KERYX BIOPHARMACEUTICALS INC
Form 424B5
July 11, 2005

FILED PURSUANT TO RULE 424(B)(5)
REGISTRATION NO. 333-119376
AND NO. 333-126494

THE INFORMATION IN THIS PROSPECTUS SUPPLEMENT IS NOT COMPLETE AND MAY BE CHANGED. THIS PROSPECTUS IS NOT AN OFFER TO SELL SECURITIES, AND WE ARE NOT SOLICITING AN OFFER TO BUY THESE SECURITIES, IN ANY STATE WHERE THE OFFER OR SALE IS NOT PERMITTED.

SUBJECT TO COMPLETION, DATED JULY 11, 2005

PROSPECTUS SUPPLEMENT

(TO PROSPECTUS DATED OCTOBER 13, 2004)

# 5,000,000 SHARES

KERYX LOGO

## COMMON STOCK

This is a public offering of 5,000,000 shares of common stock of Keryx Biopharmaceuticals, Inc.

Our common stock is traded on the Nasdaq National Market under the symbol KERX. On July 7, 2005, the last reported sale price for our common stock on the Nasdaq National Market was $13.50.

| | PER SHARE | TOTAL |
|---|---|---|
| Public offering price | $ | $ |
| Underwriting discounts and commissions | $ | $ |
| Proceeds to Keryx Biopharmaceuticals, Inc., before expenses | $ | $ |

Keryx Biopharmaceuticals, Inc. has granted the underwriters an option for a period of 30 days to purchase up to 780,000 additional shares of common stock to cover any overallotments.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE S-8 OF THIS PROSPECTUS SUPPLEMENT.

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July , 2005

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PROSPECTUS SUPPLEMENT
PROSPECTUS

## SUMMARY

This summary highlights information contained elsewhere or incorporated by reference in this prospectus supplement and the accompanying prospectus. This summary does not contain all of the information that you should consider before deciding to invest in our common stock. You should read this entire prospectus supplement and the accompanying prospectus carefully, including the "Risk factors" section contained in this prospectus supplement and our consolidated financial statements and the related notes and the other documents that we have filed with the Securities and Exchange Commission and incorporated by reference in this prospectus supplement or the accompanying prospectus before making an investment decision.

### KERYX BIOPHARMACEUTICALS, INC.

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Our lead compound under development is KRX-101 (sulodexide), a first-in-class, oral heparinoid compound for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes. KRX-101 is in a pivotal Phase III and Phase IV clinical program under a Special Protocol Assessment, or SPA, with the Food & Drug Administration, or FDA. Additionally, we are developing clinical-stage oncology compounds, including KRX-0401, a novel, first-in-class, oral modulator of Akt, a pathway associated with tumor survival and growth, and other important signal transduction pathways. KRX-0401 is currently in Phase II clinical development for multiple tumor types. We also have an active in-licensing and acquisition program designed to identify and acquire additional drug candidates.

### KRX-101 (SULODEXIDE): OUR APPROACH TO THE TREATMENT OF DIABETIC NEPHROPATHY

We are currently conducting pivotal Phase III and Phase IV clinical trials of KRX-101 for the treatment of diabetic nephropathy under a SPA with the FDA. The SPA defines clinical endpoints that will potentially support accelerated FDA approval for KRX-101. Diabetic nephropathy is a long-term complication of diabetes in which the kidneys are progressively damaged. One of the key markers of diabetic nephropathy is proteinuria or albuminuria, which is the presence of albumin, a protein commonly found in the serum or blood, in the urine. As kidney damage progresses, the degree of albuminuria increases, possibly leading to further kidney damage which could then result in end-stage renal disease, or ESRD, requiring dialysis.

There are currently two classes of compounds that are used to treat diabetic nephropathy: angiotensin converting enzyme, or ACE, inhibitors and angiotensin

receptor blockers, or ARBs. While both ACE inhibitors and ARBs have been helpful in treating diabetic nephropathy, a significant share of patients continue to have progressive diabetic kidney disease. Moreover, some patients experience adverse drug reactions with these medications, such as a persistent cough with ACE inhibitors and life-threatening hyperkalemia, when ACE inhibitors and ARBs are combined. We believe that a significant unmet medical need exists for an agent that can effectively reduce the level of albuminuria and ultimately slow or halt the progression of diabetic kidney disease in patients that are currently receiving maximum doses of ARBs or ACE inhibitors.

Our lead compound under development is KRX-101, a glycosaminoglycan with structural similarities to the broad family of marketed heparins, including both slow-moving and low-molecular weight heparins. Specifically, KRX-101 is primarily comprised of heparan sulfate, also referred to as fast-moving heparin, dermatan sulfate and slow-moving heparin.



KRX-101 is believed to work via one or more mechanisms of action that have the potential to be complementary to existing treatments for diabetic nephropathy. It has undergone testing in this indication in multiple clinical trials conducted in Europe, including a randomized 223 patient, double-blind, placebo-controlled Phase II study, known as the DiNAS study. In this study, Type I and Type II diabetic nephropathy patients were treated daily for four months with 50, 100 and 200 milligram gelcaps of KRX-101. These patients showed substantial dose-dependent reduction in proteinuria or pathological urinary albumin excretion rates. In this study, the higher the dose administered daily, the greater the demonstrated decrease in albumin excretion. The DiNAS study was published in the June 2002 issue of the Journal of the American Society of Nephrology.

KRX-101 has an established safety profile with no known dose limiting toxicities, at doses similar to those we are using in our current clinical trials. Moreover, it has been evaluated in over 20 clinical trials encompassing approximately 3,000 patients and has been marketed by our licensor for more than 20 years in a number of European, Asian and South American countries for certain cardiovascular conditions. We own the exclusive rights to use KRX-101 for the treatment of diabetic nephropathy in North America, Japan and certain other markets. Upon approval from the FDA, we anticipate building our own sales and marketing franchise targeting specialist physicians, including endocrinologists, nephrologists and diabetologists.

Currently, the use of KRX-101 to treat diabetic nephropathy is covered by an issued U.S. patent which expires in 2014 and a pending U.S. patent application which, if allowed, will expire in 2022. Based on the provisions of the Patent Term Extension Act, we currently believe that we would qualify for patent term extension of at least three years, thereby extending our patent exclusivity, for the issued U.S. patent to at least 2017. We, therefore, believe that we will have sufficient time to commercially utilize the inventions directed to the treatment of diabetic nephropathy.

In May 2005, we announced positive interim results from the Phase II clinical study for KRX-101, presented at the National Kidney Foundation's Spring Clinical Meeting. The Phase II study, which is currently on-going, compares two oral doses of KRX-101, 200 and 400 milligrams, versus a placebo in patients with diabetic microalbuminuria who are receiving an ACE inhibitor or ARBs. In this study, patients are treated with KRX-101 or a placebo for six months and followed for an additional two months post-treatment. The primary endpoint for the study is "therapeutic success" of the two dose levels combined versus a placebo at six months. Therapeutic success is a binary composite endpoint defined as: conversion from microalbuminuria to normoalbuminuria (with at least a 25% reduction in microalbuminuria) as measured by the albumin/creatinine

ratio, or ACR; or at least a 50% reduction in the ACR level relative to baseline.

Patients were randomized 1:1:1, placebo, 200 milligrams and 400 milligrams of KRX-101, respectively. Of the 149 patients randomized, 120 were considered evaluable for this interim analysis of the primary efficacy outcome at six months. Other data presented related to secondary endpoints of the study, including KRX-101 versus placebo analysis of the individual endpoints comprising therapeutic success--return to normal and 50% reduction from baseline. The data presented confirmed the activity of KRX-101 as a potentially effective treatment for diabetic nephropathy in patients who are on maximum approved or tolerated doses of ACE



inhibitors or ARBs. See the table below for the results from the interim efficacy analysis. We anticipate presenting the full data analysis of this Phase II study at a scientific conference in November 2005.

Interim Efficacy Analysis for KRX-101 vs. Placebo(1)

| | KRX-101 (200mg and 400mg) n=82 | KRX-101 (200mg) n=38 | Placebo n=38 |
|---|---|---|---|
| Therapeutic Success | 24% | 29% | 13% |
| >50% reduction | 21% | 24% | 11% |
| Normalization | 13% | 16% | 8% |

(1) Patients were considered evaluable only if the patient had both baseline and 6-month data available at the date of the data cut-off. One patient in the placebo arm was censored pending re-evaluation of that patient's baseline value. If that patient were included, the therapeutic success, 50% reduction and normalization percentages of the placebo group would be 15%, 13% and 7%, respectively.

The Collaborative Study Group, or the CSG, the world's largest standing renal clinical trial group comprised of academic and tertiary nephrology care centers, is completing the Phase II trial and is conducting the pivotal Phase III and Phase IV clinical program of KRX-101 for the treatment of diabetic nephropathy. The CSG has conducted multiple large-scale clinical trials resulting in over 40 publications in peer-reviewed journals. In addition, the CSG conducted the pivotal studies for two of the three drugs, including an ACE inhibitor and an ARB, that are currently approved for the treatment of diabetic nephropathy.

On June 29, 2005, we announced the initiation of our pivotal Phase III and Phase IV clinical program for KRX-101. We are conducting both of these trials under our SPA with the FDA. This clinical plan consists of: a single Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; supportive data from previously conducted clinical studies; and substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria. This Phase IV study is required to enable a comparison of the clinical events experienced by patients taking KRX-101 to historical results of earlier trials of other drugs.

The Phase III portion of the program is a randomized, double-blind,

placebo-controlled study comparing a 200 milligram daily dose of KRX-101 versus a placebo in patients with persistent microalbuminuria. The Phase III study is designed to enroll approximately 1,000 patients with Type II diabetes and is expected to take approximately 12 to 18 months to complete enrollment. The Phase IV portion of the program is a randomized, double-blind, placebo-controlled study comparing a 200 milligram daily dose of KRX-101 versus a placebo in patients with persistent macroalbuminuria. The Phase IV study is designed to enroll approximately 2,200 patients with Type II diabetes and is expected to take approximately 24 months to complete enrollment. Over 250 U.S., European, and Asia-Pacific clinical centers are expected to participate in our pivotal Phase III and Phase IV program.



KRX-101 MARKET OPPORTUNITY

According to the American Diabetes Association, or the ADA, there are 18.2 million people in the United States, or approximately 6.3% of the population, who have diabetes. Of this population, approximately 13 million have been diagnosed with diabetes, of whom approximately 90-95% have been diagnosed with Type II diabetes. Type II diabetes results from the combination of insulin deficiency and the body's relative insensitivity to the insulin present, as opposed to Type I diabetes, in which severe insulin deficiency results from destruction of the insulin-producing beta cells of the pancreas. Moreover, an August 2003 study published by Datamonitor estimates that approximately 50% of all diabetics in the U.S., or approximately nine million people, have diabetic nephropathy. Diabetes is the most common cause of ESRD in the United States and in many other developed nations and represents approximately 45% of all new cases of ESRD in the United States. Despite advances in clinical care, including improvements in glycemic or blood sugar control and blood pressure control, the number of Type I and Type II diabetes-related cases of ESRD continues to rise. In particular, the incidence of Type II diabetes-related ESRD is rapidly increasing. Approximately 20% of diabetics on dialysis in the United States survive for five years, making the mortality of end-stage renal failure in this group higher than most forms of cancer. Unfortunately, renal transplantation is an option for less than 15% of diabetics with ESRD, as compared to 35-40% of non-diabetics, principally due to age and concomitant vascular disease. Despite recent advances, diabetic nephropathy remains a potentially catastrophic illness for which partial but insufficient treatment is currently available.

