in the prospectus supplement or appearing or incorporated by reference in this prospectus. You should also consider the risks, uncertainties and assumptions discussed under the heading. Risk Factors included in our most recent Annual Report on Form 10-K, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K on file with the SEC, all of which are incorporated herein by reference, and which may be amended, supplemented or superseded from time to time by other reports we file with the SEC in the future. The risks and uncertainties we have described are not the only ones we face. Additional risks and uncertainties not presently known to us or that we currently deem immaterial may also affect our operations.

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## RATIO OF EARNINGS TO FIXED CHARGES

Any time debt securities are offered pursuant to this prospectus, we will provide a table setting forth our ratio of earnings to fixed charges on a historical basis in the applicable prospectus supplement, if required.

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## SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company s future prospects and make informed investment decisions. This prospectus and the documents we have filed with the SEC that are incorporated herein by reference contain such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Such statements in connection with any discussion of future operations or financial performance are identified by the use of words such as may, anticipate, estimate, expect, project, intend, plan, believe, and other words a similar meaning. Such statements are based on management s expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to: our ability to quickly and successfully identify and resolve the production-related issue; our ability to quickly and successfully identify and engage additional suppliers of finished drug product; our ability to receive FDA approval of any additional suppliers of finished drug product; whether we can increase adoption of Auryxia in patients with CKD on dialysis; whether we can maintain our operating expenses to projected levels while continuing our current clinical, regulatory and commercial activities; whether we will be able to identify and negotiate acceptable terms with a commercialization partner in the European Union; whether we or a partner can successfully launch Fexeric in the European Union; whether Riona will be successfully marketed in Japan by our Japanese partner; the risk that the FDA may not concur with our interpretation of our Phase 3 study results in NDD-CKD, supportive data, conduct of the studies, or any other part of our regulatory submission and could ultimately deny approval of ferric citrate for the treatment of iron deficiency anemia in adults with stage 3-5 NDD-CKD; the risk that if approved for use in NDD-CKD that we may not be able to successfully market Auryxia for use in this indication; and other factors detailed under the heading Risk Factors in this prospectus as updated and supplemented by the discussion of risks and uncertainties under Risk Factors contained in any supplements to this prospectus and in our most recent Annual Report on Form 10-K, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. The information contained in this document is believed to be current as of the date of this document. We do not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in our expectations, except as required by law.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated herein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

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## **USE OF PROCEEDS**

We cannot assure you that we will receive any proceeds in connection with securities which may be offered pursuant to this prospectus. Unless otherwise indicated in the applicable prospectus supplement, we intend to use any net proceeds from the sale of securities under this prospectus for our operations and for other general corporate purposes, including, but not limited to, repayment or refinancing of existing indebtedness or other corporate borrowings, working capital, intellectual property protection and enforcement, capital expenditures, investments, acquisitions or collaborations, repurchases and redemption of our securities, research and development and product development. We have not determined the amounts we plan to spend on any of the areas listed above or the timing of these expenditures. As a result, our management will have broad discretion to allocate the net proceeds, if any, we receive in connection with securities offered pursuant to this prospectus for any purpose. Pending application of the net proceeds as described above, we may initially invest the net proceeds in short-term, investment-grade, interest-bearing securities or apply them to the reduction of short-term indebtedness.

## PLAN OF DISTRIBUTION

We may offer securities under this prospectus from time to time pursuant to underwritten public offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities (1) through underwriters or dealers, (2) through agents or (3) directly to one or more purchasers, or through a combination of such methods. We may distribute the securities from time to time in one or more transactions at:

a fixed price or prices, which may be changed from time to time;

market prices prevailing at the time of sale;

prices related to the prevailing market prices; or

negotiated prices.

We may directly solicit offers to purchase the securities being offered by this prospectus. We may also designate agents to solicit offers to purchase the securities from time to time. We will name in a prospectus supplement any underwriter or agent involved in the offer or sale of the securities.

If we utilize a dealer in the sale of the securities being offered by this prospectus, we will sell the securities to the dealer, as principal. The dealer may then resell the securities to the public at varying prices to be determined by the dealer at the time of resale.

If we utilize an underwriter in the sale of the securities being offered by this prospectus, we will execute an underwriting agreement with the underwriter at the time of sale, and we will provide the name of any underwriter in the prospectus supplement which the underwriter will use to make resales of the securities to the public. In connection with the sale of the securities, we, or the purchasers of the securities for whom the underwriter may act as agent, may compensate the underwriter in the form of underwriting discounts or commissions. The underwriter may sell the securities to or through dealers, and the underwriter may compensate those dealers in the form of discounts, concessions or commissions.

With respect to underwritten public offerings, negotiated transactions and block trades, we will provide in the applicable prospectus supplement information regarding any compensation we pay to underwriters, dealers or agents in connection with the offering of the securities, and any discounts, concessions or commissions allowed by underwriters to participating dealers. Underwriters, dealers and agents participating in the distribution of the securities may be deemed to be underwriters within the meaning of the Securities Act of 1933, as amended, or the Securities Act, and any discounts and commissions received by them and any profit realized by them on resale of the securities may be deemed to be underwriting discounts and commissions. We may enter into agreements to indemnify underwriters, dealers and agents against civil liabilities, including liabilities under the Securities Act, or to contribute to payments they may be required to make in respect thereof.

If so indicated in the applicable prospectus supplement, we will authorize underwriters or other persons acting as our agents to solicit offers by certain institutions to purchase securities from us pursuant to delayed delivery contracts providing for payment and delivery on the date stated in the prospectus supplement. Each contract will be for an

amount not less than, and the aggregate amount of securities sold pursuant to such contracts shall not be less nor more than, the respective amounts stated in the prospectus supplement. Institutions with whom the contracts, when authorized, may be made include commercial and savings banks, insurance companies, pension funds, investment companies, educational and charitable institutions and other institutions, but shall in all cases be subject to our approval. Delayed delivery contracts will not be subject to any conditions except that:

the purchase by an institution of the securities covered under that contract shall not at the time of delivery be prohibited under the laws of the jurisdiction to which that institution is subject; and

if the securities are also being sold to underwriters acting as principals for their own account, the underwriters shall have purchased such securities not sold for delayed delivery. The underwriters and

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other persons acting as our agents will not have any responsibility in respect of the validity or performance of delayed delivery contracts.

Shares of our common stock sold pursuant to the registration statement of which this prospectus is a part will be authorized for quotation and trading on The NASDAQ Capital Market. The applicable prospectus supplement will contain information, where applicable, as to any other listing, if any, on The NASDAQ Capital Market or any securities market or other securities exchange of the securities covered by the prospectus supplement. We can make no assurance as to the liquidity of or the existence of trading markets for any of the securities.

In order to facilitate the offering of the securities, certain persons participating in the offering may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. This may include over-allotments or short sales of the securities, which involve the sale by persons participating in the offering of more securities than we sold to them. In these circumstances, these persons would cover such over-allotments or short positions by making purchases in the open market or by exercising their over-allotment option. In addition, these persons may stabilize or maintain the price of the securities by bidding for or purchasing the applicable security in the open market or by imposing penalty bids, whereby selling concessions allowed to dealers participating in the offering may be reclaimed if the securities sold by them are repurchased in connection with stabilization transactions. The effect of these transactions may be to stabilize or maintain the market price of the securities at a level above that which might otherwise prevail in the open market. These transactions may be discontinued at any time.

The underwriters, dealers and agents may engage in other transactions with us, or perform other services for us, in the ordinary course of their business.

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## DESCRIPTION OF COMMON STOCK

The following summary of certain provisions of our common stock does not purport to be complete. You should refer to our amended and restated certificate of incorporation and our amended and restated bylaws, both of which are included as exhibits to the registration statement of which this prospectus is a part. The summary below is also qualified by provisions of applicable law.

#### General

We are authorized to issue 180,000,000 shares of common stock, par value \$0.001 per share. On October 31, 2016, we had 105,960,364 shares of common stock outstanding and approximately 51 stockholders of record. All shares of common stock outstanding as of the date of this prospectus and, upon issuance and sale, all shares of common stock that we may offer pursuant to this prospectus, will be fully paid and nonassessable.

#### **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 and Registrar**

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

## **NASDAQ Capital Market**

Our common stock is listed for quotation on The NASDAQ Capital Market under the symbol KERX.

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## DESCRIPTION OF PREFERRED STOCK

The following summary of certain provisions of our preferred stock does not purport to be complete. You should refer to our amended and restated certificate of incorporation and our amended and restated bylaws, both of which are included as exhibits to the registration statement of which this prospectus is a part. The summary below is also qualified by provisions of applicable law.

#### General

We are authorized to issue 5,000,000 shares of preferred stock, par value \$0.001 per share. As of October 31, 2016, no shares of our preferred stock were outstanding or designated.

Our board of directors may, with approval of the action by our stockholders, from time to time, direct the issuance of shares of preferred stock in series and may, at the time of issuance, determine the rights, preferences and limitations of each series, including voting rights, dividend rights and redemption and liquidation preferences. Satisfaction of any dividend preferences of outstanding shares of preferred stock would reduce the amount of funds available for the payment of dividends on shares of our common stock. Holders of shares of preferred stock may be entitled to receive a preference payment in the event of any liquidation, dissolution or winding-up of our company before any payment is made to the holders of shares of our common stock. In some circumstances, the issuance of shares of preferred stock may render more difficult or tend to discourage a merger, tender offer or proxy contest, the assumption of control by a holder of a large block of our securities or the removal of incumbent management. Upon the affirmative vote of our board of directors and with stockholder approval, we may issue shares of preferred stock with voting and conversion rights which could adversely affect the holders of shares of our common stock.

