KERYX BIOPHARMACEUTICALS INC
Form S-3
March 16, 2004

AS FILED WITH THE SECURITIES AND EXCHANGE COMMISSION ON MARCH 16, 2004
REGISTRATION NO. 333-

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM S-3
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

KERYX BIOPHARMACEUTICALS, INC.
(EXACT NAME OF REGISTRANT AS SPECIFIED IN ITS CHARTER)

DELAWARE	13-4087132
(STATE OR OTHER JURISDICTION OF INCORPORATION OR ORGANIZATION)	(I.R.S. EMPLOYER IDENTIFICATION NO.)

750 LEXINGTON AVENUE
NEW YORK, NEW YORK 10022
(212) 531-5965
(ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF REGISTRANT'S PRINCIPAL EXECUTIVE OFFICES)

RON BENTSUR
VICE PRESIDENT FINANCE AND INVESTOR RELATIONS
KERYX BIOPHARMACEUTICALS, INC.
750 LEXINGTON AVENUE
NEW YORK, NEW YORK 10022
(212) 531-5965
(NAME, ADDRESS, INCLUDING ZIP CODE, AND TELEPHONE NUMBER, INCLUDING AREA CODE, OF AGENT FOR SERVICE)

The Commission is requested to send copies of all communications to:

MARK F. MCELREATH
ALSTON & BIRD LLP
90 PARK AVENUE
NEW YORK, NEW YORK 10016-1387
(212) 922-3995

APPROXIMATE DATE OF COMMENCEMENT OF PROPOSED SALE TO THE PUBLIC: From time

to time after the registration statement becomes effective.

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

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

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box. [ ]

CALCULATION OF REGISTRATION FEE

TITLE OF EACH CLASS OF SECURITIES TO BE REGISTERED	AMOUNT TO BE REGISTERED (1)	PROPOSED MAXIMUM OFFERING PRICE PER UNIT	PROPOSED MAXIMUM AGGREGATE OFFERING PR
Common Stock, $0.001 par value per share	3,200,000 shares	$ 12.55(2)	$ 40,160,000

(1) Pursuant to Rule 416 under the Securities Act of 1933, as amended, such number of shares of common stock registered hereby shall include an indeterminate number of shares of common stock that may be issued in connection with a stock split, stock dividend, recapitalization or similar event.

(2) Estimated solely for purposes of determining the registration fee. This amount, calculated pursuant to Rule 457(c), was based on the average of the high and low prices of the Registrant's common stock on March 11, 2004, as reported on the Nasdaq Stock Market.

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

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

SUBJECT TO COMPLETION -- DATED MARCH 16, 2004

PROSPECTUS

3,200,000 SHARES

KERYX BIOPHARMACEUTICALS, INC.

COMMON STOCK

This prospectus relates to the offer and sale by the selling stockholders named herein of up to an aggregate of 3,200,000 shares of common stock of Keryx Biopharmaceuticals, Inc. The selling stockholders may, from time to time, sell any or all of their shares of common stock on the Nasdaq Stock Market or in private transactions using any of the methods described in the section of this prospectus entitled "Plan of Distribution." We will not receive any proceeds from the sale of the shares of our common stock by the selling stockholders. We issued these shares of our common stock to the selling stockholders in a private placement transaction on or about February 17, 2004.

Our common stock is traded on the Nasdaq Stock Market under the symbol "KERX." On March 11, 2004, the last sales price for the shares of our common stock as reported on the Nasdaq Stock Market was $12.50 per share.

INVESTING IN OUR COMMON STOCK INVOLVES A HIGH DEGREE OF RISK. SEE "RISK FACTORS" BEGINNING ON PAGE 3 OF THIS PROSPECTUS FOR CERTAIN CONSIDERATIONS RELEVANT TO AN INVESTMENT IN 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 March __, 2004