ONCOLOGY PORTFOLIO

We are developing a series of proprietary small molecule oncology compounds for a variety of cancer indications. Several of these compounds are being evaluated by the National Cancer Institute, or the NCI, a division of the National Institutes of Health in various phases of clinical trials. Our most advanced candidate, KRX-0401, is currently in Phase II clinical development for multiple tumor types. We are currently planning additional company-sponsored clinical trials of our cancer portfolio.

KRX-0401 (PERIFOSINE)

OVERVIEW

KRX-0401 is a novel, first-in-class, oral modulator of Akt and other important signal transduction pathways. This compound has demonstrated preliminary single agent anti-tumor activity and is currently in a Phase II clinical program where it is being studied both as a single agent and in combination with other anti-cancer treatments for multiple forms of cancer.

KRX-0401 is an alkylphosphocholine, which is a class of anti-cancer drugs that block proliferation and induce the apoptosis of cancer cells. This effect is

relatively specific for cancer cells compared to normal cells. Although the mechanism of action for these drugs remains unclear, they are known to modulate signaling in a number of pathways known to function abnormally during the development of cancer. One of the pathways inhibited by the alkylphosphocholines is Akt, a pathway associated with tumor survival and growth. Akt appears to be inherently activated in approximately 10-50% of most tumor types and is also believed to confer resistance to most types of anti-cancer therapies. Based on its prevalence across cancer types and importance in the control of cell survival and cell proliferation, Akt is considered to be one of the most important cancer targets being researched today.



CLINICAL DEVELOPMENT

In vitro, KRX-0401 inhibits the growth of a variety of human tumor cell lines and has substantial activity in vivo against a number of murine tumor models and human xenografts. In most model systems the drug appears to be synergistic with radiotherapy and additive or synergistic with cytotoxics such as cisplatin, adriamycin, and cyclophosphamide. In these experiments, the combination regimens were superior to chemotherapy alone and were well-tolerated.

Five Phase I studies of KRX-0401 have been completed, including two in the U.S. by the NCI as part of a Cooperative Research and Development Agreement. These trials demonstrated that KRX-0401 can be safely given to humans with an acceptable toxicity profile and no observed myelosuppression, or bone marrow suppression. We believe that the Phase I data provides clinical evidence of the anti-cancer effects of KRX-0401.

The NCI has completed a number of Phase II clinical trials studying KRX-0401 as a single agent, including studies in prostate, breast, head and neck and pancreatic cancers, as well as melanoma and sarcomas. In total, nine clinical trials have been conducted across the six tumor types mentioned. The NCI and its collaborators have presented data from four of their Phase II studies, including from Phase II studies involving prostate, sarcoma, head and neck and breast cancers. Findings from these studies led the investigators to conclude that the drug was safe and well-tolerated at the Phase II dose utilized. In the sarcoma study, the investigators reported a partial response (greater than 50% decrease in tumor mass) as well as several disease stabilizations. With the responses seen in the Phase I trials, there are now three sarcoma patients with durable partial responses. This has led us to consider exploring additional studies in sarcoma.

In May 2005, we announced that Phase II data presented at the annual meeting of the American Society of Clinical Oncology in Orlando, Florida demonstrated the tolerability and potential efficacy of KRX-0401 in the treatment of patients with biochemically recurrent hormone-sensitive prostate cancer, or HSPC, patients. The investigators concluded that KRX-0401 in HSPC patients is feasible, well-tolerated and has been shown to reduce prostate-specific antigen levels in some patients. Because of its inhibitory effects on the Akt and related pathways, we believe that further studies of KRX-0401 in combination with androgen ablation and chemotherapy are warranted.

During the second quarter of 2004, we announced the initiation of a Phase II program utilizing KRX-0401 as a single agent and in combination with a number of standard anti-cancer therapies in multiple tumor types. To date, we have initiated several trials under this program. The first is a multi-center study that will evaluate the safety and efficacy of KRX-0401 as a single agent administered weekly to patients with non-small cell lung cancer who have progressed despite standard therapy. We have also initiated additional multi-center trials evaluating KRX-0401 in combination with gemcitabine, paclitaxel and docetaxel, all common forms of chemotherapy used to treat

multiple tumor types. Recently, we started an "all-comers" Phase II clinical trial evaluating KRX-0401 as a single-agent, administered either weekly or daily in a variety of tumor types.



OUR STRATEGY

We are focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. Under our strategy, we currently plan to:

- -- continue our pivotal program for KRX-101, including our pivotal Phase III and Phase IV trials;
- -- establish the commercial infrastructure required to manufacture, market and sell our drug candidates following approval, if any, by the FDA;
- -- continue our company-sponsored Phase II clinical program for KRX-0401 exploring the use of KRX-0401 as a single-agent and in combination with other anti-cancer therapies in multiple cancer types;
- -- support additional scientific collaborations for KRX-101 and KRX-0401;
- -- conduct additional pre-clinical and clinical trials for our other product candidates; and
- -- seek to in-license or acquire additional compounds.

CORPORATE INFORMATION

We were incorporated in Delaware in October 1998. We commenced operations in November 1999, following our acquisition of substantially all of the assets and certain of the liabilities of Partec Ltd., our predecessor company that began its operations in January 1997. Our executive offices are located at 750 Lexington Avenue, New York, New York 10022. Our telephone number is 212-531-5965 and our e-mail address is info@keryx.com.



## THE OFFERING

| | |
|---|---|
| COMMON STOCK OFFERED BY US | 5,000,000 shares |
| COMMON STOCK TO BE OUTSTANDING AFTER THE OFFERING | 36,504,180 shares |
| USE OF PROCEEDS | We intend to use the net proceeds from the sale of our common stock to fund the ongoing development of KRX-101 and KRX-0401, for research and development activities related to our other drug candidates, to in-license, acquire and develop additional drug candidates, to establish the commercial infrastructure required to manufacture, market and sell our drug candidates and for other general corporate purposes. See "Use of Proceeds" on page S-23. |
| RISK FACTORS | See "Risk factors" and other information included in this prospectus supplement and the accompanying prospectus for a discussion of factors you should |

carefully consider before deciding to invest in our common stock.

NASDAQ NATIONAL MARKET SYMBOL.....KERX

The number of shares of common stock to be outstanding after the offering is based on 31,504,180 shares of common stock outstanding as of March 31, 2005. Unless otherwise indicated, all information in this prospectus supplement assumes that the underwriters do not exercise their overallotment option.

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

-- 8,288,426 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2005, with a weighted average exercise price of $3.56 per share;

-- 479,623 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2005 with a weighted average exercise price of $5.17 per share;

-- 3,372,422 shares of common stock issuable to the former stockholders of ACCESS Oncology upon the achievement of certain milestones related to the ACCESS Oncology drug candidates we acquired upon our merger with ACCESS Oncology in February 2004; and

-- an aggregate of 3,407,822 shares of common stock reserved for future issuance under our stock option plans.



## RISK FACTORS

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

### RISKS RELATED TO OUR BUSINESS

#### WE HAVE A LIMITED OPERATING HISTORY AND HAVE INCURRED SUBSTANTIAL OPERATING LOSSES SINCE OUR INCEPTION. WE EXPECT TO CONTINUE TO INCUR LOSSES IN THE FUTURE AND MAY NEVER BECOME PROFITABLE.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred operating losses since our inception and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of March 31, 2005, we had an accumulated deficit of approximately $92.4 million. As we expand our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates or technologies.

We have not yet commercialized any products or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidates, successfully complete any post-approval regulatory obligations and successfully commercialize our drug candidates and technologies.

IF WE ARE UNABLE TO SUCCESSFULLY COMPLETE OUR CLINICAL TRIAL PROGRAMS, OR IF SUCH CLINICAL TRIALS TAKE LONGER TO COMPLETE THAN WE PROJECT, OUR ABILITY TO EXECUTE OUR CURRENT BUSINESS STRATEGY WILL BE ADVERSELY AFFECTED.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study, the existence of competitive clinical trials, and whether existing or new drugs are approved for the indication we are studying. We are aware that other companies are planning clinical trials that will seek to enroll patients with the same diseases as we are studying. In addition, one of our current trials for KRX-101 is designed to continue until a pre-specified number of events have occurred to the patients enrolled. Trials such as this are subject to delays stemming from patient withdrawal and from lower than expected event rates and may also incur increased costs if enrollment is increased in order to achieve the desired number of events. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective basis.

Additionally, we have finalized with the FDA our SPA, regarding a subpart H clinical development plan for the clinical development of KRX-101 for diabetic nephropathy. This clinical plan consists of: a single Phase III trial in patients with microalbuminuria based on the surrogate marker of regression of microalbuminuria as the primary endpoint; supportive data



from previously conducted clinical studies; and substantial recruitment into our Phase IV confirmatory study that will measure clinical outcomes in patients with overt nephropathy, or macroalbuminuria, before filing a New Drug Application, or NDA, with the agency. The subpart H process is complex and requires careful execution and no assurance can be given that we will be able to meet the requirements set forth in the SPA. Even if we meet those requirements, the FDA is not obligated to grant approval of our NDA for KRX-101. If the FDA approves KRX-101 for marketing on the basis of our SPA, our Phase IV clinical trial may yield insufficient efficacy data or give rise to safety concerns, which could result in withdrawal of such approval or could cause us to withdraw the product from the market. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

IF OUR DRUG CANDIDATES DO NOT RECEIVE THE NECESSARY REGULATORY APPROVALS, WE WILL BE UNABLE TO COMMERCIALIZE OUR DRUG CANDIDATES.

We have not received, and may never receive, regulatory approval for the commercial sale of any of our drug candidates. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. It may take us many years to complete the testing of our drug

candidates and failure can occur at any stage of this process. Negative or inconclusive results or medical events during a clinical trial could cause us to delay or terminate our development efforts.

Furthermore, interim results of preclinical or clinical studies do not necessarily predict their final results, and acceptable results in early studies might not be obtained in later studies. Drug candidates in the later stages of clinical development may fail to show the desired safety and efficacy traits despite having progressed through initial clinical testing. Specifically, we received the recommendation to proceed, as planned, into our pivotal Phase III and Phase IV program for KRX-101 from the CSG based on a safety and efficacy assessment of a first interim analysis of data from our ongoing Phase II study for KRX-101, and we recently announced further interim results from this trial. There can be no assurance that the full data from the Phase II study will track the data from these interim analyses of the Phase II study. Moreover, the recommendation to move into our pivotal program, as well as the announced interim data, may not be indicative of results from future clinical trials and the risk remains that the pivotal program for KRX-101 may generate efficacy data that will be insufficient for the approval of the drug, or may raise safety concerns that may prevent approval of the drug.

Clinical trials also have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. If we experience delays in the testing or approval process or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates may be materially impaired. In addition, we have limited experience in conducting and



managing the clinical trials necessary to obtain regulatory approval in the United States and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process.

BECAUSE ALL OF OUR PROPRIETARY TECHNOLOGIES ARE LICENSED TO US BY THIRD PARTIES, TERMINATION OF THESE LICENSE AGREEMENTS WOULD PREVENT US FROM DEVELOPING OUR DRUG CANDIDATES.

We do not own any of our drug candidates. We have licensed the patent rights to these drugs candidates from others. These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our license agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates.

WE RELY ON THIRD PARTIES TO MANUFACTURE OUR PRODUCTS. IF THESE THIRD PARTIES DO NOT SUCCESSFULLY MANUFACTURE OUR PRODUCTS, OUR BUSINESS WILL BE HARMED.

We have no experience in manufacturing products for clinical or commercial purposes and do not have any manufacturing facilities. We intend to continue, in whole or in part, to use third parties to manufacture our products for use in clinical trials and for future sales. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms to us, if at all.