If we offer a specific series of preferred stock under this prospectus, we will describe the terms of the preferred stock in the prospectus supplement for such offering and will file a copy of the certificate establishing the terms of the preferred stock with the SEC. To the extent required, this description will include:

the title and stated value;

the number of shares offered, the liquidation preference, if any, per share and the purchase price;

the dividend rate(s), period(s) and/or payment date(s), or method(s) of calculation for such dividends;

whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;

the procedures for any auction and remarketing, if any;

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the provisions for a sinking fund, if any;

the provisions for redemption, if applicable;

any listing of the preferred stock on any securities exchange or market;

whether the preferred stock will be convertible into our common stock, and, if applicable, the conversion price (or how it will be calculated) and conversion period;

whether the preferred stock will be exchangeable into debt securities, and, if applicable, the exchange price (or how it will be calculated) and exchange period;

voting rights, if any, of the preferred stock;

a discussion of any material and/or special U.S. federal income tax considerations applicable to the preferred stock;

the relative ranking and preferences of the preferred stock as to dividend rights and rights upon liquidation, dissolution or winding up of our affairs; and

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any material limitations on issuance of any class or series of preferred stock ranking *pari passu* with or senior to the series of preferred stock as to dividend rights and rights upon our liquidation, dissolution or winding up.

## **Transfer Agent and Registrar**

The transfer agent and registrar for our preferred stock will be set forth in the applicable prospectus supplement.

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## **DESCRIPTION OF DEBT SECURITIES**

The following description, together with the additional information we include in any applicable prospectus supplements, summarizes the material terms and provisions of the debt securities that we may offer under this prospectus. While the terms we have summarized below will apply generally to any future debt securities we may offer pursuant to this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. If we so indicate in a prospectus supplement, the terms of any debt securities offered under such prospectus supplement may differ from the terms we describe below, and to the extent the terms set forth in a prospectus supplement differ from the terms described below, the terms set forth in the prospectus supplement shall control.

We may sell from time to time, in one or more offerings under this prospectus, debt securities, which may be senior or subordinated. We will issue any such senior debt securities under a senior indenture that we will enter into with a trustee to be named in the senior indenture. We will issue any such subordinated debt securities under a subordinated indenture, which we will enter into with a trustee to be named in the subordinated indenture. We have filed forms of these documents as exhibits to the registration statement, of which this prospectus is a part. We use the term indentures to refer to either the senior indenture or the subordinated indenture, as applicable. The indentures will be qualified under the Trust Indenture Act of 1939, as in effect on the date of the indenture. We use the term debenture trustee to refer to either the trustee under the senior indenture or the trustee under the subordinated indenture, as applicable.

The following summaries of material provisions of the senior debt securities, the subordinated debt securities and the indentures are subject to, and qualified in their entirety by reference to, all the provisions of the indenture applicable to a particular series of debt securities.

#### General

Each indenture provides that debt securities may be issued from time to time in one or more series and may be denominated and payable in foreign currencies or units based on or relating to foreign currencies. Neither indenture limits the amount of debt securities that may be issued thereunder, and each indenture provides that the specific terms of any series of debt securities shall be set forth in, or determined pursuant to, an authorizing resolution and/or a supplemental indenture, if any, relating to such series.

We will describe in each prospectus supplement the following terms relating to a series of debt securities:

the title or designation;

the aggregate principal amount and any limit on the amount that may be issued;

the currency or units based on or relating to currencies in which debt securities of such series are denominated and the currency or units in which principal or interest or both will or may be payable;

whether we will issue the series of debt securities in global form, the terms of any global securities and who the depositary will be;

the maturity date and the date or dates on which principal will be payable;

the interest rate, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the date or dates interest will be payable and the record dates for interest payment dates or the method for determining such dates;

whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;

the terms of the subordination of any series of subordinated debt;

the place or places where payments will be payable;

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our right, if any, to defer payment of interest and the maximum length of any such deferral period;

the date, if any, after which, and the price at which, we may, at our option, redeem the series of debt securities pursuant to any optional redemption provisions;

the date, if any, on which, and the price at which we are obligated, pursuant to any mandatory sinking fund provisions or otherwise, to redeem, or at the holder s option to purchase, the series of debt securities;

whether the indenture will restrict our ability to pay dividends, or will require us to maintain any asset ratios or reserves;

whether we will be restricted from incurring any additional indebtedness;

a discussion on any material or special U.S. federal income tax considerations applicable to a series of debt securities:

the denominations in which we will issue the series of debt securities, if other than denominations of \$1,000 and any integral multiple thereof; and

any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities. We may issue debt securities that provide for an amount less than their stated principal amount to be due and payable upon declaration of acceleration of their maturity pursuant to the terms of the indenture. We will provide you with information on the federal income tax considerations and other special considerations applicable to any of these debt securities in the applicable prospectus supplement.

## **Conversion or Exchange Rights**

We will set forth in the prospectus supplement the terms, if any, on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

# Consolidation, Merger or Sale; No Protection in Event of a Change of Control or Highly Leveraged Transaction

The indentures do not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of all or substantially all of our assets. However, any successor to or acquirer of such assets must assume all of our obligations under the indentures or the debt securities, as appropriate.

Unless we state otherwise in the applicable prospectus supplement, the debt securities will not contain any provisions that may afford holders of the debt securities protection in the event we have a change of control or in the event of a highly leveraged transaction (whether or not such transaction results in a change of control), which could adversely affect holders of debt securities.

## **Events of Default Under the Indenture**

The following are events of default under the indentures with respect to any series of debt securities that we may issue:

if we fail to pay interest when due and our failure continues for 90 days and the time for payment has not been extended or deferred;

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if we fail to pay the principal, or premium, if any, when due and the time for payment has not been extended or delayed;

if we fail to observe or perform any other covenant set forth in the debt securities of such series or the applicable indentures, other than a covenant specifically relating to and for the benefit of holders of another series of debt securities, and our failure continues for 90 days after we receive written notice from the debenture trustee or holders of not less than a majority in aggregate principal amount of the outstanding debt securities of the applicable series; and

if specified events of bankruptcy, insolvency or reorganization occur as to us.

No event of default with respect to a particular series of debt securities (except as to certain events of bankruptcy, insolvency or reorganization) necessarily constitutes an event of default with respect to any other series of debt securities. The occurrence of an event of default may constitute an event of default under any bank credit agreements we may have in existence from time to time. In addition, the occurrence of certain events of default or an acceleration under the indenture may constitute an event of default under certain of our other indebtedness outstanding from time to time.

If an event of default with respect to debt securities of any series at the time outstanding occurs and is continuing, then the trustee or the holders of not less than a majority in principal amount of the outstanding debt securities of that series may, by a notice in writing to us (and to the debenture trustee if given by the holders), declare to be due and payable immediately the principal (or, if the debt securities of that series are discount securities, that portion of the principal amount as may be specified in the terms of that series) of and premium and accrued and unpaid interest, if any, on all debt securities of that series. Before a judgment or decree for payment of the money due has been obtained with respect to debt securities of any series, the holders of a majority in principal amount of the outstanding debt securities of that series (or, at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) may rescind and annul the acceleration if all events of default, other than the non-payment of accelerated principal, premium, if any, and interest, if any, with respect to debt securities of that series, have been cured or waived as provided in the applicable indenture (including payments or deposits in respect of principal, premium or interest that had become due other than as a result of such acceleration). We refer you to the prospectus supplement relating to any series of debt securities that are discount securities for the particular provisions relating to acceleration of a portion of the principal amount of such discount securities upon the occurrence of an event of default.

Subject to the terms of the indentures, if an event of default under an indenture shall occur and be continuing, the debenture trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the debenture trustee reasonable indemnity. The holders of a majority in principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the debenture trustee, or exercising any trust or power conferred on the debenture trustee, with respect to the debt securities of that series, provided that:

the direction so given by the holder is not in conflict with any law or the applicable indenture; and

subject to its duties under the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act, the debenture trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will only have the right to institute a proceeding under the indentures or to appoint a receiver or trustee, or to seek other remedies if:

the holder previously has given written notice to the debenture trustee of a continuing event of default with respect to that series;

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the holders of at least a majority in aggregate principal amount of the outstanding debt securities of that series have made written request, and such holders have offered reasonable indemnity to the debenture trustee to institute the proceeding as trustee; and

the debenture trustee does not institute the proceeding, and does not receive from the holders of a majority in aggregate principal amount of the outstanding debt securities of that series (or at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) other conflicting directions within 60 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal, premium, if any, or interest on, the debt securities.

We will periodically file statements with the applicable debenture trustee regarding our compliance with specified covenants in the applicable indenture.

## **Modification of Indenture; Waiver**

The debenture trustee and we may change the applicable indenture without the consent of any holders with respect to specific matters, including:

to fix any ambiguity, defect or inconsistency in the indenture; and

to change anything that does not materially adversely affect the interests of any holder of debt securities of any series issued pursuant to such indenture.

In addition, under the indentures, the rights of holders of a series of debt securities may be changed by us and the debenture trustee with the written consent of the holders of at least a majority in aggregate principal amount of the outstanding debt securities of each series (or, at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) that is affected. However, the debenture trustee and we may make the following changes only with the consent of each holder of any outstanding debt securities affected:

extending the fixed maturity of the series of debt securities;

reducing the principal amount, reducing the rate of or extending the time of payment of interest, or any premium payable upon the redemption of any debt securities;

reducing the principal amount of discount securities payable upon acceleration of maturity;

making the principal of or premium or interest on any debt security payable in currency other than that stated in the debt security; or

reducing the percentage of debt securities, the holders of which are required to consent to any amendment or waiver.

Except for certain specified provisions, the holders of at least a majority in principal amount of the outstanding debt securities of any series (or, at a meeting of holders of such series at which a quorum is present, the holders of a majority in principal amount of the debt securities of such series represented at such meeting) may on behalf of the holders of all debt securities of that series waive our compliance with provisions of the indenture. The holders of a majority in principal amount of the outstanding debt securities of any series may on behalf of the holders of all the debt securities of such series waive any past default under the indenture with respect to that series and its consequences, except a default in the payment of the principal of, premium or any interest on any debt security of that series or in respect of a covenant or provision, which cannot be modified or amended without the consent of the holder of each outstanding debt securities of any series may rescind an acceleration and its consequences, including any related payment default that resulted from the acceleration.