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PROSPECTUS SUMMARY

OUR COMPANY

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. To date, we have not received approval for the sale of any of our drug candidates in any market and, therefore, have not generated any revenues from our drug candidates. We have two product candidates in late-stage 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 other markets. Between 1996 and 1999, a randomized, double-blind, placebo-controlled, Phase II study of the use of Sulodexide for treatment of diabetic nephropathy in 223 patients was conducted in Europe. The results of this Phase II study showed a dose-dependent reduction in proteinuria or pathological urinary albumin excretion rates. This study was published in the June 2002 issue of the Journal of the American Society of Nephrology. In 2001, KRX-101 was granted Fast-Track designation for the treatment of diabetic nephropathy and, in 2002, we announced that the Food and Drug Administration, or 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 we had initiated the Sulodexide Open Access Research, or S.O.A.R., program to expand the knowledge and understanding of the potential clinical applications of Sulodexide in scientific and medical communities. Under the S.O.A.R. program, we collaborate with top academic investigators who wish to explore the potential utility of KRX-101 in a wide variety of indications, including diabetic nephropathy. To date, we have signed collaborations with the National Institutes of Health, or NIH, University of Michigan (Ann Arbor), University of Texas, Baylor University, Vanderbilt University, University of British Columbia and Thomas Jefferson University.

In addition, 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 a multi-center, Phase II/III clinical program for our diabetic nephropathy drug candidate, KRX-101.

In the first quarter of 2004, we announced that we had acquired ACCESS Oncology, Inc., or 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 broad Phase II clinical program evaluating KRX-0401 as a single agent in the treatment of multiple forms of cancer. The current Phase II program is being conducted and funded by the National Cancer Institute, or NCI, a department of the NIH, under a Collaborative Research and Development Agreement, or CRADA, arrangement. Additionally, we are planning to conduct a series of additional Phase II clinical trials for KRX-0401 both as a single agent and in combination with other anti-cancer therapies. 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. In addition, as a part of the acquisition of ACCESS Oncology, we acquired a division of ACCESS Oncology referred to as OCOG, which provides clinical trial services to other biotechnology and pharmaceuticals 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, raising capital, purchasing assets for our former corporate offices and laboratory 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 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.

RECENT DEVELOPMENTS

On February 17, 2004, we completed a private placement in which 3,200,000 shares of our common stock were sold for $10.00 per share to institutional investors.

We entered into a registration rights agreement with the selling stockholders on or about February 17, 2004. The registration rights agreement provides that we must file a registration statement on or prior to the 30th day following February 17, 2004, covering the resale of all of the shares of our

common stock sold by us in the private placement. This prospectus is part of the registration statement filed to meet our obligations under the registration rights agreement.

We must cause this registration statement to become effective as soon as practicable, but in no event later than the 60th calendar day, or 75th calendar day in the event of a full review by the Securities and Exchange Commission, following February 17, 2004. If this registration statement is not declared effective by the Securities and Exchange Commission on or before the 60th day, or 75th day, if applicable, registration deadline, or if after this registration statement has been declared effective by the Securities and Exchange Commission, sales of the shares of common stock covered by the registration statement cannot be made pursuant to this registration statement for any reason, then at the time of the event, we are required to make payments to the selling stockholders in the amount of 2.0% per month of the aggregate purchase price paid in the private placement by the selling stockholders for the shares of our common stock held by the selling stockholders. If we fail to make this payment within seven days after the date payable, we will pay interest at a rate of 15% per annum (or such lesser maximum amount that is permitted to be paid by applicable law) to the holder until such payment and the interest thereon is paid in full.

RISK FACTORS

RISKS RELATING 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, expect to continue to incur operating losses for the foreseeable future and may never become profitable. As of September 30, 2003, we had an accumulated deficit of approximately $52.4 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 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 ACHIEVE 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 most recent 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 precise 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. Preclinical 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 preclinical 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 these drugs from others. These license agreements require us to meet development or financing milestones and impose development and commercialization due diligence 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 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.

There can be 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 recently 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 our manufacturing of KRX-101 to our new 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 MATERIAL 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, 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 adversely 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 18 full and part-time employees and several other persons working under research agreements or consulting agreements. 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 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 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 reasonably adequate 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 are 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 at least 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.

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 December 31, 2003, our executive officers, directors and principal stockholders (including their affiliates) beneficially own, in the aggregate, approximately 23.85% 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.