Contract manufacturers often encounter difficulties in scaling up production,

including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and foreign regulations, production costs and development of advanced manufacturing techniques and process controls. Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidates. In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple manufacturers may be difficult because the number of potential manufacturers is limited and, particularly in the case of KRX-101, the process by which multiple manufacturers make the drug substance must be identical at each manufacturing facility. It may be difficult for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. Moreover, if we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to deliver the required quantities of our drug candidates on a timely basis and at commercially reasonable prices, we will not be able to commercialize our products as planned.

We have entered into a contract manufacturing relationship with a U.S.-based contract manufacturer for KRX-101 which we believe will be adequate to satisfy our current clinical and initial commercial supply needs; however, as we transition the manufacturing of KRX-101 to



our U.S.-based contract manufacturer, we will need to create a reproducible manufacturing process that will ensure consistent manufacture of KRX-101 across multiple batches and sources. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, the creation of a reproducible process will be required for the successful commercialization of KRX-101. There can be no assurance that we will be successful in this endeavor.

IF WE ARE NOT ABLE TO OBTAIN THE RAW MATERIALS REQUIRED FOR THE MANUFACTURE OF OUR LEAD PRODUCT CANDIDATE, KRX-101, OUR ABILITY TO DEVELOP AND MARKET THIS PRODUCT CANDIDATE WILL BE SUBSTANTIALLY HARMED.

Source materials for KRX-101, our lead product candidate, are derived from porcine mucosa. Long-term supplies for KRX-101 could be affected by limitations in the supply of porcine mucosa and the demand for other heparin products, over which we will have no control. Additionally, diseases affecting the world supply of pigs could have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell KRX-101. Such negative impact could materially affect the commercial success of KRX-101.

IF WE DO NOT ESTABLISH OR MAINTAIN DRUG DEVELOPMENT AND MARKETING ARRANGEMENTS WITH THIRD PARTIES, WE MAY BE UNABLE TO COMMERCIALIZE OUR PRODUCTS.

We are an emerging company and do not possess all of the capabilities to fully commercialize our products on our own. From time to time, we may need to contract with third parties to:

-- assist us in developing, testing and obtaining regulatory approval for and

commercializing some of our compounds and technologies; and

-- market and distribute our drug products.

We can provide no assurance that we will be able to successfully enter into agreements with such third parties on terms that are acceptable to us, if at all. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our products independently, which could result in delays. Furthermore, such failure could result in the termination of license rights to one or more of our products. If these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of our products. Accordingly, to the extent that we rely on third parties to research, develop or commercialize our products, we are unable to control whether such products will be scientifically or commercially successful.

IF WE ARE UNABLE TO DEVELOP ADEQUATE SALES, MARKETING OR DISTRIBUTION CAPABILITIES OR ENTER INTO AGREEMENTS WITH THIRD PARTIES TO PERFORM SOME OF THESE FUNCTIONS, WE WILL NOT BE ABLE TO COMMERCIALIZE OUR PRODUCTS EFFECTIVELY.

In the event KRX-101 receives marketing approval, we anticipate conducting our own sales and marketing effort to support the drug, and we may adopt this strategy with respect to future drug products. We currently have no experience in sales, marketing or distribution. To directly market and distribute any products, we must build a sales and marketing organization with



appropriate technical expertise and distribution capabilities. We may attempt to build such a sales and marketing organization on our own or with the assistance of a contract sales organization. For some market opportunities, we may need to enter into co-promotion or other licensing arrangements with larger pharmaceutical or biotechnology firms in order to increase the commercial success of our products. We may not be able to establish sales, marketing and distribution capabilities of our own or enter into such arrangements with third parties in a timely manner or on acceptable terms. To the extent that we enter into co-promotion or other licensing arrangements, our product revenues are likely to be lower than if we directly marketed and sold our products, and some or all of the revenues we receive will depend upon the efforts of third parties, and these efforts may not be successful. Additionally, building marketing and distribution capabilities may be more expensive than we anticipate, requiring us to divert capital from other intended purposes or preventing us from building our marketing and distribution capabilities to the desired levels.

EVEN IF WE OBTAIN FDA APPROVAL TO MARKET OUR DRUG PRODUCTS, IF THEY FAIL TO ACHIEVE MARKET ACCEPTANCE, WE WILL NEVER RECORD MEANINGFUL REVENUES.

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

-- perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidates;

-- the rates of adoption of our products by medical practitioners and the target populations for our products;

-- the potential advantages that our products offer over existing treatment methods;

-- the cost-effectiveness of our products relative to competing products;

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

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

-- the effectiveness of our sales, marketing and distribution efforts.

Because we expect sales of our products, if approved, to generate substantially all of our revenues in the long-term, the failure of our drugs to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

IF OUR COMPETITORS DEVELOP AND MARKET PRODUCTS THAT ARE LESS EXPENSIVE, MORE EFFECTIVE OR SAFER THAN OUR DRUG PRODUCTS, OUR COMMERCIAL OPPORTUNITIES MAY BE REDUCED OR ELIMINATED.

The pharmaceutical industry is highly competitive. Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our drug products obsolete or noncompetitive. To compete successfully in this industry we must



identify novel and unique drugs or methods of treatment and then complete the development of those drugs as treatments in advance of our competitors.

The drugs that we are attempting to develop will have to compete with existing therapies. In addition, our commercial opportunities may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug products. Other companies have drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug products. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

IF WE LOSE OUR KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN ADDITIONAL PERSONNEL, OUR OPERATIONS COULD BE DISRUPTED AND OUR BUSINESS COULD BE HARMED.

We currently have 29 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be materially impaired. In addition, while we have an employment agreement with Mr. Weiss, this agreement

would not prevent him from terminating his employment with us.

ANY ACQUISITIONS WE MAKE MAY REQUIRE A SIGNIFICANT AMOUNT OF OUR AVAILABLE CASH AND MAY NOT BE SCIENTIFICALLY OR COMMERCIALLY SUCCESSFUL.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions involve a number of operational risks, including:

-- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;

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

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

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

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

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



THE STATUS OF REIMBURSEMENT FROM THIRD-PARTY PAYORS FOR NEWLY APPROVED HEALTH CARE DRUGS IS UNCERTAIN AND FAILURE TO OBTAIN ADEQUATE REIMBURSEMENT COULD LIMIT OUR ABILITY TO GENERATE REVENUE.

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

-- government and health administration authorities;

-- private health insurers;

-- managed care programs; and

-- other third-party payors.

Significant uncertainty exists as to the reimbursement status of newly approved health care products. Third-party payors, including Medicare, are challenging the prices charged for medical products and services. Government and other third-party payors increasingly are attempting to contain health care costs by limiting both coverage and the level of reimbursement for new drugs and by refusing, in some cases, to provide coverage for uses of approved products for disease indications for which the FDA has not granted labeling approval. Third-party insurance coverage may not be available to patients for our products. If government and other third-party payors do not provide adequate coverage and reimbursement levels for our products, their market acceptance may be reduced.

HEALTH CARE REFORM MEASURES COULD ADVERSELY AFFECT OUR BUSINESS.

The business and financial condition of pharmaceutical and biotechnology companies are affected by the efforts of governmental and third-party payors to contain or reduce the costs of health care. In the United States and in foreign jurisdictions there have been, and we expect that there will continue to be, a number of legislative and regulatory proposals aimed at changing the health care system, such as those relating to reimportation of drugs into the U.S. from other countries where they are sold at a lower price and government control of prescription drug pricing. The pendency or approval of such proposals could result in a decrease in our stock price or limit our ability to raise capital or to obtain strategic partnerships or licenses.

WE FACE PRODUCT LIABILITY RISKS AND MAY NOT BE ABLE TO OBTAIN ADEQUATE INSURANCE.

The use of our drug candidates in clinical trials, and the future sale of any approved products, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

-- decreased demand for a product;

-- injury to our reputation;



-- our inability to continue to develop a drug candidate;

-- withdrawal of clinical trial volunteers; and

-- loss of revenues.

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

IN CONNECTION WITH PROVIDING OUR CLINICAL TRIAL MANAGEMENT AND SITE RECRUITMENT SERVICES, WE MAY BE EXPOSED TO LIABILITY THAT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

The Online Collaborative Oncology Group, Inc., or OCOG, a subsidiary we acquired through our acquisition of ACCESS Oncology, provides clinical trial management and site recruitment services to us as well as other biotechnology and pharmaceutical companies. In conducting the activities of OCOG, any failure on our part to comply with applicable governmental regulations or contractual obligations could expose us to liability to our clients and could have a material adverse effect on us. We also could be held liable for errors or omissions in connection with the services we perform. In addition, the wrongful or erroneous delivery of health care information or services may expose us to liability. If we were required to pay damages or bear the costs of defending any such claims, the losses could be material.

OUR CORPORATE COMPLIANCE EFFORTS CANNOT GUARANTEE THAT WE ARE IN COMPLIANCE WITH ALL POTENTIALLY APPLICABLE REGULATIONS.

The development, manufacturing, pricing, sales, and reimbursement of our products, together with our general operations, are subject to extensive regulation by federal, state and other authorities within the United States and numerous entities outside of the United States. We are a relatively small company with 29 employees. We also have significantly fewer employees than many other companies that have a product candidate in late-stage clinical development, and we rely heavily on third parties to conduct many important functions. While we have developed and instituted a corporate compliance program based on what we believe are the current best practices, we cannot assure you that we are or will be in compliance with all potentially applicable regulations. If we fail to comply with any of these regulations we could be subject to a range of regulatory actions, including suspension or termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of products from the market, significant fines, or other sanctions or litigation.

RISKS RELATED TO OUR FINANCIAL CONDITION

OUR CURRENT CASH, CASH EQUIVALENTS AND SHORT-TERM SECURITIES MAY NOT BE ADEQUATE TO SUPPORT OUR OPERATIONS FOR THE NEXT 24 MONTHS AS WE HAVE ESTIMATED.

We believe that our $44.8 million in cash, cash equivalents, interest receivable and short-term and long-term securities as of March 31, 2005, and the proceeds from this offering, will be sufficient to enable us to meet our planned operating needs and capital expenditures for at least the next 24 months. Our forecast of the period of time through which our cash, cash equivalents and short-term securities will be adequate to support our operations is a forward-looking statement that involves risks and uncertainties. The actual amount of funds we will



need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- -- the timing of expenses associated with manufacturing and product development of the proprietary drug candidates within our portfolio and those that may be in-licensed, partnered or acquired;
- -- the timing of the in-licensing, partnering and acquisition of new product opportunities;
- -- the progress of the development efforts of parties with whom we have entered, or may enter, into research and development agreements;
- -- our ability to achieve our milestones under our licensing arrangements; and
- -- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

IF WE ARE UNABLE TO OBTAIN ADDITIONAL FUNDS ON TERMS FAVORABLE TO US, OR AT ALL, OUR BUSINESS WOULD BE HARMED.

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash and cash equivalents, interest receivable and short-term and long-term securities and the proceeds of this offering will be sufficient to fund our operating expenses and capital requirements for at least the next 24 months; however, the

actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate, depending upon:

- -- the progress of our development activities;
- -- the progress of our research activities;
- -- the number and scope of our development programs;
- -- the costs associated with commercialization activities, including manufacturing, marketing and sales;
- -- our ability to establish and maintain current and new licensing or acquisition arrangements;
- -- our ability to achieve our milestones under our licensing arrangements;
- -- the costs involved in enforcing patent claims and other intellectual property rights; and
- -- the costs and timing of regulatory approvals.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our intellectual property. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we need to raise additional funds through the sale or license of our intellectual property, we may be unable to do so on terms favorable to us.

OUR PRIOR RESTRUCTURINGS MAY RESULT IN ADDITIONAL ISRAELI-RELATED LIABILITIES.