# **Discharge**

Each indenture provides that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for obligations to:

register the transfer or exchange of debt securities of the series;
replace stolen, lost or mutilated debt securities of the series;
maintain paying agencies;
hold monies for payment in trust;
compensate and indemnify the trustee; and

appoint any successor trustee.

In order to exercise our rights to be discharged with respect to a series, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, the premium, if any, and interest on, the debt securities of the series on the dates payments are due.

# Form, Exchange, and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we otherwise specify in the applicable prospectus supplement, in denominations of \$1,000 and any integral multiple thereof. The indentures provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company or another depositary named by us and identified in a prospectus supplement with respect to that series.

At the option of the holder, subject to the terms of the indentures and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indentures and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange or in the applicable indenture, we will make no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

If we elect to redeem the debt securities of any series, we will not be required to:

issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the day of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the day of the mailing; or

register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except the unredeemed portion of any debt securities we are redeeming in part.

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### **Information Concerning the Debenture Trustee**

The debenture trustee, other than during the occurrence and continuance of an event of default under the applicable indenture, undertakes to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the debenture trustee under such indenture must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the debenture trustee is under no obligation to exercise any of the powers given it by the indentures at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

# **Payment and Paying Agents**

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

We will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that unless we otherwise indicate in the applicable prospectus supplement, will we make interest payments by check which we will mail to the holder. Unless we otherwise indicate in a prospectus supplement, we will designate the corporate trust office of the debenture trustee in the City of New York as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the debenture trustee for the payment of the principal of or any premium or interest on any debt securities which remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the security thereafter may look only to us for payment thereof.

# **Governing Law**

The indentures and the debt securities will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

# **Subordination of Subordinated Debt Securities**

Our obligations pursuant to any subordinated debt securities will be unsecured and will be subordinate and junior in priority of payment to certain of our other indebtedness to the extent described in a prospectus supplement. The subordinated indenture does not limit the amount of senior indebtedness we may incur. It also does not limit us from issuing any other secured or unsecured debt.

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# **DESCRIPTION OF WARRANTS**

#### General

We may issue warrants to purchase shares of our common stock, preferred stock and/or debt securities in one or more series together with other securities or separately, as described in the applicable prospectus supplement. Below is a description of certain general terms and provisions of the warrants that we may offer. Particular terms of the warrants will be described in the warrant agreements and the prospectus supplement relating to the warrants.

The applicable prospectus supplement will contain, where applicable, the following terms of and other information relating to the warrants:

the specific designation and aggregate number of, and the price at which we will issue, the warrants;

the currency or currency units in which the offering price, if any, and the exercise price are payable;

the designation, amount and terms of the securities purchasable upon exercise of the warrants;

if applicable, the exercise price for shares of our common stock and the number of shares of common stock to be received upon exercise of the warrants;

if applicable, the exercise price for shares of our preferred stock, the number of shares of preferred stock to be received upon exercise, and a description of that series of our preferred stock;

if applicable, the exercise price for our debt securities, the amount of debt securities to be received upon exercise, and a description of that series of debt securities;

the date on which the right to exercise the warrants will begin and the date on which that right will expire or, if you may not continuously exercise the warrants throughout that period, the specific date or dates on which you may exercise the warrants;

whether the warrants will be issued in fully registered form or bearer form, in definitive or global form or in any combination of these forms, although, in any case, the form of a warrant included in a unit will correspond to the form of the unit and of any security included in that unit;

any applicable material U.S. federal income tax consequences;

the identity of the warrant agent for the warrants and of any other depositaries, execution or paying agents, transfer agents, registrars or other agents;

the proposed listing, if any, of the warrants or any securities purchasable upon exercise of the warrants on any securities exchange;

if applicable, the date from and after which the warrants and the common stock, preferred stock and/or debt securities will be separately transferable;

if applicable, the minimum or maximum amount of the warrants that may be exercised at any one time;

information with respect to book-entry procedures, if any;

the anti-dilution provisions of the warrants, if any;

any redemption or call provisions;

whether the warrants may be sold separately or with other securities as parts of units; and

any additional terms of the warrants, including terms, procedures and limitations relating to the exchange and exercise of the warrants.

# **Transfer Agent and Registrar**

The transfer agent and registrar for any warrants will be set forth in the applicable prospectus supplement.

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# **DESCRIPTION OF RIGHTS**

#### General

We may issue rights to our stockholders to purchase shares of our common stock, preferred stock or the other securities described in this prospectus. We may offer rights separately or together with one or more additional rights, debt securities, preferred stock, common stock, warrants or purchase contracts, or any combination of those securities in the form of units, as described in the applicable prospectus supplement. Each series of rights will be issued under a separate rights agreement to be entered into between us and a bank or trust company, as rights agent. The rights agent will act solely as our agent in connection with the certificates relating to the rights of the series of certificates and will not assume any obligation or relationship of agency or trust for or with any holders of rights certificates or beneficial owners of rights. The following description sets forth certain general terms and provisions of the rights to which any prospectus supplement may relate. The particular terms of the rights to which any prospectus supplement may relate and the extent, if any, to which the general provisions may apply to the rights so offered will be described in the applicable prospectus supplement. To the extent that any particular terms of the rights, rights agreement or rights certificates described in a prospectus supplement differ from any of the terms described below, then the terms described below will be deemed to have been superseded by that prospectus supplement. We encourage you to read the applicable rights agreement and rights certificate for additional information before you decide whether to purchase any of our rights.

We will provide in a prospectus supplement the following terms of the rights being issued:

the date of determining the stockholders entitled to the rights distribution;

the aggregate number of shares of common stock, preferred stock or other securities purchasable upon exercise of the rights;

the exercise price;

the aggregate number of rights issued;

whether the rights are transferrable and the date, if any, on and after which the rights may be separately transferred;

the date on which the right to exercise the rights will commence, and the date on which the right to exercise the rights will expire;

the method by which holders of rights will be entitled to exercise;

the conditions to the completion of the offering, if any;

the withdrawal, termination and cancellation rights, if any;

whether there are any backstop or standby purchaser or purchasers and the terms of their commitment, if any;

whether stockholders are entitled to oversubscription rights, if any;

any applicable U.S. federal income tax considerations; and

any other terms of the rights, including terms, procedures and limitations relating to the distribution, exchange and exercise of the rights, as applicable.

Each right will entitle the holder of rights to purchase for cash the principal amount of shares of common stock, preferred stock or other securities at the exercise price provided in the applicable prospectus supplement. Rights may be exercised at any time up to the close of business on the expiration date for the rights provided in the applicable prospectus supplement.

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Holders may exercise rights as described in the applicable prospectus supplement. Upon receipt of payment and the rights certificate properly completed and duly executed at the corporate trust office of the rights agent or any other office indicated in the prospectus supplement, we will, as soon as practicable, forward the shares of common stock, preferred stock or other securities, as applicable, purchasable upon exercise of the rights. If less than all of the rights issued in any rights offering are exercised, we may offer any unsubscribed securities directly to persons other than stockholders, to or through agents, underwriters or dealers or through a combination of such methods, including pursuant to standby arrangements, as described in the applicable prospectus supplement.

# **Rights Agent**

The rights agent for any rights we offer will be set forth in the applicable prospectus supplement.

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# **DESCRIPTION OF PURCHASE CONTRACTS**

We may issue purchase contracts, including contracts obligating holders to purchase from us, and for us to sell to holders, a specific or variable number of our debt securities, shares of common stock, preferred stock, warrants or rights, or securities of an entity unaffiliated with us, or any combination of the above, at a future date or dates. Alternatively, the purchase contracts may obligate us to purchase from holders, and obligate holders to sell to us, a specific or variable number of our debt securities, shares of common stock, preferred stock, warrants, rights or other property, or any combination of the above. The price of the securities or other property subject to the purchase contracts may be fixed at the time the purchase contracts are issued or may be determined by reference to a specific formula described in the purchase contracts. We may issue purchase contracts separately or as a part of units each consisting of a purchase contract and one or more of our other securities described in this prospectus or securities of third parties, including U.S. Treasury securities, securing the holder s obligations under the purchase contract. The purchase contracts may require us to make periodic payments to holders or vice versa and the payments may be unsecured or pre-funded on some basis. The purchase contracts may require holders to secure the holder s obligations in a manner specified in the applicable prospectus supplement.

The applicable prospectus supplement will describe the terms of any purchase contracts in respect of which this prospectus is being delivered, including, to the extent applicable, the following:

whether the purchase contracts obligate the holder or us to purchase or sell, or both purchase and sell, the securities subject to purchase under the purchase contract, and the nature and amount of each of those securities, or the method of determining those amounts;

whether the purchase contracts are to be prepaid;

whether the purchase contracts are to be settled by delivery, or by reference or linkage to the value, performance or level of the securities subject to purchase under the purchase contract;

any acceleration, cancellation, termination or other provisions relating to the settlement of the purchase contracts;

any applicable U.S. federal income tax considerations; and

whether the purchase contracts will be issued in fully registered or global form.

The preceding description sets forth certain general terms and provisions of the purchase contracts to which any prospectus supplement may relate. The particular terms of the purchase contracts to which any prospectus supplement may relate and the extent, if any, to which the general provisions may apply to the purchase contracts so offered will be described in the applicable prospectus supplement. To the extent that any particular terms of the purchase contracts described in a prospectus supplement differ from any of the terms described above, then the terms described above will be deemed to have been superseded by that prospectus supplement. We encourage you to read the applicable purchase contract for additional information before you decide whether to purchase any of our purchase contracts.

# **DESCRIPTION OF UNITS**

The following description, together with the additional information that we include in any applicable prospectus supplements summarizes the material terms and provisions of the units that we may offer under this prospectus. While the terms we have summarized below will apply generally to any units that we may offer under this prospectus, we will describe the particular terms of any series of units in more detail in the applicable prospectus supplement. The terms of any units offered under a prospectus supplement may differ from the terms described below.

