

KERYX BIOPHARMACEUTICALS INC
Form 424B3
January 28, 2011
PROSPECTUS

\$100,000,000

Keryx Biopharmaceuticals, Inc.

Common Stock
Warrants

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

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

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

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

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

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

The date of this prospectus is January 28, 2011.

Table of Contents

	Page
Keryx Biopharmaceuticals, Inc.	1
The Offering	1
Where You Can Find More Information	1
Important Information About This Prospectus	2
Incorporation of Certain Information by Reference	2
Description of Securities We May Offer	3
Description of Common Stock	3
Description of Warrants	4
Plan of Distribution	5
Legal Matters	6
Experts	6

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KERYX BIOPHARMACEUTICALS, INC.

We are a biopharmaceutical company focused on the acquisition, development and commercialization of medically important pharmaceutical products for the treatment of life-threatening diseases, including cancer and renal disease. We are developing KRX-0401, which we also refer to as perifosine, a novel, potentially first-in-class, oral anti-cancer agent that inhibits Akt activation in the phosphoinositide 3-kinase pathway, and also affects a number of other key signal transduction pathways, including the JNK pathway, all of which are pathways associated with programmed cell death, growth, differentiation and survival. KRX-0401 has demonstrated both safety and clinical efficacy in several tumor types, both as a single agent and in combination with novel therapies. KRX-0401 is currently in Phase 3 clinical development for both refractory advanced colorectal cancer and multiple myeloma, and in Phase 1 and 2 clinical development for several other tumor types. Each of the KRX-0401 Phase 3 programs is being conducted under Special Protocol Assessment, or SPA, agreements with the FDA.

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

We also actively engage in business development activities that include seeking strategic relationships for our product candidates, as well as evaluating compounds and companies for in-licensing or acquisition. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any product sales from our drug candidates. We have generated, and expect to continue to generate, revenue from the licensing of rights to Zerenex in Japan to our Japanese partners, Japan Tobacco and Torii.

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

THE OFFERING

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

Nasdaq Symbol KERX

WHERE YOU CAN FIND MORE INFORMATION

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

IMPORTANT INFORMATION ABOUT THIS PROSPECTUS

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

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

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

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

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

- (a) Our Annual Report on Form 10-K for the year ended December 31, 2009;
- (b) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2010;
- (c) Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2010;
- (d) Our Quarterly Report on Form 10-Q for the quarter ended September 30, 2010;
- (e) Our Current Reports on Form 8-K filed with the SEC on January 5, 2010, January 25, 2010, July 14, 2010, July 21, 2010, August 5, 2010, September 29, 2010, October 26, 2010 and November 30, 2010; and
- (f) The description of our common stock contained in our registration statement on Form 8-A filed with the SEC on June 30, 2000 (File No. 000-30929).

We will provide to each person, including any beneficial owner, to whom a copy of this prospectus is delivered, a copy of any or all of the information that we have incorporated by reference into this prospectus. We will provide this

information upon written or oral request at no cost to the requester. You may request this information by contacting our corporate headquarters at the following address: 750 Lexington Avenue, New York, New York 10022, Attn: Chief Financial Officer, or by calling (212) 531-5965.

DESCRIPTION OF SECURITIES WE MAY OFFER

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

DESCRIPTION OF COMMON STOCK

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

Common Stock

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

Dividends

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

Voting Rights

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

Liquidation and Dissolution

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

Other

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

Transfer Agent

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

DESCRIPTION OF WARRANTS

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

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

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

PLAN OF DISTRIBUTION

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

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

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

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

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

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

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

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

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

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

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

LEGAL MATTERS

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

EXPERTS

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

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