In July 2003, our Israeli subsidiary vacated its Jerusalem facility, after giving advance notice to the landlord. On May 1, 2005, the landlord of the Jerusalem facility filed suit in Israel claiming that we were liable as a result of the alleged breach of the lease agreement by our subsidiary. The amount demanded by the landlord totals 4,345,313 NIS or approximately $940,000 at the current exchange rate, and includes rent for the entire remaining term of the lease, as well as



property taxes and other costs allegedly incurred by the landlord. In August 2003, the landlord claimed a bank deposit, in the amount of $222,000, which was previously provided as security in connection with the lease agreement. We intend to vigorously defend the suit. To date, we have not yet recorded a charge to reflect any potential liability associated with this suit.

In September 2001, one of our Israeli subsidiaries received the status of an "Approved Enterprise," a status which grants certain tax benefits in Israel in accordance with the "Law for the Encouragement of Capital Investments, 1959." Through December 31, 2003, our Israeli subsidiary, which ceased operations in 2003, has received tax benefits in the form of exemptions of approximately $744,000 as a result of our subsidiary's status as an "Approved Enterprise." As part of the restructuring implemented during 2003, we closed down our Jerusalem laboratory facility. In October 2003, the subsidiary received a letter from the Israeli Ministry of Industry and Trade that its Approved Enterprise status was cancelled as of July 2003 and that past benefits would not need to be repaid.

The Israeli tax authorities have yet to confirm this position; however, we believe that, based on the letter received from the Ministry of Industry and Trade, it is unlikely that past benefits will need to be repaid, and therefore, we have not recorded any charge with respect to this potential liability. There can be no assurances that the Israeli tax authorities will confirm this position. As a result, we may be liable to repay some or all of the tax benefits received to date, which could adversely affect our cash flow and results of operations.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

IF WE ARE UNABLE TO ADEQUATELY PROTECT OUR INTELLECTUAL PROPERTY, THIRD PARTIES MAY BE ABLE TO USE OUR INTELLECTUAL PROPERTY, WHICH COULD ADVERSELY AFFECT OUR ABILITY TO COMPETE IN THE MARKET.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative drug products or technologies or design around our patented drug products and technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

We rely on trade secrets to protect our intellectual property where we believe patent protection is not appropriate or obtainable. Trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to some of our drug products and technologies with our research collaborators and scientific advisors. If we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our trade secrets or other proprietary information will be at risk.



LITIGATION OR THIRD-PARTY CLAIMS OF INTELLECTUAL PROPERTY INFRINGEMENT COULD REQUIRE US TO SPEND SUBSTANTIAL TIME AND MONEY DEFENDING SUCH CLAIMS AND ADVERSELY AFFECT OUR ABILITY TO DEVELOP AND COMMERCIALIZE OUR PRODUCTS.

Third parties may assert that we are using their proprietary intellectual property without authorization. In addition, third parties may have or obtain patents in the future and claim that our drug products or technologies infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected our drug products or technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected our drug products or technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

RISKS RELATED TO THIS OFFERING

CONCENTRATION OF OWNERSHIP OF OUR COMMON STOCK AMONG OUR EXISTING EXECUTIVE OFFICERS, DIRECTORS AND PRINCIPAL STOCKHOLDERS MAY PREVENT NEW INVESTORS FROM INFLUENCING SIGNIFICANT CORPORATE DECISIONS.

As of March 31, 2005, our executive officers, directors and principal stockholders (including their affiliates) beneficially owned, in the aggregate, approximately 24.6% of our outstanding common stock, including, for this purpose, currently exercisable options and warrants held by our executive officers, directors and principal stockholders. After this offering, our executive officers, directors and principal stockholders (including their affiliates) will beneficially own, in the aggregate, approximately 21.5% of our outstanding common stock, including currently exercisable options and warrants. As a result, these persons, acting together, may have the ability to significantly influence the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may depress the market price of our common stock.

FUTURE SALES OR OTHER ISSUANCES OF OUR COMMON STOCK COULD DEPRESS THE MARKET FOR OUR COMMON STOCK.

Sales of a substantial number of shares of our common stock, or the perception by the market that those sales could occur, could cause the market price of our common stock to decline or could make it more difficult for us to raise funds through the sale of equity in the future.

If we make one or more significant acquisitions in which the consideration includes stock or other securities, your equity in us may be significantly diluted. We may be required to issue up to 3,372,422 shares of our common stock to former shareholders of ACCESS Oncology upon achievement of certain milestones. In addition, in the past we have entered and in the future we may enter into arrangements permitting us to issue shares of common stock in lieu of certain cash payments such as milestones.



Additionally, our executive officers, directors, and principal stockholders beneficially owned, in the aggregate, approximately 24.6% of our common stock as of March 31, 2005, and will own approximately 21.5% of our common stock after this offering, including currently exercisable warrants and options held by them. If some or all of them should decide to sell a substantial number of their holdings, it could have a material adverse effect on the market for our common stock.

OUR STOCK PRICE CAN BE VOLATILE, WHICH INCREASES THE RISK OF LITIGATION, AND MAY RESULT IN A SIGNIFICANT DECLINE IN THE VALUE OF YOUR INVESTMENT.

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

-- developments concerning our drug candidates;

-- announcements of technological innovations by us or our competitors;

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

-- announcements by us of significant acquisitions, strategic partnerships,

joint ventures or capital commitments;

-- changes in financial estimates by securities analysts;

-- actual or anticipated variations in quarterly operating results;

-- expiration or termination of licenses, research contracts or other collaboration agreements;

-- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

-- changes in the market valuations of similar companies; and

-- additions or departures of key personnel.

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

WE HAVE BROAD DISCRETION TO USE THE NET PROCEEDS FROM THIS OFFERING AND OUR INVESTMENT OF THESE PROCEEDS MAY NOT YIELD A FAVORABLE RETURN.

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



CERTAIN ANTI-TAKEOVER PROVISIONS IN OUR CHARTER DOCUMENTS AND DELAWARE LAW COULD MAKE A THIRD-PARTY ACQUISITION OF US DIFFICULT. THIS COULD LIMIT THE PRICE INVESTORS MIGHT BE WILLING TO PAY IN THE FUTURE FOR OUR COMMON STOCK.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These factors could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock with rights senior to those of the common stock. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock. Our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. Any of these provisions could also have the effect of delaying or preventing a change in control.

## INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The Securities and Exchange Commission, or the SEC, allows us to "incorporate by reference" into this prospectus supplement and the related 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 is deemed to be part of this prospectus supplement and the related prospectus, and later information that we file with the SEC will automatically update and supersede that information. This prospectus supplement and the related prospectus incorporate by reference the documents set forth below that we have previously filed with the SEC, except to the extent information in those documents differs from information contained in this prospectus supplement and the related prospectus, and also incorporate by reference any future filings made by us with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, including exhibits:

(a) Our Annual Report on Form 10-K for the year ended December 31, 2004;

(b) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2005; and

(c) Our Current Report on Form 8-K filed with the SEC on May 6, 2005.

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



## SPECIAL CAUTIONARY NOTICE REGARDING FORWARD-LOOKING STATEMENTS

When used in this prospectus supplement and the related prospectus and elsewhere by management or us from time to time, the words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the development, manufacturing, and approval of KRX-101, KRX-0401, and our additional product candidates or any other products we may acquire or in-license;
- expectations for incurring additional capital expenditures to expand our research and development capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;

-- expectations or ability to enter into product acquisition and in-licensing transactions;

-- expectations or ability to build our own commercial infrastructure to manufacture, market and sell our drug candidates;

-- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our business strategy;

-- expected losses; and

-- expectations for future capital requirements.

Our actual results could differ materially from those results expressed in, or implied by, these forward looking statements. Potential risks and uncertainties that could affect our actual results include those discussed in the section titled "Risk Factors," beginning on page S-8 of this prospectus supplement, and any risk factors we may include in other documents incorporated by reference into this prospectus supplement and the related prospectus. The list of factors that may affect future performance and the accuracy of forward-looking statements is illustrative, but by no means exhaustive.

All forward-looking statements should be evaluated with the understanding of their inherent uncertainty. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements. We do not intend to update any of the forward-looking statements after the date of this prospectus supplement to conform them to actual results.



## USE OF PROCEEDS

Based on the closing sales price of our common stock on the Nasdaq National Market on July 7, 2005 of $13.50 per share, we estimate the net proceeds to us from the sale of 5,000,000 shares of our common stock will be approximately $63,618,000 (approximately $73,543,000 if the underwriters exercise their over-allotment option in full) after deducting underwriting discounts.

We expect to use the net proceeds from this offering:

-- to fund the ongoing development of KRX-101 and KRX-0401;

-- for research and development activities related to our other drug candidates;

-- to establish the commercial infrastructure required to manufacture, market and sell our drug candidates;

-- to in-license, acquire and develop additional drug candidates; and

-- for general corporate purposes.

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

## PRICE RANGE OF COMMON STOCK

Our common stock is listed on the Nasdaq National Market under the symbol "KERX." Trading of our common stock commenced on July 28, 2000, following the completion of our initial public offering. The following table sets forth the quarterly high and low last sales prices per share of our common stock for the periods indicated.

| | HIGH | LOW |
|---|---|---|
| FISCAL YEAR ENDED DECEMBER 31, 2003 | | |
| First quarter | $ 1.60 | $ 1.28 |
| Second quarter | 2.68 | 1.10 |
| Third quarter | 3.85 | 2.15 |
| Fourth quarter | 5.46 | 3.23 |
| FISCAL YEAR ENDED DECEMBER 31, 2004 | | |
| First quarter | $15.42 | $ 4.59 |
| Second quarter | 19.07 | 10.57 |
| Third quarter | 12.90 | 7.13 |
| Fourth quarter | 13.80 | 9.65 |
| FISCAL YEAR ENDING DECEMBER 31, 2005 | | |
| First quarter | $15.38 | $10.77 |
| Second quarter | 14.49 | 11.74 |
| Third quarter (through July 7, 2005) | 13.50 | 13.23 |

The last reported sales price for our common stock on July 7, 2005 was $13.50 per share.



## CAPITALIZATION

The following table sets forth our capitalization as of March 31, 2005:

- on an actual basis; and
- on an as adjusted basis to reflect the sale of the 5,000,000 shares of common stock offered by us in this offering based on the closing sales price of our common stock on the Nasdaq National Market on July 7, 2005, of $13.50 per share after deducting the estimated underwriting discounts and commissions.

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

| AS OF MARCH 31, 2005 (IN THOUSANDS, EXCEPT SHARE DATA) | (UNAUDITED) ACTUAL | AS ADJUSTED |
|---|---|---|

| | | |
|---|---|---|
| Cash and cash equivalents | $ 23,093 | $ 86,711 |
| Short-term investment securities | 15,156 | 15,156 |
| Long-term investment securities | 6,509 | 6,509 |
| Long-term obligations | - | - |
| Stockholders' equity: | | |
| Common stock, $.001 par value per share, 60,000,000 shares authorized; 31,560,280 shares actual and 36,560,280 shares as adjusted, issued; 31,504,180 shares actual and 36,504,180 shares as adjusted, issued and outstanding | 32 | 37 |
| Additional paid-in capital | 133,896 | 197,509 |
| Treasury stock, at cost, 56,100 shares, actual and as adjusted | (89) | (89) |
| Unearned compensation | (2,877) | (2,877) |
| Deficit accumulated during the development stage | (92,385) | (92,385) |
| Total stockholders' equity | 38,577 | 102,195 |
| Total capitalization | $ 38,577 | $ 102,195 |

The table assumes no exercise of the underwriters' overallotment option and excludes the following shares:

- 8,288,426 shares of common stock issuable upon the exercise of stock options outstanding as of June 30, 2005, with a weighted average exercise price of $3.56 per share;

- 479,623 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2005, with a weighted average exercise price of $5.17 per share;

- 3,372,422 shares of common stock issuable to the former stockholders of ACCESS Oncology upon the achievement of certain milestones related to the ACCESS Oncology drug candidates we acquired upon our merger with ACCESS Oncology in February 2004; and

- an aggregate of 3,407,822 shares of common stock reserved for future issuance under our stock option plans.