We will incorporate by reference from reports that we file with the SEC, the form of unit agreement that describes the terms of the series of units we are offering, and any supplemental agreements, before the issuance of the related series of units. The following summaries of material terms and provisions of the units are subject to, and qualified in their entirety by reference to, all the provisions of the unit agreement and any supplemental agreements applicable to a particular series of units. We urge you to read the applicable prospectus supplements related to the particular series of units that we may offer under this prospectus, as well as any related free writing prospectuses and the complete unit agreement and any supplemental agreements that contain the terms of the units.

#### General

We may issue units consisting of common stock, preferred stock, one or more debt securities, warrants, rights or purchase contacts for the purchase of common stock, preferred stock and/or debt securities in one or more series, in any combination. Each unit will be issued so that the holder of the unit is also the holder of each security included in the unit. Thus, the holder of a unit will have the rights and obligations of a holder of each security included in the unit. The unit agreement under which a unit is issued may provide that the securities included in the unit may not be held or transferred separately, at any time or at any time before a specified date.

We will describe in the applicable prospectus supplement the terms of the series of units being offered, including:

the designation and terms of the units and of the securities comprising the units, including whether and under what circumstances those securities may be held or transferred separately;

any provisions of the governing unit agreement that differ from those described below; and

any provisions for the issuance, payment, settlement, transfer or exchange of the units or of the securities comprising the units.

The provisions described in this section, as well as those set forth in any prospectus supplement or as described under Description of Common Stock, Description of Preferred Stock, Description of Debt Securities, Description of Warrants, Description of Rights and Description of Purchase Contracts will apply to each unit, as applicable, and to any common stock, preferred stock, debt security, warrant, right or purchase contract included in each unit, as applicable.

# **Unit Agent**

The name and address of the unit agent for any units we offer will be set forth in the applicable prospectus supplement.

# **Issuance in Series**

We may issue units in such amounts and in such numerous distinct series as we determine.

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# **Enforceability of Rights by Holders of Units**

Each unit agent will act solely as our agent under the applicable unit agreement and will not assume any obligation or relationship of agency or trust with any holder of any unit. A single bank or trust company may act as unit agent for more than one series of units. A unit agent will have no duty or responsibility in case of any default by us under the applicable unit agreement or unit, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a unit may, without the consent of the related unit agent or the holder of any other unit, enforce by appropriate legal action its rights as holder under any security included in the unit.

# CERTAIN PROVISIONS OF DELAWARE LAW AND OF THE COMPANY S CERTIFICATE OF INCORPORATION AND BYLAWS

# Anti-Takeover Provisions of our Certificate of Incorporation and Bylaws

Our amended and restated certificate of incorporation and amended and restated bylaws contain provisions that are intended to enhance the likelihood of continuity and stability in the composition of the board of directors and which may have the effect of delaying, deferring or preventing a future takeover or change in control of our company unless such takeover or change in control is approved by our board of directors.

These provisions, summarized below, are expected to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of increased protection of our potential ability to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Advance notice provisions for stockholder proposals. Our amended and restated bylaws establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors, as well as procedures for including proposed nominations at special meetings at which directors are to be elected. Stockholders at our annual meeting may only consider proposals or nominations specified in the notice of meeting or brought before the meeting by or at the direction of our board or by a stockholder who was a stockholder of record on the record date for the meeting, who is entitled to vote at the meeting and who has given to our secretary timely written notice, in proper form, of the stockholder s intention to bring that business before the meeting, and who has complied with the procedures and requirements set forth in our amended and restated bylaws. Although our amended and restated bylaws do not give our board of directors the power to approve or disapprove stockholder nominations of candidates or proposals regarding other business to be conducted at a special or annual meeting, our amended and restated bylaws may have the effect of precluding the conduct of some business at a meeting if the proper procedures are not followed or may discourage or defer a potential acquirer from conducting a solicitation of proxies to elect its own slate of directors or otherwise attempting to obtain control of us.

Special meetings of stockholders. Special meetings of the stockholders may be called only by our board of directors, our chairman of the board, our chief executive officer, our president and, in certain circumstances, a committee of our board of directors or an officer. Stockholders are not permitted to call a special meeting or to require our board of directors to call a special meeting.

*No stockholder action by written consent.* Our amended and restated certificate of incorporation and amended and restated bylaws do not permit our stockholders to act by written consent. As a result, any action to be effected by our stockholders must be effected at a duly called annual or special meeting of the stockholders.

Super-majority stockholder vote required for certain actions. The Delaware General Corporation Law provides generally that the affirmative vote of a majority of the shares entitled to vote on any matter is required to amend a corporation s certificate of incorporation or bylaws, unless the corporation s certificate of incorporation or bylaws, as the case may be, requires a greater percentage. A 75% vote is required for any amendment to, or rescission, alteration or repeal of, our amended and restated bylaws by our stockholders. Our amended and restated bylaws may be amended or repealed by a vote of a majority of the number of directors then in office.

# **Provisions of Delaware Law Governing Business Combinations**

We are subject to the business combination provisions of Section 203 of the Delaware General Corporation Law. In general, such provisions prohibit a publicly held Delaware corporation from engaging in any

business combination transactions with any interested stockholder for a period of three years after the date on which the person became an interested stockholder, unless:

prior to such date, the board of directors approved either the business combination or the transaction which resulted in the interested stockholder obtaining such status; or

upon consummation of the transaction which resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85% of the voting stock of the corporation outstanding at the time the transaction commenced, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned by (a) persons who are directors and also officers and (b) employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; or

at or subsequent to such time the business combination is approved by the board of directors and authorized at an annual or special meeting of stockholders, and not by written consent, by the affirmative vote of at least 66 2/3% of the outstanding voting stock which is not owned by the interested stockholder.

A business combination is defined to include mergers, asset sales and other transactions resulting in financial benefit to a stockholder. In general, an interested stockholder is a person who, together with affiliates and associates, owns 15% or more of a corporation s voting stock or within three years did own 15% or more of a corporation s voting stock. The statute could prohibit or delay mergers or other takeover or change in control attempts with respect to us and, accordingly, may discourage attempts to acquire us.

# Limitations on Liability and Indemnification of Officers and Directors

Our amended and restated certificate of incorporation limits the liability of our officers and directors to the fullest extent permitted by the Delaware General Corporation Law, and our amended and restated certificate of incorporation and amended and restated bylaws provide that we will indemnify our officers and directors to the fullest extent permitted by such law. We have also entered into indemnification agreements with our officers and directors and expect to enter into a similar agreement with any new officers and directors.

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#### **LEGAL MATTERS**

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts, will pass upon the validity of the issuance of the securities offered by this prospectus. Additional legal matters may be passed upon for us or any underwriters, dealers or agents, by counsel that we will name in the applicable prospectus supplement.

#### **EXPERTS**

UHY LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, and the effectiveness of our internal control over financial reporting as of December 31, 2015, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on UHY LLP s reports, given on their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC s public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC s web site at <a href="http://www.sec.gov">http://www.sec.gov</a>. Our common stock is listed on The NASDAQ Capital Market, and you can read and inspect our filings at the offices of the Financial Industry Regulatory Authority at 1735 K Street, Washington, D.C. 20006.

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

We also maintain a website at www.keryx.com, through which you can access our SEC filings. The information set forth on our website is not part of this prospectus.

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#### INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities we may offer pursuant to this prospectus. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities we may offer pursuant to this prospectus. Statements in this prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in Where You Can Find More Information. The documents we are incorporating by reference are:

our Annual Report on Form 10-K for the year ended December 31, 2015 filed on February 26, 2016;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016 filed on April 28, 2016, August 5, 2016 and November 9, 2016, respectively;

our Current Reports on Form 8-K filed on March 11, 2016, March 29, 2016, April 1, 2016, May 27, 2016, June 21, 2016, August 1, 2016 (solely with respect to the information filed under Item 8.01 in such Current Report on Form 8-K), October 17, 2016 (solely with respect to the information filed under Item 1.01 in such Current Report on Form 8-K) and November 9, 2016;

the portions of our Definitive Proxy Statement on Schedule 14A filed on April 15, 2016 that are deemed filed with the SEC under the Exchange Act;

the description of our common stock contained in our Registration Statement on Form 8-A filed on June 30, 2000, including any amendment or report filed for the purpose of updating such description; and

all reports and other documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this prospectus and prior to the termination or completion of the offering of securities under this prospectus shall be deemed to be incorporated by reference in this prospectus and to be a part hereof from the date of filing such reports and other documents.

The SEC file number for each of the documents listed above is 000-30929.

In addition, all reports and other documents filed by us pursuant to the Exchange Act after the date of the initial registration statement and prior to effectiveness of the registration statement shall be deemed to be incorporated by reference into this prospectus.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request, orally or in writing, a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Investor Relations, Keryx Biopharmaceuticals, Inc., One Marina Park Drive, Boston, MA 02210, (617) 466-3500.

You should rely only on information contained in, or incorporated by reference into, this prospectus and any prospectus supplement. We have not authorized anyone to provide you with information different from that contained in this prospectus or incorporated by reference in this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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THE INFORMATION IN THIS PROSPECTUS IS NOT COMPLETE AND MAY BE CHANGED. WE MAY NOT SELL THESE SECURITIES UNTIL THE REGISTRATION STATEMENT FILED WITH THE SECURITIES AND EXCHANGE COMMISSION IS EFFECTIVE. THIS PROSPECTUS IS NOT AN OFFER TO SELL THESE SECURITIES AND IS NOT SOLICITING AN OFFER TO BUY THESE SECURITIES IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

# SUBJECT TO COMPLETION, DATED NOVEMBER 30, 2016

# **PROSPECTUS**

Up to \$75,000,000

**Common Stock** 

We have entered into a Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor Fitzgerald & Co. relating to shares of our common stock offered by this prospectus. In accordance with the terms of the sales agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to \$75,000,000 from time to time through Cantor Fitzgerald & Co., acting as sales agent.

Our common stock is listed on The NASDAQ Capital Market under the symbol KERX. On November 29, 2016, the last reported sale price of our common stock was \$5.96 per share.