OUR STOCK PRICE COULD BE VOLATILE AND YOUR INVESTMENT COULD DECLINE IN VALUE.

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.

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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 without any further vote or action by the stockholders 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.

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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 increases or decreases in research and development and general and administrative expenses in order to develop and in-license new products and manufacture commercial quantities of products;
- 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;
- ability to enter into marketing and other partnership agreements;
- ability to enter into product acquisition and in-licensing transactions;
- estimate 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 this prospectus under the heading "Risk Factors." Such risks and uncertainties also include the possibility that we may fail to establish and correctly apply our critical accounting policies and estimates to our financial statements. The list of factors that may affect future performance and the accuracy of forward-looking statements is illustrative, but by no means exhaustive.

Accordingly, 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

We will not receive any proceeds from the sale of the shares of common stock by the selling stockholders. All net proceeds from the sale of shares of common stock covered by this prospectus will go to the selling stockholders upon the offer and sale of their shares. See "Selling Stockholders" and "Plan of Distribution" described below.

SELLING STOCKHOLDERS

We issued shares of our common stock in a private placement transaction on February 17, 2004. Selling stockholders, including any non-sale transferees, pledgees, donees, assignees or their successors-in-interest, may from time to time offer and sell any or all of the common stock pursuant to this prospectus. Because the selling stockholders may offer all or some portion of the common stock, no estimate can be given as to the amount of the common stock that will be held by the selling stockholders upon consummation or termination of any sales.

Information about the selling stockholders may change over time. Any changed information given to us by the selling stockholders will be set forth in prospectus supplements or amendments to this prospectus if and when necessary. The table below sets forth information as of March 1, 2004 with respect to the number of shares of common stock beneficially owned by each of the selling stockholders and the number of shares being offered for sale by each selling stockholder.

NAME OF SELLING STOCKHOLDER	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED PRIOR TO OFFERING	NUMBER OF SHARES OF COMMON STOCK REGISTERED HEREIN
Adage Capital Management, L.P.....	550,000	250,000
Atlas Equity I, Ltd.....	527,482	200,000
Deerfield International Limited.....	490,000	490,000
Deerfield Partners, L.P.....	510,000	510,000
Maverick Fund II, Ltd. (2).....	172,700	172,700
Maverick Fund, L.D.C. (2).....	569,700	569,700
Maverick Fund USA, Ltd. (2).....	257,600	257,600
S.A.C. Capital Associates, LLC.....	200,000	200,000
Sonostar Ventures, LLC (3).....	249,750	50,000
T. Rowe Price Health Sciences Fund, Inc. (4).....	305,000	130,000
T. Rowe Price Health Sciences Portfolio, Inc. (4).	1,400	600
TD Mutual Funds - TD Health Sciences Fund (4).....	79,100	39,000

VALIC Company I - Health Sciences Fund (4).....	34,100	11,000
Manufacturers Investment Trust - Health Sciences Trust (4).....	47,500	25,000
IDEX Mutual Funds - IDEX - T. Rowe Price Health Sciences (4).....	24,100	8,000
Raytheon Company Combined DB/DC Master Trust - Health Sciences (4).....	9,000	4,400
Raytheon Master Pension Trust - Health Sciences (4).....	14,400	7,000
T. Rowe Price New Horizons Fund, Inc. (4).....	275,000	275,000
TOTAL	4,316,832	3,200,000

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(1) Assumes sale of all of the shares of common stock offered hereby.

(2) Based on the most recent information available to the company. This information was not confirmed by the selling stockholder prior to the filing of this registration statement.

(3) Number includes 83,250 shares held in the Kiernan Family Trust, an irrevocable trust for family members of Greg Kiernan, the President and CEO of Sonostar Ventures. For purposes of the reporting requirements of the Securities Exchange Act of 1934, as amended, Sonostar Ventures or Greg Kiernan may be deemed to be the beneficial owner of all of the shares listed above; however, Sonostar Ventures and Greg Kiernan expressly disclaim that they are, in fact, the beneficial owners of such securities.