## UNDERWRITING

We are offering the shares of our common stock described in this prospectus supplement through the underwriters named below. J.P. Morgan Securities Inc. is acting as the representative of the underwriters. We have entered into an underwriting agreement with the underwriters named below. Subject to the terms and conditions set forth in the underwriting agreement, each of the underwriters has severally agreed to purchase the number of shares of common stock set forth opposite its name in the following table:

| UNDERWRITERS | NUMBER OF SHARES |
|---|---|
| J.P. Morgan Securities Inc. | |

| | |
|---|---|
| Bear, Stearns & Co. Inc. ..... | |
| Jefferies & Company, Inc. ..... | |
| Oppenheimer & Co. Inc. ..... | |
| Brean Murray & Co., Inc. ..... | |
| Punk, Ziegel & Company, L.P. ..... | |
| Total..... | 5,000,000 |

The underwriting agreement provides that the obligations of the underwriters to purchase the shares included in this offering are subject to conditions customary for offerings of this type. The underwriters must buy all of the shares if they buy any of them. However, the underwriters are not required to take or pay for the shares covered by the underwriters' overallotment option described below.

OVERALLOTMENT OPTION

We have granted the underwriters an option to buy up to an aggregate of 780,000 additional shares of our common stock. The underwriters may exercise this option solely for the purpose of covering overallotments, if any, made in connection with this offering. The underwriters have 30 days from the date of this prospectus supplement to exercise this option. If the underwriters exercise this option, they will each purchase additional shares approximately in proportion to the amounts specified in the table above.

COMMISSIONS AND DISCOUNTS

Shares sold by the underwriters to the public will initially be offered at the offering price set forth on the cover of this prospectus supplement. Any shares sold by the underwriters to securities dealers may be sold at a discount of up to $ per share from the public offering price. Any of these securities dealers may resell any shares purchased from the underwriters to other brokers or dealers at a discount of up to $ per share from the public offering price. If all the shares are not sold at the public offering price, the representative may change the offering price and the other selling terms. Upon execution of the underwriting agreement, the underwriters will be obligated to purchase the shares at the prices and upon the terms stated therein, and, as a result, will thereafter bear any risk associated with changing the offering price to the public or other selling terms.



The following table shows the per share and total underwriting discounts and commissions we will pay to the underwriters assuming both no exercise and full exercise of the underwriters' option to purchase up to an additional 780,000 shares.

| | NO EXERCISE | FULL EXERCISE |
|---|---|---|
| Per share..... | $ | $ |
| Total..... | $ | $ |

We estimate that the total expenses of this offering payable by us, not including the underwriting discounts and commissions, will be approximately

$ .

NO SALES OF SIMILAR SECURITIES

We, our executive officers and our directors have entered into lock-up agreements with the underwriters prior to commencement of this offering. The shares covered by these agreements do not include approximately 7.5% as of March 31, 2005, and 6.5% as adjusted for the offering, of our outstanding shares of common stock that are held in a trust to which they were transferred by one of our directors, Dr. Lindsay Rosenwald, who disclaims beneficial ownership of the shares held by the trust and has entered into a lock-up agreement with respect to the other shares of our common stock beneficially owned by him. Under these agreements, we and each of these persons may not, without the prior written approval of J.P. Morgan Securities Inc., subject to certain permitted exceptions, sell, offer to sell, contract or agree to sell, hypothecate, pledge, grant any option to purchase or otherwise dispose of or agree to dispose of, our common stock or securities convertible into or exercisable or exchangeable for our common stock or warrants or rights to purchase our common stock. These restrictions will be in effect for a period of 90 days after the date of the final prospectus supplement. At any time and without public notice, J.P. Morgan Securities Inc. may in its sole discretion, release all or some of the securities from these lock-up agreements.

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

NASDAQ NATIONAL MARKET LISTING

Our common stock is traded on the Nasdaq National Market under the symbol "KERX."

PRICE STABILIZATION, SHORT POSITIONS

The underwriters may engage in overallotment, stabilizing transactions, syndicate covering transactions, and penalty bids or purchases for the purpose of pegging, fixing or maintaining the price of the common stock, in accordance with Regulation M under the Securities Exchange Act of 1934, as amended:

- Overallotment involves sales by the underwriters of shares in excess of the number of shares the underwriters are obligated to purchase, which creates a syndicate short position. The short position may be either a covered short position or a naked short position. In a covered short position, the number of shares overallotted by the underwriters is not greater than the number of shares that they may purchase in the overallotment option. In a naked short position, the number of shares involved is greater than the number of shares in the



overallotment option. The underwriters may close out any short position by either exercising their overallotment option and/or purchasing shares in the open market.

- Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum.

- Syndicate covering transactions involve purchases of the common stock in the open market after the distribution has been completed in order to cover syndicate short positions. In determining the source of shares to close out

the short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market as compared to the price at which they may purchase shares through the overallotment option. If the underwriters sell more shares than could be covered by the overallotment option, a naked short position, the position can only be closed out by buying shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that there could be downward pressure on the price of the shares in the open market after pricing that could adversely affect investors who purchase in the offering.

- Penalty bids permit the underwriters to reclaim a selling concession from a syndicate member when the common stock originally sold by the syndicate member is purchased in a stabilizing or syndicate covering transaction.

As a result of these activities, the price of our common stock may be higher than the price that otherwise might exist in the open market. If these activities are commenced, they may be discontinued by the underwriters at any time. The underwriters may carry out these transactions on the Nasdaq National Market, in the over-the-counter market or otherwise.

Brean Murray & Co., Inc. and Punk, Ziegel & Company, L.P., two of the underwriters in this offering, have previously performed investment banking and advisory services for us for which they received customary fees and expenses. In addition, the underwriters and their affiliates may from time to time in the future engage in transactions with us and perform services for us in the ordinary course of their business.



## LEGAL MATTERS

Alston & Bird LLP has passed upon certain legal matters regarding the shares offered by this prospectus. Certain legal matters will be passed upon for the underwriters by Cahill Gordon & Reindel LLP.

## EXPERTS

The consolidated financial statements of Keryx Biopharmaceuticals, Inc., a development stage company, as of December 31, 2004 and 2003, and for each of the years in the three-year period ended December 31, 2004, and for the period from December 3, 1996 to December 31, 2004, and management's assessment of the effectiveness of internal control over financial reporting as of December 31, 2004 have been incorporated by reference herein and in the registration statement in reliance upon the reports 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 consolidated balance sheet of ACCESS Oncology, Inc. as of December 31, 2003, and the related consolidated statement of operations, statement of stockholders' equity, and statement for cash flows for the year then ended incorporated in this prospectus by reference from Amendment No. 1 on Form 8-K/A of Keryx Biopharmaceuticals, Inc. filed with the SEC on April 20, 2004 amending the Current Report on Form 8-K filed with the SEC on February 20, 2004, have been audited by Deloitte & Touche LLP, independent registered public accounting firm, as stated in their report (which report expresses an unqualified opinion), which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.

PROSPECTUS

5,780,000 SHARES
KERYX BIOPHARMACEUTICALS, INC.

COMMON STOCK

We may offer and sell, from time to time, up to 5,780,000 shares of our common stock. Specific terms of these offerings will be provided in supplements to this prospectus. You should read this prospectus and any supplement carefully before you invest.

We may offer our common stock 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 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.

Our common stock is traded on the Nasdaq Stock Market under the symbol "KERX." On October 12, 2004, the per share closing price of our common stock as reported on the Nasdaq Stock Market was $10.33 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 4 OF THIS PROSPECTUS, IN ANY DOCUMENT INCORPORATED BY REFERENCE, AND IN ANY ACCOMPANYING PROSPECTUS SUPPLEMENT. YOU SHOULD CAREFULLY CONSIDER THIS INFORMATION BEFORE BUYING OUR COMMON STOCK.

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 July 11, 2005

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SUMMARY

KERYX BIOPHARMACEUTICALS, INC.

We are a biopharmaceutical company focused on the acquisition, development and commercialization of novel pharmaceutical products for the treatment of life-threatening diseases, including diabetes and cancer. We have two product candidates in the later stages of clinical development: Sulodexide, or KRX-101, for the treatment of diabetic nephropathy, a life-threatening kidney disease caused by diabetes, and Perifosine, or KRX-0401, for the treatment of multiple forms of cancer.

Our lead compound under development is KRX-101, to which we have an exclusive license in North America, Japan and certain other markets. A randomized, double-blind, placebo-controlled, Phase II study of the use of Sulodexide for treatment of diabetic nephropathy was conducted in 223 patients in Europe, and the results of this study were published in the June 2002 issue of the Journal of the American Society of Nephrology. The results of this Phase II study showed a dose-dependent reduction in proteinuria or pathological urinary albumin excretion rates. In 2001, the Food and Drug Administration, or FDA, granted KRX-101 "Fast-Track" designation for the treatment of diabetic nephropathy and, in 2002, we announced that the FDA had agreed, in principle, to permit us to avail ourselves of the accelerated approval process under subpart H of the FDA's regulations governing applications for the approval to market a new drug.

In the third quarter of 2003, we announced that the Collaborative Study Group, or CSG, the largest standing renal clinical trial group in the United States comprised of academic and tertiary nephrology care centers, will conduct the U.S.-based Phase II/III clinical program for KRX-101 for the treatment of diabetic nephropathy. The CSG has conducted multiple large-scale clinical trials resulting in over 40 publications in peer-reviewed journals. The CSG conducted the pivotal studies for two of the three drugs that are currently approved for treatment of diabetic nephropathy. In the fourth quarter of 2003, we initiated the Phase II portion of our Phase II/III clinical program for our diabetic nephropathy drug candidate, KRX-101.

In the first quarter of 2004, we completed the acquisition of ACCESS Oncology, a privately-held, cancer-focused biotechnology company. The acquired drug portfolio includes three clinical stage compounds, designated as KRX-0401, KRX-0402 and KRX-0403.

KRX-0401 is a novel, first-in-class, oral Akt-inhibitor that has demonstrated preliminary single agent anti-tumor activity in Phase I studies and is currently in a Phase II clinical program evaluating KRX-0401 as a single agent in the treatment of multiple forms of cancer. The National Cancer Institute, or NCI, a department of the National Institutes of Health, or NIH, is completing several Phase II clinical trials, conducted and funded by the NCI under a Cooperative Research and Development Agreement, or CRADA, arrangement with us. During the second quarter of 2004, we announced the initiation of the Keryx-sponsored Phase II program for KRX-0401. In connection with this clinical program, we intend to initiate several single-agent and combination studies testing KRX-0401 as a treatment for various forms of cancer. To date, we have initiated two trials under this program. The first trial is a multi-center study that will evaluate the safety and efficacy of KRX-0401 as a single agent in the treatment of patients with non-small cell lung cancer (NSCLC) who have progressed despite standard therapy. The second trial is a multi-center study that will evaluate KRX-0401 in combination with Gemcitabine (Gemzar(R)), a form of chemotherapy, in the treatment of several tumor types



for which Gemcitabine is currently indicated, including non-small-cell lung cancer, breast cancer and pancreatic cancer.

The acquired cancer portfolio also includes KRX-0402, an inhibitor of DNA repair, which is also being studied by the NCI under a CRADA arrangement in multiple clinical trials. In addition, the portfolio includes KRX-0403, which is a novel spindle poison in the same general class as Navelbine(R), Taxol(R)and Taxotere(R). KRX-0403 has completed a Phase I study. As a part of the acquisition of ACCESS Oncology, we acquired the Online Collaborative Oncology Group, Inc., or OCOG, a subsidiary of ACCESS Oncology which provides clinical trial management and site recruitment services to biotechnology and pharmaceutical companies.