Sales of our common stock, if any, under this prospectus may be made in sales deemed to be an at the market offering as defined in Rule 415(a)(4) promulgated under the Securities Act of 1933, as amended, or the Securities Act. Subject to the terms of the sales agreement, Cantor Fitzgerald & Co. will act as sales agent and use commercially reasonable efforts to sell on our behalf all of the shares of common stock requested to be sold by us, consistent with its normal trading and sales practices, on mutually agreed terms between Cantor Fitzgerald & Co. and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Cantor Fitzgerald & Co. will be entitled to compensation at a commission rate of up to 3.0% of the gross sales price per share sold. In connection with the sale of shares of our common stock on our behalf, Cantor Fitzgerald & Co. will be deemed to be an underwriter within the meaning of the Securities Act and the compensation of Cantor Fitzgerald & Co. will be deemed to be underwriting commissions or discounts.

| Investing in our securities involves a high degree of risk. Before deciding whether to invest in our securities, |
|--|
| you should consider carefully the risks that we have described on page S-5 of this prospectus under the caption  |
| Risk Factors.  |

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 , 2016.

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# **ABOUT THIS PROSPECTUS**

This prospectus relates to part of a registration statement that we have filed with the Securities and Exchange Commission, or SEC, utilizing a shelf registration process. The \$75,000,000 of common stock that may be offered, issued and sold under this prospectus is included in the \$250,000,000 of securities that may be offered, issued and sold by us pursuant to our shelf registration statement. This prospectus is deemed a prospectus supplement to the base prospectus included in the registration statement of which this prospectus forms a part.

This prospectus includes or incorporates by reference important information about us, our common stock, and other matters you should know before investing. You should read this prospectus as well as additional information described under Where You Can Find More Information before making an investment decision.

You should rely only on this prospectus and the information incorporated or deemed to be incorporated by reference in this prospectus or in any free writing prospectuses we provide you. We have not, and Cantor Fitzgerald & Co. has not, authorized anyone to provide you with information that is in addition to, or different from, that contained or incorporated by reference in this prospectus. If anyone provides you with different or inconsistent information, you should not rely on it. We may also file one or more prospectus supplements to this prospectus. We are not, and Cantor Fitzgerald & Co. is not, offering to sell securities in any jurisdiction where the offer or sale is not permitted. You should not assume that the information contained or incorporated by reference in this prospectus is accurate as of any date other than as of the date of this prospectus or in the case of the documents incorporated by reference, the date of such documents regardless of the time of delivery of this prospectus or any sale of our common shares. Our business, financial condition, liquidity, results of operations, and prospects may have changed since those dates.

We further note that the representations, warranties and covenants made by us in any agreement that is filed as an exhibit the registration statement to which this prospectus forms a part or to any document that is incorporated by reference in this prospectus 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.

Unless the context otherwise requires, Keryx, the Company, we, us, our and similar terms refer to Keryx Biopharmaceuticals, Inc. and our subsidiaries. When we refer to you or yours we mean the investors and potential investors in the shares of common stock offered hereby.

Our trademarks include, without limitation, our name and corporate logo. Other service marks, trademarks and trade names contained in this prospectus, any prospectus supplement or the documents incorporated by reference herein and therein are the property of their respective owners.

# PROSPECTUS SUMMARY

The following is a summary of what we believe to be the most important aspects of our business and the offering of our securities under this prospectus. We urge you to read this entire prospectus, including the more detailed consolidated financial statements, notes to the consolidated financial statements and other information incorporated by reference from our other filings with the SEC. Investing in our securities involves risks. Therefore, carefully consider the risk factors set forth in this prospectus of incorporated by reference herein, as well as other information in this prospectus and the documents incorporated by reference herein, before purchasing our securities. Each of the risk factors could adversely affect our business, operating results and financial condition, as well as adversely affect the value of an investment in our securities.

### About Keryx Biopharmaceuticals, Inc.

We are a biopharmaceutical company focused on bringing innovative medicines to people with renal disease. Our product, Auryxia® (ferric citrate), also known as Riona® in Japan and Fexeric® in Europe, is an oral, absorbable iron-based medicine, that received marketing approval from the U.S. Food and Drug Administration, or FDA, in September 2014 for the control of serum phosphorus levels in patients with chronic kidney disease, or CKD, on dialysis. We believe that there currently are approximately 450,000 adults in the United States on dialysis of whom approximately 350,000 are on phosphate binders and eligible for treatment with Auryxia. When discussing ferric citrate in the United States in reference to our marketed product, we will refer to it as Auryxia, when discussing it in the United States in reference to our investigational medicine in Phase 3, we will refer to it as ferric citrate, when discussing it in Japan, we will refer to it as Riona, and when discussing it in Europe, we will refer to it as Fexeric.

We launched Auryxia in the United States in late December 2014. Auryxia is being marketed in the United States through our specialty salesforce and commercial infrastructure. Our sales organization is aligned to 95 territories calling on target nephrologists and their associated dialysis centers. In 2015, we reported net U.S. Auryxia product sales of \$10.1 million.

On August 1, 2016, we announced that an interruption in the supply of Auryxia tablets was imminent due to a production-related issue in converting active pharmaceutical ingredient, or API, to finished drug product at our contract manufacturer. This issue resulted in variable production yields of finished drug product and, as a result, we exhausted our reserve of finished drug product. Inventories of Auryxia were not sufficient to ensure uninterrupted patient access to this medicine. The supply interruption did not affect the safety profile of currently available Auryxia and did not affect the supply of Riona manufactured and sold by our Japanese partner in Japan. We are working with this manufacturer to resolve the production-related issue. In addition, since approval of Auryxia in 2014, we had been working to bring a secondary manufacturer online to supply finished drug product. We recently filed for approval of an additional manufacturer, Patheon Manufacturing Services LLC, or Patheon, with the FDA and entered into a long-term arrangement with Patheon in October 2016 to supply finished Auryxia drug product. On November 9, 2016, the FDA approved our application and Patheon is now an approved drug product manufacturer of Auryxia. With FDA approval of this manufacturer, we have rebuilt supply of Auryxia and made Auryxia available to wholesalers again.

In March 2016, we announced positive top-line results from our pivotal Phase 3 study of ferric citrate for the treatment of iron deficiency anemia, or IDA, in adults with stage 3-5 non-dialysis dependent chronic kidney disease, or NDD-CKD. We believe there are approximately 650,000 adults in the United States with CKD currently being treated for IDA. The Phase 3 study s primary endpoint was the between group comparison of the proportion of patients achieving a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period of the study. Secondary endpoints in the Phase 3 study include the change from baseline to the end of the randomized period for hemoglobin, ferritin, TSAT and serum phosphorus. The top-line results

showed that treatment with ferric citrate in the registration trial demonstrated statistically significant differences as compared to placebo for the primary and all pre-specified secondary endpoints. The majority of patients in the ferric citrate group (52 percent) achieved a 1 g/dL or greater increase in hemoglobin at any point during the 16-week randomized period as compared to 19 percent in the placebo group (p<0.001). Additionally, the safety profile of the drug candidate was consistent with previously reported clinical studies of ferric citrate, with the majority of adverse events reported as mild to moderate. We believe the initial data support our plan to submit a supplemental new drug application, or sNDA, with the FDA seeking to expand the label for ferric citrate to include the treatment of IDA in adults with stage 3-5 NDD-CKD. We have completed the sNDA and are ready to submit it to the FDA pending final agreement on its pediatric plan.

Our Japanese partner, Japan Tobacco Inc. or JT, together with its subsidiary Torii Pharmaceutical Co. Ltd., or Torii, received manufacturing and marketing approval of ferric citrate from the Japanese Ministry of Health, Labour and Welfare as an oral treatment for the improvement of hyperphosphatemia in patients with CKD, including dialysis and NDD-CKD, in January 2014. Torii began to market the product under the brand name Riona in May 2014. Additionally, in the third quarter of 2016, JT and Torii commenced enrollment in a Phase 2 clinical trial of ferric citrate for the treatment of IDA. Under the license agreement with JT and Torii, we receive royalty payments based on a tiered double-digit percentage of net sales of Riona in Japan escalating up to the mid-teens, as well as up to an additional \$55.0 million upon the achievement of certain annual net sales milestones. We in turn owe royalties at a mid-single digit percentage of net sales to the licensor of ferric citrate associated with net sales of Riona in Japan.

On September 23, 2015, the European Commission, or EC, approved Fexeric (ferric citrate coordination complex) for the control of elevated serum phosphorus levels, or hyperphosphatemia, in adult patients with CKD, including dialysis and NDD-CKD. The EC also considered ferric citrate coordination complex as a New Active Substance, which provides 10 years of data and marketing exclusivity in the European Union. We are currently seeking potential partners to commercialize Fexeric in the European Union.

Currently, our only product is Auryxia. In January 2015, we began to recognize product sales based on prescription sales of Auryxia in the United States. We have also generated, and expect to continue to generate, license revenue from the sublicensing of rights to ferric citrate in Japan to our Japanese partner. We may engage in business development activities that include seeking strategic relationships for ferric citrate outside of the United States, as well as evaluating other compounds and companies for in-licensing or acquisition, with a focus on complementary assets.

#### **Additional Information**

We were incorporated in Delaware in October 1998 and commenced operations in November 1999. In January 2016, we moved our executive offices to One Marina Park Drive, 12<sup>th</sup> Floor, Boston, Massachusetts 02210. Our telephone number is (617) 466-3500. Our website address is *www.keryx.com*. The information contained on our website is not incorporated by reference into, and does not form any part of, this prospectus. We have included our website address as a factual reference and do not intend it to be an active link to our website. Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports, are available free of charge through the Investors SEC Filings and Annual Reports section of our website as soon as reasonably practicable after such materials have been electronically filed with, or furnished to, the SEC.

#### THE OFFERING

The following summary contains basic information about our common stock and the offering and is not intended to be complete. It does not contain all the information that may be important to you. For a more complete understanding of our common stock, you should read this prospectus and the documents referred to herein.

