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KERYX BIOPHARMACEUTICALS INC

Form 424B3

October 13, 2004

Filed Pursuant to Rule 424(b) (3)
Registration No. 333-119376

PROSPECTUS

5,000,000 SHARES

KERYX BIOPHARMACEUTICALS, INC.

COMMON STOCK

We may offer and sell, from time to time, up to 5,000,000 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 3 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 October 13, 2004

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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

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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.

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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..... | 5,000,000 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

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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."

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RISK FACTORS

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

RISKS RELATED TO OUR BUSINESS

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

We have a limited operating history. You should consider our prospects in light of the risks and difficulties frequently encountered by early stage companies. In addition, we have incurred 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

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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

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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

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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.

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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:

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- 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

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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,

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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

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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 COMMERCIALY 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;
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- 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.

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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;

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- the costs involved in enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

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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

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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,

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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 attempting to acquire us.

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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 5,000,000 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,

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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.

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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

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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.

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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.

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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

Holder 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

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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.

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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:

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

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

If underwriters are used in the sale of any 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

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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.

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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.