To date, we have not received approval for the sale of any of our drug candidates in any market.

We were incorporated in Delaware in October 1998. We commenced operations in November 1999, following our acquisition of substantially all of the assets and certain of the liabilities of Partec Ltd., our predecessor company that began its operations in January 1997. Since commencing operations, our activities have been primarily devoted to developing our technologies and drug candidates, acquiring clinical-stage compounds, raising capital, purchasing assets for our facilities and recruiting personnel. We are a development stage company and have no product sales to date. Our major sources of working capital have been proceeds from various private placements of equity securities, option and warrant exercises and from our initial public offering.

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

| | |
|---|---|
| COMMON STOCK OFFERED HEREBY | 5,780,000 shares |
| USE OF PROCEEDS | We intend to use the net proceeds of any offering to advance our pharmaceutical products and to in-license, acquire and develop novel drug candidates. |
| 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 450 Fifth Street, N.W., 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 Stock Market under the symbol "KERX."



## RISK FACTORS

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

RISKS RELATED TO OUR BUSINESS

WE HAVE A LIMITED OPERATING HISTORY AND HAVE INCURRED SUBSTANTIAL OPERATING LOSSES SINCE OUR INCEPTION. WE EXPECT TO CONTINUE TO INCUR LOSSES IN THE FUTURE AND MAY NEVER BECOME PROFITABLE.

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred operating losses since our inception, and expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of June 30, 2004, we had an accumulated deficit of approximately $79.7 million. As we expand our research and development efforts, we will incur increasing losses. We may continue to incur substantial operating losses even if we begin to generate revenues from our drug candidates or technologies.

We have not yet commercialized any products or technologies and cannot be sure we will ever be able to do so. Even if we commercialize one or more of our drug candidates or technologies, we may not become profitable. Our ability to achieve profitability depends on a number of factors, including our ability to complete our development efforts, obtain regulatory approval for our drug candidates and successfully commercialize our drug candidates and technologies.

IF WE ARE UNABLE TO SUCCESSFULLY COMPLETE OUR CLINICAL TRIAL PROGRAMS FOR KRX-101 OR OUR RECENTLY ACQUIRED CANCER COMPOUNDS, OR IF SUCH CLINICAL TRIALS TAKE LONGER TO COMPLETE THAN WE PROJECT, OUR ABILITY TO EXECUTE OUR CURRENT BUSINESS STRATEGY WILL BE ADVERSELY AFFECTED.

Whether or not and how quickly we complete clinical trials is dependent in part upon the rate at which we are able to engage clinical trial sites and, thereafter, the rate of enrollment of patients. Patient enrollment is a function of many factors, including the size of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the study and the existence of competitive clinical trials. If we experience delays in identifying and contracting with sites and/or in patient enrollment in our clinical trial programs, we may incur additional costs and delays in our development programs, and may not be able to complete our clinical trials on a cost-effective basis.

Additionally, we have submitted a subpart H clinical development plan to the FDA for the clinical development of KRX-101 for diabetic nephropathy. A final agreement on the specifics of our clinical program for that development plan has not been agreed to with the FDA, and we cannot give any assurance that an acceptable final agreement on the specifics of such clinical program will ever be reached with the FDA. In fact, based on the FDA's comments to our last submission, we believe that additional discussions with the FDA will be required prior to final agreement on the specifics of our subpart H accelerated approval clinical program. We cannot assure you as to when those discussions will take place or that the results of such discussions will be satisfactory to us. Additionally, the FDA has stated that, based on the



novelty of the approach that we have discussed with them, they may want to refer our proposed approach to the Cardio-Renal Advisory Committee.

Moreover, even if we are able to reach final agreement with the FDA regarding the specifics of an accelerated approval approach, no assurance can be given that we will be able to meet the requirements set forth in such agreement. The subpart H process is complex and requires flawless execution. Many companies who have been granted the right to utilize an accelerated approval approach have failed to obtain approval. The clinical timeline, scope and consequent cost for the development of KRX-101 will depend, in part, on the final outcome of our discussions with the FDA. Moreover, negative or inconclusive results from the clinical trials we hope to conduct or adverse medical events could cause us to have to repeat or terminate the clinical trials. Accordingly, we may not be able to complete the clinical trials within an acceptable time frame, if at all.

IF OUR DRUG CANDIDATES DO NOT RECEIVE THE NECESSARY REGULATORY APPROVALS, WE WILL BE UNABLE TO COMMERCIALIZE OUR DRUG CANDIDATES.

We have not received, and may never receive, regulatory approval for commercial sale for any of our drug candidates. We will need to conduct significant additional research and human testing before we can apply for product approval with the FDA or with regulatory authorities of other countries. Pre-clinical testing and clinical development are long, expensive and uncertain processes. Satisfaction of regulatory requirements typically depends on the nature, complexity and novelty of the product and requires the expenditure of substantial resources. Data obtained from pre-clinical and clinical tests can be interpreted in different ways, which could delay, limit or prevent regulatory approval. It may take us many years to complete the testing of our drug candidates and failure can occur at any stage of this process. Negative or inconclusive results or medical events during a clinical trial could cause us to delay or terminate our development efforts.

Clinical trials also have a high risk of failure. A number of companies in the pharmaceutical industry, including biotechnology companies, have suffered significant setbacks in advanced clinical trials, even after achieving promising results in earlier trials. If we experience delays in the testing or approval process or if we need to perform more or larger clinical trials than originally planned, our financial results and the commercial prospects for our drug candidates may be materially impaired. In addition, we have limited experience in conducting and managing the clinical trials necessary to obtain regulatory approval in the United States and abroad and, accordingly, may encounter unforeseen problems and delays in the approval process.

BECAUSE WE LICENSE OUR PROPRIETARY TECHNOLOGIES, TERMINATION OF THESE AGREEMENTS WOULD PREVENT US FROM DEVELOPING OUR DRUG CANDIDATES.

We do not own any of our drug candidates. We have licensed the patent rights to these drugs candidates from others. These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence requirements on us. In addition, under these agreements, we must pay royalties on sales of products resulting from licensed technologies and pay the patent filing, prosecution and maintenance costs related to the licenses. If we do not meet our obligations in a timely manner or if we otherwise breach the terms of our agreements, our licensors could terminate the agreements, and we would lose the rights to our drug candidates.



BECAUSE OUR BUSINESS MODEL IS BASED, IN PART, ON THE ACQUISITION OR IN-LICENSING OF ADDITIONAL CLINICAL PRODUCT CANDIDATES, IF WE FAIL TO ACQUIRE OR IN-LICENSE SUCH CLINICAL PRODUCT CANDIDATES, OUR FUTURE GROWTH PROSPECTS MAY BE SUBSTANTIALLY IMPAIRED.

As a major part of our business strategy, we plan to continue to acquire or

in-license additional clinical stage product candidates. If we fail to acquire or in-license such product candidates, we may not achieve expectations of our future performance. Because we do not intend to engage in significant discovery research, we must rely on third parties to sell or license new product opportunities to us. Other companies, including some with substantially greater financial, development, marketing and sales resources, are competing with us to acquire or in-license such products or product candidates. We may not be able to acquire or in-license rights to additional products or product candidates on acceptable terms, if at all.

IF WE DO NOT ESTABLISH OR MAINTAIN DRUG DEVELOPMENT AND MARKETING ARRANGEMENTS WITH THIRD PARTIES, WE MAY BE UNABLE TO COMMERCIALIZE OUR TECHNOLOGIES INTO PRODUCTS.

We are an emerging company and do not possess all of the capabilities to fully commercialize our product candidates on our own. From time to time, we may need to contract with third parties to:

-- assist us in developing, testing and obtaining regulatory approval for and commercializing some of our compounds and technologies; and

-- market and distribute our drug candidates.

We can provide no assurance that we will be able to successfully enter into agreements with such partners on terms that are acceptable to us. If we are unable to successfully contract with third parties for these services when needed, or if existing arrangements for these services are terminated, whether or not through our actions, or if such third parties do not fully perform under these arrangements, we may have to delay, scale back or end one or more of our drug development programs or seek to develop or commercialize our technologies independently, which could result in delays. Further, such failure could result in the termination of license rights to one or more of our technologies. Moreover, if these development or marketing agreements take the form of a partnership or strategic alliance, such arrangements may provide our collaborators with significant discretion in determining the efforts and resources that they will apply to the development and commercialization of products based on our technologies.

Accordingly, to the extent that we rely on third parties to research, develop or commercialize products based on our technologies, we are unable to control whether such products will be scientifically or commercially successful.

EVEN IF WE OBTAIN FDA APPROVAL TO MARKET OUR PRODUCT CANDIDATES, IF OUR PRODUCTS FAIL TO ACHIEVE MARKET ACCEPTANCE, WE WILL NEVER RECORD MEANINGFUL REVENUES.

Even if our products are approved for sale, they may not be commercially successful in the marketplace. Market acceptance of our product candidates will depend on a number of factors, including:

-- perceptions by members of the health care community, including physicians, of the safety and efficacy of our product candidates;

-- the rates of adoption of our products by medical practitioners and the target populations for our products;



-- the potential advantages that our product candidates offer over existing treatment methods;

-- the cost-effectiveness of our product candidates relative to competing

products;

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

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

-- the effectiveness of our sales, marketing and distribution efforts.

Because we expect sales of our product candidates, if approved, to generate substantially all of our revenues in the long-term, the failure of our drugs to find market acceptance would harm our business and could require us to seek additional financing or other sources of revenue.

WE RELY ON THIRD PARTIES TO MANUFACTURE OUR PRODUCTS. IF THESE THIRD PARTIES DO NOT SUCCESSFULLY MANUFACTURE OUR PRODUCTS, OUR BUSINESS WILL BE HARMED.

We have no experience in manufacturing products for clinical or commercial purposes and do not have any manufacturing facilities. We intend to continue to use third parties to manufacture our products for use in clinical trials and for future sales. We may not be able to enter into future third-party contract manufacturing agreements on acceptable terms, if at all.

Contract manufacturers often encounter difficulties in scaling up production, including problems involving production yields, quality control and assurance, shortage of qualified personnel, compliance with FDA and foreign regulations, production costs and development of advanced manufacturing techniques and process controls. Our third-party manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required by us to successfully produce and market our drug candidates. In addition, our contract manufacturers will be subject to ongoing periodic, unannounced inspections by the FDA and corresponding foreign governmental agencies to ensure strict compliance with, among other things, current good manufacturing practices, in addition to other governmental regulations and corresponding foreign standards. We will not have control over, other than by contract, third-party manufacturers' compliance with these regulations and standards. Switching or engaging multiple manufacturers may be difficult because the number of potential manufacturers is limited and, particularly in the case of KRX-101, the process by which multiple manufacturers make the drug substance must be identical at each manufacturing facility. It may be difficult for us to find and engage replacement or multiple manufacturers quickly and on terms acceptable to us, if at all. Moreover, if we need to change manufacturers, the FDA and corresponding foreign regulatory agencies must approve these manufacturers in advance, which will involve testing and additional inspections to ensure compliance with FDA and foreign regulations and standards.

If third-party manufacturers fail to deliver the required quantities of our drug candidates on a timely basis and at commercially reasonable prices, and if we fail to find replacement or multiple manufacturers on acceptable terms, our ability to develop and deliver products on a timely and competitive basis may be adversely impacted and our business, financial condition or results of operations will be materially harmed.

In the event that we are unable to obtain or retain third-party manufacturers, we will not be able to commercialize our products as planned. The manufacture of our products for clinical trials and commercial purposes is subject to FDA and foreign regulations. No assurance can be given that our third-party manufacturers will comply with these regulations or other regulatory requirements now or in the future.