Issuer Keryx Biopharmaceuticals, Inc.

Common stock offered by us Shares of our common stock having an aggregate offering price of up to

\$75,000,000.

Common stock to be outstanding after this

offering

Up to 118,544,257 shares (as more fully described in the notes following this table), assuming sales of 12,583,893 shares of our common stock in this offering at an assumed offering price of \$5.96 per share, which was the last reported sale price of our common stock on the NASDAQ Capital Market on November 29, 2016. The actual number of shares issued in connection with this offering will vary depending on how many shares of our common stock we choose to sell and the prices at which

such sales occur.

Manner of offering Sales of shares of our common stock under this prospectus may be made

by any method deemed to be an at the market offering as defined in Rule 415(a)(4) under the Securities Act of 1933, as amended. Subject to the terms of the sales agreement, Cantor Fitzgerald & Co. will make all sales using commercially reasonable efforts consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The NASDAQ Capital Market, on mutually agreeable terms between Cantor Fitzgerald & Co. and us. See Plan of

Distribution beginning on page S-11 of this prospectus.

Sales agent Cantor Fitzgerald & Co.

Use of Proceeds We expect to use the net proceeds from this offering, if any, for working

capital and general corporate purposes. See Use of Proceeds beginning

on page S-8 of this prospectus.

Risk Factors Your investment in shares of our common stock involves substantial

risks. You should consider the matters referred to under the heading Risk Factors in this prospectus, including the risk factors incorporated by

reference herein and therein from our filings with the SEC.

# NASDAQ Capital Market symbol KERX

The number of shares of common stock shown above to be outstanding after this offering is based on 105,960,364 shares of our common stock outstanding as of September 30, 2016, including 1,724,839 shares of unvested restricted stock subject to repurchase by us, and excluding:

8,823,096 shares of our common stock reserved for issuance upon the exercise of outstanding stock options at a weighted average exercise price of \$7.40 per share; and

6,912,531 shares of our common stock reserved for future awards under our Amended and Restated 2013 Incentive Plan.

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# **RISK FACTORS**

An investment in our common stock involves risks. You should carefully consider the risks described below, as well as the other information included or incorporated by reference in this prospectus, including Risk Factors included in Item 1A of Part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed with the SEC on August 5, 2016, and in any subsequent Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q and Current Reports on Form 8-K, before making an investment decision. In addition, please read About this Prospectus in this prospectus and Special Note Regarding Forward-Looking Statements in this prospectus, where we describe additional uncertainties associated with our business and the forward-looking statements included or incorporated by reference in this prospectus. Please note that additional risks not currently known to us or that we currently deem immaterial may also impair our business and operations.

# Risks related to this offering

### You will incur immediate and substantial dilution as a result of this offering.

The assumed offering price per share of our common stock in this offering is substantially higher than the net tangible book value per share of our common stock. Therefore, if you purchase shares of our common stock in this offering, you will pay a price per share that substantially exceeds our net tangible book value per share after this offering. Assuming the sale of \$75,000,000 of our common stock in this offering, based on the assumed offering price of \$5.96 per share, which was the last reported sale price of our common stock on the NASDAQ Capital Market on November 29, 2016, and net tangible book value per share of our common stock of \$0.18 as of September 30, 2016, if you purchase shares in this offering, you will suffer immediate and substantial dilution of \$5.19 per share in the as adjusted net tangible book value of common stock purchased. See Dilution beginning on page S-9 of this prospectus for a more detailed description of the dilution to new investors in this offering.

### We have broad discretion in the use of net proceeds from this offering and may not use them effectively.

We currently intend to use the net proceeds, if any, from this offering for working capital and general corporate purposes. See Use of Proceeds beginning on page S-8 of this prospectus for further detail. Although we currently intend to use the net proceeds, if any, from this offering in such a manner, we will have broad discretion in the application of such net proceeds. Our failure to apply these funds effectively could result in unfavorable returns and uncertainty about our prospects, each of which could cause the price of our common stock to decline. Pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or loses value.

# You may experience future dilution as a result of future equity offerings.

To raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share in this offering. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by investors in this offering, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by investors in this offering.

Sales of a significant number of shares of our common stock in the public markets, or the perception that such sales could occur, could depress the market price of our common stock.

Sales of a substantial number of shares of our common stock in the public markets could depress the market price of our common stock and impair our ability to raise capital through the sale of additional equity or equity-based securities. We cannot predict the effect that future sales of our common stock would have on the market price of our common stock.

We have not paid dividends in the past and do not expect to pay dividends in the future on our common stock, and any return on investment may be limited to the value of our common stock.

We have never paid cash dividends and we currently intend to retain any future earnings and do not anticipate paying cash dividends in the foreseeable future. We are not legally or contractually required to pay dividends and certain of our debt agreement with our major stockholder contains restrictions on our ability to pay cash dividends. The declaration and payment of all future dividends, if any, will be at the sole discretion our board of directors, which retains the right to change our dividend policy at any time, and may be limited by our debt arrangements in place from time to time. The payment of dividends will depend on our earnings, capital requirements, financial condition, prospects and other factors our board of directors may deem relevant. If we do not pay dividends, our common stock may be less valuable because stockholders must rely on sales of their common stock after price appreciation, which may never occur, to realize any future gains on their investment.

# SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

The SEC encourages companies to disclose forward-looking information so that investors can better understand a company s future prospects and make informed investment decisions. This prospectus and the documents we have filed with the SEC that are incorporated herein by reference contain such forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995.

Such statements in connection with any discussion of future operations or financial performance are identified by the use of words such as may, anticipate, estimate, expect, project, intend, plan, believe, and other words a similar meaning. Such statements are based on management s expectations and are subject to certain factors, risks and uncertainties that may cause actual results, outcome of events, timing and performance to differ materially from those expressed or implied by such statements. These risks and uncertainties include, but are not limited to: our ability to quickly and successfully identify and resolve the production-related issue; our ability to quickly and successfully identify and engage additional suppliers of finished drug product; our ability to receive FDA approval of any additional suppliers of finished drug product; whether we can increase adoption of Auryxia in patients with CKD on dialysis; whether we can maintain our operating expenses to projected levels while continuing our current clinical, regulatory and commercial activities; whether we will be able to identify and negotiate acceptable terms with a commercialization partner in the European Union; whether we or a partner can successfully launch Fexeric in the European Union; whether Riona will be successfully marketed in Japan by our Japanese partner; the risk that the FDA may not concur with our interpretation of our Phase 3 study results in NDD-CKD, supportive data, conduct of the studies, or any other part of our regulatory submission and could ultimately deny approval of ferric citrate for the treatment of iron deficiency anemia in adults with stage 3-5 NDD-CKD; the risk that if approved for use in NDD-CKD that we may not be able to successfully market Auryxia for use in this indication; and other factors detailed under the heading Risk Factors in this prospectus as updated and supplemented by the discussion of risks and uncertainties under Risk Factors contained in our most recent Annual Report on Form 10-K, as revised or supplemented by our subsequent Quarterly Reports on Form 10-Q or our Current Reports on Form 8-K, as well as any amendments thereto, as filed with the SEC and which are incorporated herein by reference. The information contained in this document is believed to be current as of the date of this document. We do not intend to update any of the forward-looking statements after the date of this document to conform these statements to actual results or to changes in our expectations, except as required by law.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this prospectus or in any document incorporated herein by reference might not occur. Investors are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this prospectus or the date of the document incorporated by reference in this prospectus. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise. All subsequent forward-looking statements attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

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# **USE OF PROCEEDS**

We may issue and sell shares of our common stock having aggregate gross sales proceeds of up to \$75,000,000 from time to time under this prospectus. Because there is no minimum offering amount required pursuant to the sales agreement with Cantor Fitzgerald & Co., the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. Actual net proceeds will depend on the number of shares we sell and the prices at which such sales occur. There can be no assurance that we will sell any shares under or fully utilize the sales agreement with Cantor Fitzgerald & Co. as a source of financing.

We intend to use the net proceeds, if any, from sales of shares of our common stock covered by this prospectus for working capital and general corporate purposes, which may include, among other things, the funding of capital and other expenditures and the acquisition or in-license of additional drugs, product candidates or technology.

Our expected use of net proceeds, if any, from the sale of shares of common stock pursuant to the sales agreement with Cantor Fitzgerald & Co. represents our intentions based upon our present plans and business conditions, which could change in the future as our plans and business conditions evolve. The amount and timing of our actual expenditures will depend upon numerous factors, including, but not limited to, the adoption rate of Auryxia in patients with CKD on dialysis and any other indication for which we may obtain regulatory approvals, the timing and outcome of the commercialization of Auryxia in the E.U., the ability of our Japanese partner to successfully market Riona in Japan, results of our research and development efforts, the timing and success of preclinical studies, our ongoing clinical studies or clinical studies we may commence in the future, the timing of regulatory submissions and the feedback from regulatory authorities, including with respect to ferric citrate for the treatment of IDA in adults with stage 3-5 NDD-CKD. As a result, our management will have broad discretion over the use of the net proceeds from this offering, if any. We may temporarily invest the net proceeds in investment-grade, interest-bearing securities pending their use for the purposes described above. We have not determined the amount of net proceeds to be used specifically for such purposes and, as a result, management will retain broad discretion over the allocation of net proceeds, if any.

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#### **DILUTION**

If you invest in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share and the as adjusted net tangible book value per share after giving effect to this offering. We calculate net tangible book value per share by dividing the net tangible book value, which is tangible assets less total liabilities, by the number of outstanding shares of our common stock. Dilution represents the difference between the amount per share paid by purchasers of shares in this offering and the as adjusted net tangible book value per share of our common stock immediately after giving effect to this offering. Our net tangible book value as of September 30, 2016 was approximately \$18.8 million, or \$0.18 per share.