(4) T. Rowe Price Associates, Inc., or T. Rowe Price Associates, serves as investment adviser with power to direct investments and/or sole power to vote the shares owned by the funds listed under its name in the table above, as well as shares owned by certain other individual and institutional investors. For purposes of the reporting requirements of the Securities Exchange Act of 1934, as amended, T. Rowe Price Associates may be deemed to be the beneficial owner of all of the shares listed above; however, T. Rowe Price Associates expressly disclaims

that it is, in fact, the beneficial owner of such securities. T. Rowe Price Associates is a wholly owned subsidiary of T. Rowe Price Group, Inc., which is a publicly traded financial services holding company.

PLAN OF DISTRIBUTION

The selling stockholders and any of their transferees, pledgees, donees, assignees and successors-in-interest may, from time to time, sell any or all of their shares of common stock on any stock exchange, market or trading facility on which the shares are then listed, admitted to unlisted trading privileges or included for quotation or in private transactions. These sales may

be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- one or more block trades in which the broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- settlement of short sales created after the date of the private placement;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions, discounts or concessions from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders may from time to time pledge or grant a security interest in some or all of the shares of common stock or warrants owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock from time to time under this prospectus, or under an amendment to this prospectus under the applicable provision of the Securities Act of 1933, as amended, amending the list of selling stockholders to include the transferees, pledgees, donees, assignees and successors-in-interest as selling stockholders under this prospectus.

The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees, donees, assignees and successors-in-interest will be the selling beneficial owners for purposes of this prospectus.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act. The selling stockholders have

informed us that none of them has any agreement or understanding, directly or indirectly, with any person to distribute the common stock.

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We are required to pay all fees and expenses that we incur incident to the registration of the shares. We have agreed to indemnify the selling stockholders, with respect to this registration statement, against certain losses, claims, damages and liabilities, including liabilities under the Securities Act.

The anti-manipulation rules under the Securities Exchange Act of 1934, as amended, may apply to sales of the shares of common stock in the market and to the activities of the selling stockholders and their affiliates.

We have agreed to use our best efforts to keep this registration statement continuously effective under the Securities Act until the date which is two years after the date that this registration statement is declared effective by the Securities and Exchange Commission or such earlier date when all shares of the common stock covered by this registration statement have been sold or may be sold without volume restrictions pursuant to Rule 144(k) as determined by our counsel pursuant to a written opinion letter to such effect, addressed and acceptable to our transfer agent and the affected selling stockholders.

LEGAL MATTERS

The 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.

WHERE YOU CAN FIND MORE INFORMATION

We file annual, quarterly and special reports, proxy statements and other information with the SEC. You may read and copy, at prescribed rates, any documents we have filed with the Securities and Exchange Commission 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 Securities and Exchange Commission at 1-800-SEC-0330. We also file these documents with the Securities and Exchange Commission 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 Securities and Exchange Commission from our Internet website found at www.keryx.com. Our stock is quoted on The Nasdaq Stock Market under the symbol "KERX."

INCORPORATION OF CERTAIN INFORMATION BY REFERENCE

The Securities and Exchange Commission allows us to "incorporate by reference" into this prospectus the information we file with the Securities and Exchange Commission. 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 Securities and Exchange Commission from 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 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, until the termination of the offering by the selling stockholders pursuant to this prospectus:

(a) Our Annual Report on Form 10-K for the year ended December 31, 2002;

(b) Our quarterly reports on Forms 10-Q for the quarters ended March 31, 2003, June 30, 2003, and September 30, 2003;

(c) Our current reports on Forms 8-K dated March 31, 2003, May 14, 2003, August 13, 2003, November 13, 2003, November 19, 2003 and February 20, 2004; and

(d) The description of our capital stock and accompanying rights contained in our registration statement on Form 8-A dated June 28, 2000 (File No. 000-30929).

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

You should rely only on the information contained in or incorporated by reference into this prospectus. We have not authorized any dealer, salesperson or other person to give you different information. This prospectus is not an offer to sell nor is it seeking an offer to buy the securities referred to in this prospectus in any jurisdiction where

the offer or sale is not permitted. The information contained in this prospectus is correct only as of the date of this prospectus, regardless of the time of the delivery of this prospectus or any sale of the securities referred to in this prospectus.