We have entered into a contract manufacturing relationship with a U.S.-based contract manufacturer for KRX-101 which we believe will be adequate to satisfy our current clinical and commercial supply needs; however, as we seek to transition the manufacturing of KRX-101 to our U.S.-based contract manufacturer, we will need to create a reproducible manufacturing process that will ensure consistent manufacture of KRX-101 across multiple batches and sources. As with all heparin-like compounds, the end product is highly sensitive to the manufacturing process utilized. Accordingly, the creation of a reproducible process will be required for the successful commercialization of KRX-101. There can be no assurance that we will be successful in this endeavor.

IF WE ARE NOT ABLE TO OBTAIN THE RAW MATERIALS REQUIRED FOR THE MANUFACTURE OF OUR LEAD PRODUCT CANDIDATE, KRX-101, OUR ABILITY TO DEVELOP AND MARKET THIS PRODUCT CANDIDATE WILL BE SUBSTANTIALLY HARMED.

Source materials for KRX-101, our lead product candidate, are derived from porcine intestines. Long-term supplies for KRX-101 could be affected by limitations in the supply of porcine intestines and the demand for other heparin products, over which we will have no control. Additionally, diseases affecting the world supply of pigs could have an actual or perceived negative impact on our ability, or the ability of our contract manufacturers, to source, make and/or sell KRX-101. Such negative impact could materially affect the commercial success of KRX-101.

IF OUR COMPETITORS DEVELOP AND MARKET PRODUCTS THAT ARE LESS EXPENSIVE, MORE EFFECTIVE OR SAFER THAN OUR PRODUCT CANDIDATES, OUR COMMERCIAL OPPORTUNITY MAY BE REDUCED OR ELIMINATED.

The pharmaceutical industry is highly competitive. Our commercial opportunity may be reduced or eliminated if our competitors develop and market products that are less expensive, more effective or safer than our drug candidates. Other companies have products or drug candidates in various stages of pre-clinical or clinical development to treat diseases for which we are also seeking to discover and develop drug candidates. Some of these potential competing drugs are further advanced in development than our drug candidates and may be commercialized earlier. Even if we are successful in developing effective drugs, our products may not compete successfully with products produced by our competitors.

Our competitors include pharmaceutical companies and biotechnology companies, as well as universities and public and private research institutions. In addition, companies that are active in different but related fields represent substantial competition for us. Many of our competitors have significantly greater capital resources, larger research and development staffs and facilities and greater experience in drug development, regulation, manufacturing and marketing than we do. These organizations also compete with us to recruit qualified personnel, attract partners for joint ventures or other collaborations, and license technologies that are competitive with ours. As a result, our competitors may be able to more easily develop technologies and products that could render our technologies or our drug candidates obsolete or noncompetitive.

IF WE LOSE OUR KEY PERSONNEL OR ARE UNABLE TO ATTRACT AND RETAIN ADDITIONAL PERSONNEL, OUR OPERATIONS COULD BE DISRUPTED AND OUR BUSINESS COULD BE HARMED.

We currently have 22 full and part-time employees. To successfully develop our drug candidates, we must be able to attract and retain highly skilled personnel. In addition, if we lose the services of our current personnel, in particular, Michael S. Weiss, our Chairman and Chief Executive Officer, our ability to continue to execute on our business plan could be

materially impaired. In addition, while we have an employment agreement with Mr. Weiss, this agreement would not prevent him from terminating his employment with us.

ANY ACQUISITIONS WE MAKE MAY DILUTE YOUR EQUITY OR REQUIRE A SIGNIFICANT AMOUNT OF OUR AVAILABLE CASH AND MAY NOT BE SCIENTIFICALLY OR COMMERCIALLY SUCCESSFUL.

As part of our business strategy, we may effect acquisitions to obtain additional businesses, products, technologies, capabilities and personnel. If we make one or more significant acquisitions in which the consideration includes stock or other securities, your equity in us may be significantly diluted. If we make one or more significant acquisitions in which the consideration includes cash, we may be required to use a substantial portion of our available cash.

Acquisitions involve a number of operational risks, including:

-- difficulty and expense of assimilating the operations, technology and personnel of the acquired business;

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

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

-- exposure to legal claims for activities of the acquired business prior to acquisition; diversion of management attention; and

-- potential impairment of substantial goodwill and write-off of in-process research and

-- development costs, adversely affecting our reported results of operations.

WE FACE PRODUCT LIABILITY RISKS AND MAY NOT BE ABLE TO OBTAIN ADEQUATE INSURANCE.

The use of our drug candidates in clinical trials, and the sale of any approved products, exposes us to liability claims. Although we are not aware of any historical or anticipated product liability claims against us, if we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to cease clinical trials of our drug candidates or limit commercialization of any approved products.

We believe that we have obtained sufficient product liability insurance coverage for our clinical trials. We intend to expand our insurance coverage to include the commercial sale of any approved products if marketing approval is obtained; however, insurance coverage is becoming increasingly expensive. We may not be able to maintain insurance coverage at a reasonable cost. We may not be able to obtain additional insurance coverage that will be adequate to cover product liability risks that may arise. Regardless of merit or eventual outcome, product liability claims may result in:

-- decreased demand for a product;

-- injury to our reputation;

-- inability to continue to develop a drug candidate;

-- withdrawal of clinical trial volunteers; and

-- loss of revenues.

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



IN CONNECTION WITH PROVIDING OUR SERVICES, WE MAY BE EXPOSED TO LIABILITY THAT COULD HAVE A MATERIAL ADVERSE EFFECT ON OUR FINANCIAL CONDITION AND RESULTS OF OPERATIONS.

In conducting the activities of OCOG, any failure on our part to comply with applicable governmental regulations or contractual obligations could expose us to liability to our clients and could have a material adverse effect on us. We also could be held liable for errors or omissions in connection with the services we perform. In addition, the wrongful or erroneous delivery of health care information or services may expose us to liability. We could be materially and adversely affected if we were required to pay damages or bear the costs of defending any such claims.

RISKS RELATED TO OUR FINANCIAL CONDITION

IF WE ARE UNABLE TO OBTAIN ADDITIONAL FUNDS ON TERMS FAVORABLE TO US, OR AT ALL, OUR BUSINESS WOULD BE HARMED.

We expect to use, rather than generate, funds from operations for the foreseeable future. Based on our current plans, we believe our existing cash and cash equivalents will be sufficient to fund our operating expenses and capital requirements for approximately the next 36 months; however, the actual amount of funds that we will need prior to or after that date will be determined by many factors, some of which are beyond our control. As a result, we may need funds sooner or in different amounts than we currently anticipate. These factors include:

-- the progress of our development activities;

-- the progress of our research activities;

-- the number and scope of our development programs;

-- our ability to establish and maintain current and new licensing or acquisition arrangements;

-- our ability to achieve our milestones under our licensing arrangements;

-- the costs involved in enforcing patent claims and other intellectual property rights; and

-- the costs and timing of regulatory approvals.

If our capital resources are insufficient to meet future capital requirements, we will have to raise additional funds. If we are unable to obtain additional funds on terms favorable to us or at all, we may be required to cease or reduce our operating activities or sell or license to third parties some or all of our technology. If we raise additional funds by selling additional shares of our capital stock, the ownership interests of our stockholders will be diluted. If we raise additional funds through the sale or license of our technology, we may be unable to do so on terms favorable to us.

OUR PRIOR RESTRUCTURINGS MAY RESULT IN ADDITIONAL ISRAELI-RELATED LIABILITIES.

In September 2001, one of our Israeli subsidiaries received the status of an "Approved Enterprise," a status which grants certain tax benefits in Israel in accordance with the "Law for the Encouragement of Capital Investments, 1959." Through December 31, 2003, our Israeli subsidiary, which ceased operations in 2003, has received tax benefits in the form of exemptions of approximately $744,000 as a result of our subsidiary's status as an "Approved Enterprise." As part of the restructuring implemented during 2003, we closed down our Jerusalem laboratory facility. In October 2003, the subsidiary received a letter from the Israeli Ministry of Industry and Trade that its Approved Enterprise status was cancelled as of July 2003 and that past benefits would not need to be repaid. The Israeli tax authorities have yet to



confirm this position; however, we believe that, based on the letter received from the Ministry of Industry and Trade, it is unlikely that past benefits will need to be repaid, and therefore, we have not recorded any charge with respect to this potential liability. There can be no assurances that the Israeli tax authorities will confirm this position. As a result, we may be liable to repay some or all of the tax benefits received to date, which could adversely affect our cash flow and results of operations.

In July 2003, our Israeli subsidiaries vacated their Jerusalem facility and relocated to smaller facilities. The landlord of the Jerusalem facility has alleged that we were immediately liable to pay the landlord a sum in excess of $1.1 million as a result of the alleged breach of the lease agreement for the Jerusalem facility. The amount demanded by the landlord includes rent for the entire remaining term of the lease (through 2005), as well as property taxes and other costs. In August 2003, the landlord claimed a bank guarantee, in the amount of $222,000, which was previously provided as security in connection with the lease agreement, making the net amount potentially due to the landlord $776,000. To date, no litigation has been initiated, and, to our knowledge, the landlord has succeeded in leasing most, if not all, of the space to one or more new tenants.

RISKS RELATED TO OUR INTELLECTUAL PROPERTY

IF WE ARE UNABLE TO ADEQUATELY PROTECT OUR INTELLECTUAL PROPERTY, THIRD PARTIES MAY BE ABLE TO USE OUR TECHNOLOGY, WHICH COULD ADVERSELY AFFECT OUR ABILITY TO COMPETE IN THE MARKET.

Our commercial success will depend in part on our ability and the ability of our licensors to obtain and maintain patent protection on our drug products and technologies and successfully defend these patents and technologies against third-party challenges. The patent positions of pharmaceutical and biotechnology companies can be highly uncertain and involve complex legal and factual questions. No consistent policy regarding the breadth of claims allowed in biotechnology patents has emerged to date. Accordingly, the patents we use may not be sufficiently broad to prevent others from practicing our technologies or from developing competing products. Furthermore, others may independently develop similar or alternative technologies or design around our patented technologies. The patents we use may be challenged or invalidated or may fail to provide us with any competitive advantage.

Moreover, we rely on trade secrets to protect technology where we believe patent protection is not appropriate or obtainable. However, trade secrets are difficult to protect. While we require our employees, collaborators and consultants to enter into confidentiality agreements, this may not be sufficient to adequately protect our trade secrets or other proprietary information. In addition, we share ownership and publication rights to data relating to some of our drug candidates with our research collaborators and scientific advisors. If

we cannot maintain the confidentiality of this information, our ability to receive patent protection or protect our proprietary information will be at risk.

LITIGATION OR THIRD-PARTY CLAIMS OF INTELLECTUAL PROPERTY INFRINGEMENT COULD REQUIRE US TO SPEND SUBSTANTIAL TIME AND MONEY DEFENDING SUCH CLAIMS AND ADVERSELY AFFECT OUR ABILITY TO DEVELOP AND COMMERCIALIZE OUR PRODUCTS.

Third parties may assert that we are using their proprietary technology without authorization. In addition, third parties may have or obtain patents in the future and claim that our technologies infringe their patents. If we are required to defend against patent suits brought by third parties, or if we sue third parties to protect our patent rights, we may be required to pay substantial litigation costs, and our management's attention may be diverted from



operating our business. In addition, any legal action against our licensors or us that seeks damages or an injunction of our commercial activities relating to the affected technologies could subject us to monetary liability and require our licensors or us to obtain a license to continue to use the affected technologies. We cannot predict whether our licensors or we would prevail in any of these types of actions or that any required license would be made available on commercially acceptable terms, if at all.