After giving effect to the sale of our common stock in the aggregate amount of \$75.0 million at an assumed offering price of \$5.96 per share, which was the last reported sale price of our common stock on the NASDAQ Capital Market on November 29, 2016, and after deducting offering commissions and estimated expenses payable by us, our net tangible book value as of September 30, 2016 would have been \$91.7 million, or \$0.77 per share of common stock. This represents an immediate increase in the net tangible book value of \$0.59 per share to our existing stockholders and an immediate dilution in net tangible book value of \$5.19 per share to new investors. The following table illustrates this per share dilution:

| Assumed offering price per share   |        | \$ 5.96 |
|--|--------|---------|
| Net tangible book value per share as of September 30, 2016                                 | \$0.18 |         |
| Increase per share attributable to this offering   | 0.59   |         |
| As adjusted net tangible book value per share as of September 30, 2016 after this offering |        | 0.77    |
| Dilution per share to new investors  |        | \$ 5.19 |

The table above assumes for illustrative purposes that an aggregate of 12,583,893 shares of our common stock are sold at a price of \$5.96 per share, which was the last reported sale price of our common stock on the NASDAQ Capital Market on November 29, 2016, for aggregate gross proceeds of \$75.0 million. The shares sold in this offering, if any, will be sold from time to time at various prices. An increase of \$1.00 per share in the price at which the shares are sold from the assumed offering price of \$5.96 per share shown in the table above, assuming all of our common stock in the aggregate amount of \$75.0 million during the term of the sales agreement with Cantor Fitzgerald & Co. is sold at that price, would increase our as adjusted net tangible book value per share after the offering to \$0.79 per share and would increase the dilution in net tangible book value per share to new investors in this offering to \$6.17 per share, after deducting offering commissions and estimated expenses payable by us. A decrease of \$1.00 per share in the price at which the shares are sold from the assumed offering price of \$5.96 per share shown in the table above, assuming all of our common stock in the amount of \$75.0 million during the term of the sales agreement with Cantor Fitzgerald & Co. is sold at that price, would decrease our as adjusted net tangible book value per share after the offering to \$0.76 per share and would decrease the dilution in net tangible book value per share to new investors in this offering to \$4.20 per share, after deducting offering commissions and estimated offering expenses payable by us. This information is supplied for illustrative purposes only and may differ based on the actual offering price and the actual number of shares offered.

The above discussion and table are based on 105,960,364 shares of our common stock outstanding as of September 30, 2016, including 1,724,839 shares of unvested restricted stock subject to repurchase by us, and excluding:

8,823,096 shares of our common stock reserved for issuance upon the exercise of outstanding stock options at a weighted average exercise price of \$7.40 per share; and

6,912,531 shares of our common stock reserved for future awards under our Amended and Restated 2013 Incentive Plan.

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To the extent that options are exercised, investors purchasing shares in this offering could experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or equity-based securities, the issuance of these securities could result in further dilution to our stockholders.

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#### PLAN OF DISTRIBUTION

We have entered into a Controlled Equity Offering<sup>SM</sup> sales agreement with Cantor Fitzgerald & Co., or Cantor, under which we may issue and sell shares of our common stock having an aggregate gross sales price of up to \$75,000,000 from time to time through Cantor acting as agent. The sales agreement has been filed as an exhibit to our registration statement on Form S-3 of which this prospectus forms a part.

Upon delivery of a placement notice and subject to the terms and conditions of the sales agreement, Cantor may offer and sell shares of our common stock by any method permitted by law deemed to be an at the market offering as defined in Rule 415(a)(4) promulgated under the Securities Act. We may instruct Cantor not to sell common stock if the sales cannot be effected at or above the price designated by us from time to time. We or Cantor may suspend the offering of common stock upon notice and subject to other conditions.

We will pay Cantor commissions, in cash, for its services in acting as agent in the sale of our common stock. Cantor will be entitled to compensation at a commission rate of up to 3.0% of the gross sales price per share sold. Because there is no minimum offering amount required as a condition to close this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. We have also agreed to reimburse Cantor for certain specified expenses, including the reasonable and documented fees and disbursements of its legal counsel in an amount not to exceed \$50,000. We estimate that the total expenses for the offering, excluding compensation and reimbursements payable to Cantor under the terms of the sales agreement, will be approximately \$150,000.

Settlement for sales of shares of common stock will occur on the third business day following the date on which any sales are made, or on some other date that is agreed upon by us and Cantor in connection with a particular transaction, in return for payment of the net proceeds to us. Sales of our common stock as contemplated in this prospectus will be settled through the facilities of The Depository Trust Company or by such other means as we and Cantor may agree upon. There is no arrangement for funds to be received in an escrow, trust or similar arrangement.

Cantor will use its commercially reasonable efforts, consistent with its sales and trading practices, to solicit offers to purchase the shares of common stock under the terms and subject to the conditions set forth in the sales agreement. In connection with the sale of the shares of common stock on our behalf, Cantor will be deemed to be an underwriter within the meaning of the Securities Act and the compensation of Cantor will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Cantor against certain civil liabilities, including liabilities under the Securities Act.

The offering of shares of our common stock pursuant to the sales agreement will terminate upon the termination of the sales agreement as permitted therein. We and Cantor may each terminate the sales agreement at any time upon ten days prior notice.

Cantor and its affiliates may in the future provide various investment banking, commercial banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Cantor will not engage in any market making activities involving our common stock while the offering is ongoing under this prospectus.

This prospectus in electronic format may be made available on a website maintained by Cantor and Cantor may distribute this prospectus electronically.

#### **LEGAL MATTERS**

The validity of the shares of common stock offered hereby will be passed upon for us by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., Boston, Massachusetts. Cantor Fitzgerald & Co. is being represented in connection with this offering by Cooley LLP, New York, New York.

#### **EXPERTS**

UHY LLP, independent registered public accounting firm, has audited our consolidated financial statements included in our Annual Report on Form 10-K for the year ended December 31, 2015, and the effectiveness of our internal control over financial reporting as of December 31, 2015, as set forth in their reports, which are incorporated by reference in this prospectus and elsewhere in the registration statement. Our financial statements are incorporated by reference in reliance on UHY LLP s reports, given on their authority as experts in accounting and auditing.

#### WHERE YOU CAN FIND MORE INFORMATION

We are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy these reports, proxy statements and other information at the SEC s public reference facilities at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. You can request copies of these documents by writing to the SEC and paying a fee for the copying cost. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the public reference facilities. SEC filings are also available at the SEC s web site at <a href="http://www.sec.gov">http://www.sec.gov</a>. Our common stock is listed on The NASDAQ Capital Market, and you can read and inspect our filings at the offices of the Financial Industry Regulatory Authority at 1735 K Street, Washington, D.C. 20006.

This prospectus is only part of a registration statement on Form S-3 that we have filed with the SEC under the Securities Act and therefore omits certain information contained in the registration statement. We have also filed exhibits and schedules with the registration statement that are excluded from this prospectus, and you should refer to the applicable exhibit or schedule for a complete description of any statement referring to any contract or other document. You may inspect a copy of the registration statement, including the exhibits and schedules, without charge, at the public reference room or obtain a copy from the SEC upon payment of the fees prescribed by the SEC.

We also maintain a website at www.keryx.com, through which you can access our SEC filings. The information set forth on our website is not part of this prospectus.

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#### INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to incorporate by reference information that we file with them. Incorporation by reference allows us to disclose important information to you by referring you to those other documents. The information incorporated by reference is an important part of this prospectus, and information that we file later with the SEC will automatically update and supersede this information. We filed a registration statement on Form S-3 under the Securities Act with the SEC with respect to the securities we may offer pursuant to this prospectus. This prospectus omits certain information contained in the registration statement, as permitted by the SEC. You should refer to the registration statement, including the exhibits, for further information about us and the securities we may offer pursuant to this prospectus. Statements in this prospectus regarding the provisions of certain documents filed with, or incorporated by reference in, the registration statement are not necessarily complete and each statement is qualified in all respects by that reference. Copies of all or any part of the registration statement, including the documents incorporated by reference or the exhibits, may be obtained upon payment of the prescribed rates at the offices of the SEC listed above in Where You Can Find More Information. The documents we are incorporating by reference are:

our Annual Report on Form 10-K for the year ended December 31, 2015 filed on February 26, 2016;

our Quarterly Reports on Form 10-Q for the quarters ended March 31, 2016, June 30, 2016 and September 30, 2016 filed on April 28, 2016, August 5, 2016 and November 9, 2016, respectively;

our Current Reports on Form 8-K filed on March 11, 2016, March 29, 2016, April 1, 2016, May 27, 2016, June 21, 2016, August 1, 2016 (solely with respect to the information filed under Item 8.01 in such Current Report on Form 8-K), October 17, 2016 (solely with respect to the information filed under Item 1.01 in such Current Report on Form 8-K) and November 9, 2016;

the portions of our Definitive Proxy Statement on Schedule 14A filed on April 15, 2016 that are deemed filed with the SEC under the Exchange Act;

the description of our common stock contained in our Registration Statement on Form 8-A filed on June 30, 2000, including any amendment or report filed for the purpose of updating such description; and

all reports and other documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Exchange Act after the date of this prospectus and prior to the termination or completion of the offering of securities under this prospectus shall be deemed to be incorporated by reference in this prospectus and to be a part hereof from the date of filing such reports and other documents.

The SEC file number for each of the documents listed above is 000-30929.

In addition, all reports and other documents filed by us pursuant to the Exchange Act after the date of the initial registration statement and prior to effectiveness of the registration statement shall be deemed to be incorporated by reference into this prospectus.

Any statement contained in this prospectus or in a document incorporated or deemed to be incorporated by reference into this prospectus will be deemed to be modified or superseded for purposes of this prospectus to the extent that a statement contained in this prospectus or any other subsequently filed document that is deemed to be incorporated by reference into this prospectus modifies or supersedes the statement. Any statement so modified or superseded will not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

You may request, orally or in writing, a copy of any or all of the documents incorporated herein by reference. These documents will be provided to you at no cost, by contacting: Investor Relations, Keryx Biopharmaceuticals, Inc., One Marina Park Drive, Boston, MA 02210, (617) 466-3500.