PART II

INFORMATION NOT REQUIRED IN THE PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The table below itemizes the expenses payable by the Registrant in connection with the registration and issuance of the securities being registered hereunder, other than underwriting discounts and commissions. All amounts except the Securities and Exchange Commission registration fee are estimated.

Securities and Exchange Commission Registration Fee	$
Legal Fees and Expenses	2
Accountants' Fees and Expenses	1
Printing and Duplicating Expenses	
Miscellaneous Expenses	
Total	$ 4

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Under the General Corporation Law of the State of Delaware, or DGCL, a corporation may include provisions in its certificate of incorporation that will relieve its directors of monetary liability for breaches of their fiduciary duty to the corporation, except under certain circumstances, including a breach of the director's duty of loyalty, acts or omissions of the director not in good faith or which involve intentional misconduct or a knowing violation of law, the approval of an improper payment of a dividend or an improper purchase by the corporation of stock or any transaction from which the director derived an improper personal benefit. The Registrant's Amended and Restated Certificate of Incorporation, as amended, eliminates the personal liability of directors to the Registrant or its stockholders for monetary damages for breach of fiduciary duty as a director with certain limited exceptions set forth in the DGCL.

Section 145 of the DGCL grants to corporations the power to indemnify each officer and director against liabilities and expenses incurred by reason of the fact that he or she is or was an officer or director of the corporation if he or she acted in good faith and in a manner he or she reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. The Registrant's Amended and Restated Certificate of Incorporation, as amended, and Amended and Restated Bylaws provide for indemnification of each officer and director of the Registrant to the fullest extent permitted by the DGCL. Section 145 of the DGCL also empowers corporations to purchase and maintain insurance on behalf of any person who is or was an officer or director of the corporation against liability asserted against or incurred by him in any such capacity, whether or not the corporation would have the power to indemnify such officer or director against such liability under the provisions of Section 145 of the DGCL.

ITEM 16. EXHIBITS.

EXHIBIT NUMBER	DESCRIPTION
5.1	Opinion of Alston & Bird LLP.*
10.1	Securities Purchase Agreement dated as of February 12, 2004, by and between Keryx Biopharmaceuticals, Inc. and the purchasers named therein.
10.2	Registration Rights Agreement dated as of February 17, 2004, by and between Keryx Biopharmaceuticals, Inc. and the purchasers named therein.
23.1	Consent of KPMG LLP.*

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* To be filed by amendment.

ITEM 17. UNDERTAKINGS.

(a) The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in the volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b)) if, in the aggregate, the changes in volume and price represent no more than 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

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

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

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(b) The undersigned registrant hereby undertakes that, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(h) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the

successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, as amended, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized in the City of New York, State of New York, on March 16, 2004.

KERYX BIOPHARMACEUTICALS, INC.

By: /s/ MICHAEL S. WEISS

Michael S. Weiss
Chairman and Chief Executive Officer

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Michael S. Weiss and Ron Bentsur, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for him and his name, place and stead, in any and all capacities, to sign any or all amendments (including post-effective amendments) to this registration statement, and to file the same, with all exhibits thereto and other documents in connection therewith, with the SEC, granting unto said attorney-in-fact and agent, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorney-in-fact and agent or any of his substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, as amended, this registration statement has been signed by the following persons in the capacities indicated as of March 16, 2004.

Signatures	Title
/s/ Michael S. Weiss Michael S. Weiss	Chairman and Chief Executive Officer (principal executive officer)
/s/ Ron Bentsur Ron Bentsur	Vice President Finance and Investor Relations (principal financial and accounting officer)
Malcolm Hoenlein	Director
/s/ Peter Morgan Kash	

Peter Morgan Kash	Vice Chairman
/s/ Lawrence Jay Kessel, M.D.	
Lawrence Jay Kessel, M.D.	Director
Peter Salomon, M.D.	Director
Lindsay A. Rosenwald, M.D.	Director
/s/ I. Craig Henderson, M.D.	
I. Craig Henderson, M.D.	Director

EXHIBIT INDEX

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