RISKS RELATED TO OUR COMMON STOCK

CONCENTRATION OF OWNERSHIP OF OUR COMMON STOCK AMONG OUR EXISTING EXECUTIVE OFFICERS, DIRECTORS AND PRINCIPAL STOCKHOLDERS MAY PREVENT NEW INVESTORS FROM INFLUENCING SIGNIFICANT CORPORATE DECISIONS.

As of June 30, 2004, our executive officers, directors and principal stockholders (including their affiliates) beneficially owned, in the aggregate, approximately 28.24% of our outstanding common stock, including, for this purpose, currently exercisable options and warrants held by our executive officers, directors and principal stockholders. As a result, these persons, acting together, may have the ability to effectively determine the outcome of all matters submitted to our stockholders for approval, including the election and removal of directors and any merger, consolidation or sale of all or substantially all of our assets. In addition, such persons, acting together, may have the ability to effectively control our management and affairs. Accordingly, this concentration of ownership may harm the market price of our common stock by discouraging a potential acquirer from at tempting to acquire us.

OUR STOCK PRICE COULD BE VOLATILE WHICH INCREASES THE RISK OF LITIGATION, AND MAY RESULT IN A SIGNIFICANT DECLINE IN THE VALUE OF YOUR INVESTMENT.

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

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

-- actual or anticipated variations in quarterly operating results;

-- expiration or termination of licenses, research contracts or other collaboration agreements;

-- conditions or trends in the regulatory climate and the biotechnology and pharmaceutical industries;

-- changes in the market valuations of similar companies; and

-- additions or departures of key personnel.

In addition, equity markets in general, and the market for biotechnology and life sciences companies in particular, have experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of companies traded



in those markets. These broad market and industry factors may materially affect the market price of our common stock, regardless of our development and operating performance. In the past, following periods of volatility in the market price of a company's securities, securities class-action litigation has often been instituted against that company. Such litigation, if instituted against us, could cause us to incur substantial costs to defend such claims and divert management's attention and resources, which could seriously harm our business.

ANTI-TAKEOVER PROVISIONS IN OUR CHARTER DOCUMENTS AND DELAWARE LAW COULD MAKE A THIRD-PARTY ACQUISITION OF US DIFFICULT. THIS COULD LIMIT THE PRICE INVESTORS MIGHT BE WILLING TO PAY IN THE FUTURE FOR OUR COMMON STOCK.

Provisions in our amended and restated certificate of incorporation and bylaws could have the effect of making it more difficult for a third party to acquire, or of discouraging a third party from attempting to acquire, or control us. These provisions could limit the price that certain investors might be willing to pay in the future for shares of our common stock. Our amended and restated certificate of incorporation allows us to issue preferred stock with rights senior to those of the common stock and our amended and restated bylaws eliminate the right of stockholders to call a special meeting of stockholders, which could make it more difficult for stockholders to effect certain corporate actions. These provisions could also have the effect of delaying or preventing a change in control. The issuance of preferred stock could decrease the amount of earnings and assets available for distribution to the holders of our common stock or could adversely affect the rights and powers, including voting rights, of such holders. In certain circumstances, such issuance could have the effect of decreasing the market price of our common stock.



## 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 common stock, 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 up to a total of 5,780,000 shares of our common stock. Each time we sell our common stock, we will provide a 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 of our common stock, 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 the 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 our common stock 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. Our business, financial condition, results of operations and prospects may have changed since that date.

We will not use this prospectus to offer and sell our common stock unless it is accompanied by a 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 after the date of this prospectus 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 Securities and Exchange Commission under Sections 13(a), 13(c), 14 or 15(d) of the Securities Exchange Act of 1934, as amended, including exhibits:

(a) Our Annual Report on Form 10-K for the year ended December 31, 2003;

(b) Our Quarterly Report on Form 10-Q for the quarter ended March 31, 2004;

(c) Our Quarterly Report on Form 10-Q for the quarter ended June 30, 2004;

(d) Our Current Report on Form 8-K filed with the SEC on January 15, 2004;

(e) Our Current Report on Form 8-K filed with the SEC on February 20, 2004, and as amended on Form 8-K/A filed with the SEC on April 20, 2004;

(f) Our Current Report on Form 8-K filed with the SEC on September 23, 2004; and

(g) The description of our common stock found on page 13 of this prospectus.



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: Vice President Finance and Investor Relations, or by calling (212) 531-5965.

## FORWARD LOOKING STATEMENTS

When used in this prospectus and elsewhere by management or us from time to time, the words "anticipate," "believe," "estimate," "may," "expect" and similar expressions are generally intended to identify forward-looking statements. These forward-looking statements include, but are not limited to, statements about our:

- expectations for increases or decreases in expenses;
- expectations for the development, manufacturing, and approval of KRX-101, KRX-0401, KRX-0402, KRX-0403 or any other products we may acquire or in-license;
- expectations for incurring additional capital expenditures to expand our research and development capabilities;
- expectations for generating revenue or becoming profitable on a sustained basis;
- expectations or ability to enter into marketing and other partnership agreements;
- expectations or ability to enter into product acquisition and in-licensing transactions;
- estimates of the sufficiency of our existing cash and cash equivalents and investments to finance our operating and capital requirements;
- expected losses; and
- expectations for future capital requirements.

Our actual results could differ materially from those results expressed in, or implied by, these forward-looking statements. Potential risks and uncertainties that could affect our actual results include those discussed in the section titled "Risk Factors," beginning on page 3 of this prospectus, the risk factors we may include in a supplement to this prospectus, and any risk factors we may include in other documents incorporated by reference into this prospectus. The list of factors that may affect future performance and the accuracy of forward-looking statements is illustrative, but by no means exhaustive.

All forward-looking statements should be evaluated with the understanding of their inherent uncertainty. Although we believe that the expectations reflected in the forward-looking statements are reasonable, we cannot guarantee future results, events, levels of activity, performance or achievements. We do not assume responsibility for the accuracy and completeness of the forward-looking statements. We do not intend to update any of the forward-looking statements after the date of this prospectus to conform them to actual results.



## USE OF PROCEEDS

Unless otherwise indicated in a prospectus supplement, the net proceeds from the sale of the common stock will be used to advance our pharmaceutical products and to in-license, acquire and develop novel drug candidates. The timing and amounts of our actual expenditures will depend on several factors, including the progress of our clinical trials, the progress of our research and development

programs, the results of other pre-clinical and clinical studies and the timing and costs of regulatory approvals.

## 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 certificate of incorporation and our bylaws. You should refer to, and read this summary together with, our certificate of incorporation and 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 60,000,000 shares of common stock, par value $0.001 per share. As of September 28, 2004, we had issued and outstanding 30,834,180 shares of our common stock. There are approximately 73 holders of record. All outstanding shares of our common stock are fully paid and nonassessable. Our common stock is listed on the Nasdaq National 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.

## PLAN OF DISTRIBUTION

We may sell the common stock 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 our common stock, 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 such common stock, including:

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

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

If underwriters are used in the sale of any common stock, the common stock 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 common stock 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 common stock will be subject to certain conditions precedent. The underwriters will be obligated to purchase all of the common stock if they purchase any of the common stock.

We may sell the common stock through agents from time to time. The prospectus supplement will name any agent involved in the offer or sale of the common stock 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 common stock 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, 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 common stock 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 common stock covered by this

prospectus and the applicable prospectus supplement, including in short sale transactions. If so, the third party may use common stock pledged by us or



borrowed from us or others to settle those sales or to close out any related open borrowings of stock, and may use common stock received from us in settlement of those derivatives to close out any related open borrowings of stock. The third party in such sale transactions will be an underwriter and, if not identified in this prospectus, will be identified in the applicable prospectus supplement (or a post-effective amendment).

The maximum compensation we will pay to underwriters in connection with any offering of the securities will not exceed 8% of the maximum proceeds of such offering. All post-effective amendments or prospectus supplements disclosing the actual price and selling terms of each offering of the securities will be submitted to the NASD Corporate Financing Department at the same time they are filed with the SEC. The NASD Corporate Financing Department will be advised if, subsequent to the filing of any offering of the securities, any of our 5% or greater stockholders is or becomes an affiliate or associated person of an NASD member participating in the distribution of such securities. All NASD members participating in offerings of the securities understand the requirements that have to be met in connection with SEC Rule 415 and Notice to Members 88-101.

## LEGAL MATTERS

The legality and validity of the shares of common stock 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., a development stage company, as of December 31, 2003 and 2002, and for each of the years in the three-year period ended December 31, 2003, and for the period from December 3, 1996 to December 31, 2003, have been incorporated by reference herein and in the registration statement in reliance upon the report of KPMG LLP, independent accountants, incorporated by reference herein, and upon the authority of said firm as experts in accounting and auditing.

The consolidated balance sheet of ACCESS Oncology, Inc. as of December 31, 2003, and the related consolidated statement of operations, statement of stockholders' equity, and statement for cash flows for the year then ended incorporated in this prospectus by reference from Amendment No. 1 on Form 8-K/A of Keryx Biopharmaceuticals, Inc. filed with the SEC on April 20, 2004 amending the Current Report on Form 8-K filed with the SEC on February 20, 2004, have been audited by Deloitte & Touche LLP, independent auditors, as stated in their report (which report expresses an unqualified opinion), which is incorporated herein by reference, and have been so incorporated in reliance upon the report of such firm given upon their authority as experts in accounting and auditing.



5,000,000 SHARES

keryx pharmaceutical logo

COMMON STOCK

PROSPECTUS

JPMORGAN

BEAR, STEARNS & CO. INC.

Sole Book-Running Manager

JEFFERIES & COMPANY, INC.
OPPENHEIMER & CO.
BREAN MURRAY & CO., INC.
PUNK, ZIEGEL & COMPANY

YOU SHOULD RELY ONLY ON THE INFORMATION CONTAINED OR INCORPORATED BY REFERENCE IN THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS. WE HAVE NOT AUTHORIZED ANYONE TO PROVIDE YOU WITH INFORMATION DIFFERENT FROM THAT CONTAINED OR INCORPORATED BY REFERENCE IN THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS. WE ARE OFFERING TO SELL, AND SEEKING OFFERS TO BUY, COMMON SHARES ONLY IN JURISDICTIONS WHERE OFFERS AND SALES ARE PERMITTED. THE INFORMATION CONTAINED IN THIS PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS IS ACCURATE ONLY AS OF THE DATE OF THIS PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS, REGARDLESS OF THE TIME OF DELIVERY OF THIS PROSPECTUS SUPPLEMENT AND THE ACCOMPANYING PROSPECTUS OR OF ANY SALE OF OUR COMMON SHARES.

NO ACTION IS BEING TAKEN IN ANY JURISDICTION OUTSIDE THE UNITED STATES TO PERMIT A PUBLIC OFFERING OF THE COMMON SHARES OR POSSESSION OR DISTRIBUTION OF THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS IN THAT JURISDICTION. PERSONS WHO COME INTO POSSESSION OF THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS IN JURISDICTIONS OUTSIDE THE UNITED STATES ARE REQUIRED TO INFORM THEMSELVES ABOUT AND TO OBSERVE ANY RESTRICTIONS AS TO THIS OFFERING AND THE DISTRIBUTION OF THIS PROSPECTUS SUPPLEMENT OR THE ACCOMPANYING PROSPECTUS APPLICABLE TO THAT JURISDICTION.

UNTIL JULY , 2005, ALL DEALERS THAT BUY, SELL OR TRADE IN OUR COMMON SHARES, WHETHER OR NOT PARTICIPATING IN THIS OFFERING, MAY BE REQUIRED TO DELIVER A PROSPECTUS. THIS IS IN ADDITION TO THE DEALERS' OBLIGATION TO DELIVER A PROSPECTUS WHEN ACTING AS UNDERWRITERS AND WITH RESPECT TO THEIR UNSOLD ALLOTMENTS OR SUBSCRIPTIONS.

July , 2005