You should rely only on information contained in, or incorporated by reference into, this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus or

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incorporated by reference in this prospectus. We may also file one or more prospectus supplements to this prospectus. We are not making offers to sell the securities in any jurisdiction in which such an offer or solicitation is not authorized or in which the person making such offer or solicitation is not qualified to do so or to anyone to whom it is unlawful to make such offer or solicitation.

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Up to \$75,000,000

**Common Stock** 

**PROSPECTUS** 

, 2016

#### **PART II**

# INFORMATION NOT REQUIRED IN PROSPECTUS

#### Item 14. Other Expenses of Issuance and Distribution

The following table sets forth an itemization of the various expenses, all of which we will pay, in connection with the issuance and distribution of the securities being registered:

| SEC Registration Fee              | \$ 28,9 | 75 |
|-----------------------------------|---------|----|
| Legal Fees and Expenses           |         | *  |
| Accounting Fees and Expenses      |         | *  |
| Printing and Duplicating Expenses |         | *  |
| Miscellaneous Expenses            |         | *  |
|                                   |         |    |
| Total                             | \$      | *  |

#### Item 15. Indemnification of Directors and Officers

Our amended and restated certificate of incorporation and amended and restated bylaws provide for indemnification of each of our officers and directors and certain other persons to the fullest extent permitted by the Delaware General Corporation Law. Section 145 of the Delaware General Corporation Law permits a corporation to indemnify any director or officer of the corporation against expenses (including attorneys fees), judgments, fines and amounts paid in settlement actually and reasonably incurred in connection with any action, suit or proceeding brought by reason of the fact that such person is or was a director or officer of the corporation, if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, and, with respect to any criminal action or proceeding, if he or she had no reason to believe his or her conduct was unlawful. In a derivative action, (i.e., one brought by or on behalf of the corporation), indemnification may be provided only for expenses actually and reasonably incurred by any director or officer in connection with the defense or settlement of such an action or suit if such person acted in good faith and in a manner that he or she reasonably believed to be in, or not opposed to, the best interests of the corporation, except that no indemnification shall be provided if such person shall have been adjudged to be liable to the corporation, unless and only to the extent that the court in which the action or suit was brought shall determine that the defendant is fairly and reasonably entitled to indemnity for such expenses despite such adjudication of liability.

Pursuant to Section 102(b)(7) of the Delaware General Corporation Law, Article Eighth of our amended and restated certificate of incorporation eliminates the liability of a director to us or our stockholders for monetary damages for such a breach of fiduciary duty as a director, except for liabilities arising:

<sup>\*</sup> Estimated expenses not presently known. The foregoing sets forth the general categories of fees and expenses (other than underwriting discounts and commissions) that we anticipate we will incur in connection with the offering of securities under this registration statement. An estimate of the aggregate fees and expenses in connection with the issuance and distribution of the securities being offered will be included in the applicable prospectus supplement.

from any breach of the director s duty of loyalty to us or our stockholders;

from acts or omissions not in good faith or which involve intentional misconduct or a knowing violation of law;

under Section 174 of the Delaware General Corporation Law; and

from any transaction from which the director derived an improper personal benefit.

We carry insurance policies insuring our directors and officers against certain liabilities that they may incur in their capacity as directors and officers. In addition, we have entered into indemnification agreements with our directors and officers.

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Any underwriting agreements that we may enter into will likely provide for the indemnification of us, our controlling persons, our directors and certain of our officers by the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended.

#### Item 16. Exhibits

The exhibits to this registration statement are listed in the Exhibit Index to this registration statement, which Exhibit Index is hereby incorporated by reference.

#### Item 17. Undertakings

- (a) The undersigned registrant hereby undertakes:
  - (1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:
    - (i) To include any prospectus required by section 10(a)(3) of the Securities Act of 1933;
    - (ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the Calculation of Registration Fee table in the effective registration statement; and
    - (iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

provided, however, that paragraphs (a)(1)(i), (a)(1)(ii) and (a)(1)(iii) do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2)

That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.

- (3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.
- (4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:
  - (i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and
  - (ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the

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registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof. *Provided, however*, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

- (5) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:
  - (i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;
  - (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;
  - (iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and
  - (iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.
- (b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant s annual report pursuant to section 13(a) or section 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan s annual report pursuant to section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial *bona fide* offering thereof.
- (c) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the

registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

(d) The undersigned registrant hereby undertakes to file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act ( Act ) in accordance with the rules and regulations prescribed by the Commission under section 305(b)(2) of the Act.

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Michael Heffernan

# **SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in Boston, Massachusetts, on November 30, 2016.

#### KERYX BIOPHARMACEUTICALS, INC.

By /s/ Gregory P. Madison Gregory P. Madison

Chief Executive Officer, President and Director Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed below by the

following persons in the capacities and on the dates indicated.

| Title                         | Date   |
|-------------------------------|--|
| Chief Executive Officer,      | November 30, 2016  |
| President and Director        |  |
| (principal executive officer) |  |
| Chief Financial Officer       | November 30, 2016  |
| officer)                      |  |
| Chairman of the Board         | November 30, 2016  |
|                               |  |
| Director                      | November 30, 2016  |
|                               |  |
| Director                      | November 30, 2016  |
|                               |  |
| Director                      | November 30, 2016  |
|                               | Chief Executive Officer, President and Director (principal executive officer) Chief Financial Officer (principal financial and accounting officer) Chairman of the Board  Director |

# Table of Contents Signature Title Date November 30, 2016 Jodie Morrison Director November 30, 2016 Daniel P. Regan Director November 30, 2016

Michael Rogers

\*By: /s/ Gregory P. Madison

Gregory P. Madison Attorney-in-Fact

# **EXHIBIT INDEX**

# **Exhibit**

| <u>Number</u> | Description  |
|---------------|--|
| 1.1*          | Form of Underwriting Agreement.  |
| 1.2           | Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated November 9, 2016, by and between Keryx Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co.  |
| 4.1.1         | Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated December 17, 2003, and the Amendment thereto, dated June 18, 2004, filed as Exhibit 3.1 to the Registrant's Quarterly Report on Form 10-Q for the quarter ended June 30, 2004, filed on August 12, 2004 (File No. 000-30929), and incorporated herein by reference. |
| 4.1.2         | Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc., dated July 24, 2007, filed as Exhibit 3.3 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2007, filed on August 9, 2007 (File No. 000-30929), and incorporated herein by reference.   |
| 4.1.3         | Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated June 18, 2013, filed as Exhibit 3.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, filed on August 2, 2013 (File No. 000-30929), and incorporated herein by reference.  |
| 4.1.4         | Amendment to Amended and Restated Certificate of Incorporation of Keryx Biopharmaceuticals, Inc. dated May 25, 2016, filed as Exhibit 3.4 to the Registrant s Quarterly Report on Form 10-Q for the quarter ended June 30, 2016, filed on August 5, 2016 (File No. 000-30929), and incorporated herein by reference.   |
| 4.2           | Amended and Restated Bylaws of Keryx Biopharmaceuticals, Inc., filed as Exhibit 3.2 to the Registrant s Annual Report on Form 10-K for the year ended December 31, 2001, filed on March 26, 2002 (File No. 000-30929), and incorporated herein by reference.   |
| 4.3           | Specimen Common Stock Certificate, filed as Exhibit 4.1 to the Registrant s First Amendment to the Registration Statement on Form S-1, filed on June 30, 2000 (File No. 333-37402), and incorporated herein by reference.  |
| 4.4           | Indenture, dated as of October 15, 2015, between Keryx Biopharmaceuticals, Inc. and The Bank of New York Mellon Trust Company, N.A., filed as Exhibit 10.2 to the Registrant s Current Report on Form 8-K, filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.   |
| 4.5           | Registration Rights Agreement, dated as of October 15, 2015, between Keryx Biopharmaceuticals, Inc. and Baupost Group Securities, L.L.C., filed as Exhibit 10.3 to the Registrant s Current Report on Form 8-K, filed on October 19, 2015 (File No. 000-30929), and incorporated herein by reference.  |
| 4.6*          | Form of Certificate of Amendment or Designation with respect to Preferred Stock.   |
| 4.7*          | Form of Senior Debt Security.  |
| 4.8*          | Form of Subordinated Debt Security.  |
|               |  |

| 4.9   | Form of Senior Indenture.                          |
|-------|--|
| 4.10  | Form of Subordinated Indenture.                    |
| 4.11* | Form of Warrant Agreement and Warrant Certificate. |
| 4.12* | Form of Rights Agreement and Right Certificate.    |
| 4.13* | Form of Purchase Contract.                         |
| 4.14* | Form of Unit Agreement and Unit.                   |
|       |  |

# **Exhibit**

| <u>Number</u> | Description  |
|---------------|--|
| 5.1           | Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. with respect to the legality of the securities being registered.  |
| 5.2           | Opinion of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. with respect to the legality of the shares issuable pursuant to the Controlled Equity Offering <sup>SM</sup> Sales Agreement, dated November 9, 2016, by and between Keryx Biopharmaceuticals, Inc. and Cantor Fitzgerald & Co. filed as Exhibit 1.2. |
| 12.1*         | Computation of Ratio of Earnings to Fixed Charges.   |
| 23.1          | Consent of UHY LLP.  |
| 23.2          | Consent of Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C. (included in the opinions filed as Exhibit 5.1 and Exhibit 5.2).  |
| 24.1          | Powers of Attorney (included on the signature page of this registration statement).  |
| 25.1**        | Statement of Eligibility on Form T-1 under the Trust Indenture Act of 1939, as amended, of the Trustee under the Senior Indenture.   |
| 25.2**        | Statement of Eligibility on Form T-1 under the Trust Indenture Act of 1939, as amended, of the Trustee under the Subordinated Indenture.   |

# Previously filed.

- \* To be subsequently filed, if applicable, by an amendment to this registration statement or by a current report on Form 8-K.
- \*\* To be subsequently filed, if applicable, in accordance with Section 305(b)(2) of the Trust Indenture Act of 1939.